HELPING PATIENTS CHOOSE THEIR IDEAL TREATMENT FOR ACHILLES TENDON RUPTURES: A NETWORK META-ANALYSIS AND PROTOCOL FOR DEVELOPMENT AND FIELD TESTING A PATIENT DECISION AID

DR. BRAD MEULENKAMP

Thesis submitted to the University of Ottawa
in partial Fulfillment of the requirements for the
Master of Science in Clinical Epidemiology

School of Epidemiology and Public Health
Faculty of Medicine
University of Ottawa

Preface

The following is a manuscript-based thesis that has been performed as part of a Master of Science in Clinical Epidemiology degree at the University of Ottawa. It has been formatted in accordance to the guidance set out by the intended submitting peer-reviewed journals.

No ethics approval was needed or obtained for either of the manuscripts. The first article, 'Management for Acute Achilles Tendon Ruptures: A Systematic Review and Network Meta-Analysis' has been accepted to *Clinical Orthopedics and Related Research* (decision pending). I designed this analysis and published the protocol in *Systematic Reviews* in 2018.[34] I subsequently carried out the study in its entirety. Collaboration from co-authors was provided for duplicate study review and data extraction. Dr. Wei Cheng and Dr. Taylor Woolnough provided assistance with analysis software. The second paper, 'Development and Field-Testing a Patient Decision Aid for Management of Acute Achilles Tendon Rupture: A Protocol' has been formatted but not yet submitted to *BMC Medical Informatics and Decision Making*. I designed this study in its entirety with feedback and guidance from supervisors and co-authors.

I certify that I am and will be the first and corresponding author on each of these papers. I wrote the papers with guidance from supervisors and co-authors and will be the primary author to review feedback and address from peer reviewers.

Acknowledgements

The culmination of work in this thesis would not have been possible if it wasn't for many others. Before anyone, I would like to thank my brilliant, loving, and beautiful wife, Dr. Carly Kirshen for her love, support, guidance and above all patience through this drawn-out thesis process. Our first son, Ezra, was born just as my thesis journey began and two years later we added his brother Arlo. It has been a wild ride, not always smooth sailing, but always with lots of laughs and love. Carly knows I can be easily distracted, most easily by my clinical practice as an academic orthopaedic trauma and foot and ankle surgeon - which I also started coincident with starting this thesis. Carly tirelessly pushed me to stay on track with my writing and for that I am thankful.

Ezra and Arlo – my dudes. I deeply regret missing time from you in these early years, and I am thankful that you are unlikely to remember. I am happy to be done with this journey so that I can give you both more of my undivided attention. I hope you both grow to be more efficient in these tasks than your Dad.

To my supervisor, Dr. Ian Graham, and advisory committee members Dr. Dawn Stacey and Dr. Dean Fergusson. Ian, you inspired me from our first class together and stimulated my interest and passion for shared decision-making in an otherwise paternalistic clinical field. Dawn, you entertained my thoughts and ideas from early in my epidemiology journey and have been always available for the guidance I needed. Thank you both for your thoughtful discussions, prompt revisions from all ends of the world, and on-going quest to rid my writing of the passive voice. Your guidance and patience have meant a lot to me and unfortunately I will not go quietly into the night. I will continue to bother you for your wisdom as I strive to grow my program. Dean, I met you

long ago prior to my application to the epidemiology program. Your advice has always been steady, thoughtful and positive. Thank you for not giving up on my journey and for tolerating my many misspellings of your name.

Pushing me along the way were my mentors and supervisors. Dr. Paul Beaulé, thank you for your passion and vision in helping me make my way. Dr. Steve Papp, without you and Victoria blocking out some of my clinical time I would never have gotten to the finish line. Thank you for your accommodations. Dr. Karl Lalonde, my mentor and friend, thank you for your discussions, guidance and ideas. I appreciate all of you very much and would never been able to complete this without you.

Table of Contents

List of Tables

List of Figures

Abbreviations

CPG: Clinical Practice Guideline

CQI: Continuous Quality Improvement

CrI: Credible Interval

DIC: Deviance Information Criteria

EMR: Electronic Medical Record

GRADE: Grades of Recommendation, Assessment, Development, and Evaluation

iKT: Integrated Knowledge Translation

IPDAS: International Patient Decision Aid Standards

MIS: Minimally Invasive Surgery

NICE: National Institute for Health and Care Excellence

NMA: Network Meta-Analysis

OAT: Ottawa Acceptability Tool

ODSF: Ottawa Decision Support Framework

OHRI: Ottawa Hospital Research Institute

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PtDA: Patient Decision Aid

RCT: Randomized Controlled Trial

ROB: Risk of Bias

ROM: Range of Motion

SDM: Shared Decision-Making

SSI: Semi-structured Interview

SUCRA: Surface under the Cumulative Ranking

Thesis Abstract

Treatment of acute Achilles tendon ruptures has long been controversial. Several treatment options exist for patient with variable harms and benefits to each. Recognizing that decision of treatment option is preference-sensitive, this thesis focused on updating the current literature on Achilles tendon rupture management to facilitate the creation of a patient decision aid.

A network meta-analysis of all treatment options for acute Achilles tendon ruptures was performed. Results demonstrated that minimally invasive surgery options were associated with lower complications and lower complications requiring surgery. Return to sport was similar amongst all treatment groups.

With guidance from the Ottawa Decision Support Framework and the International Patient Decision Aid Standards, a three-tiered protocol for development, alpha testing and field-testing a novel patient decision aid is outlined next. The patient decision aid will be reviewed and revised iteratively by multi-disciplinary steering group. This protocol will act as a framework for further orthopaedic patient decision aid development.

Chapter 1:

Introduction

This chapter provides both the background and rationale for the body of work. This thesis takes the form of a thesis by articles, the first of which is a Network Meta-Analysis incorporating all methods of Achilles tendon rupture treatment. The second article is a protocol for the development and field-testing of a novel patient decision aid (PtDA) for patients presenting with an acute Achilles tendon rupture. An overview of all chapters will follow at the conclusion of the introduction.

The division of Orthopedic Surgery at the University of Ottawa is a regional and national leader in Continuous Quality Improvement (CQI),[1] which focuses on health care delivery that is efficient, patient-centered, and equitable. Patient decision aids are one of many tools that will help in the delivery of these objectives. One of the goals of the division is to develop the Ottawa Orthopedic Decision Aid Program as a central component of the CQI program. This thesis was, in part, designed to support this goal by providing the foundational groundwork to develop, evaluate and implement PtDAs for the orthopedic community at both the local and national level.

Background and Rationale

Shared Decision Making

Patients are frequently asked to make informed treatment decisions regarding their care with limited background knowledge of their relevant pathology.[2,3] While some decisions may be relatively easy or obvious to make, for example the decision to have

surgery for a broken femur, for other decisions there are often several reasonable treatment options available. In this situation, the physician provides the patient with relevant information, and the patient is left to weigh the pros and cons of each option prior to making a 'best' decision.[1,4]

Many treatment decisions have no single 'best' option, and variable levels of evidence guide treatment options.[2,3,5] Each option has a unique risks and benefits. How an individual decides to weigh the risk-benefit ratio is not universal and is based on their unique preferences and values. Even with high-level evidence, it is important, yet challenging for physicians to help translate population-level data to the individual.[6] 'Preference-sensitive' decisions are decisions made by the patient after balancing the relevant information with their unique personal values and needs. Achieving a high quality decision, defined as one that is based on high-quality evidence and in keeping with a patient's values,[7] is the goal central to shared-decision making (SDM). There are two experts in this reciprocal relationship. Clinicians bring expertise in the medical condition and its treatment, but have been shown to be poor judges of patient preference.[8] The patient thus brings this expertise, in how the disease or ailment impacts their daily life and values. Patient engagement in health-care decisions improves the patient experience and leads to improved patient outcomes.[9,10] The importance of SDM cannot be understated in the evolution of health-care delivery from paternalistic to more patient-centered care.[11,12] Engaging in SDM strategies is being actively built into policy in many jurisdictions[13] as a requisite prior to approving some interventional procedures, with massive implications for both patent and clinician.

There are several strategies to facilitate SDM, including decision coaching,

questions prompts, and patient decision aids.[14] Patient decision aids are communication tools that can be used either prior-to or following consultation between physician and patient.[7] They may take on many formats, including print, web-based, audio and visual resources amongst others. PtDAs act to supplement, not replace the patient-physician discussion. By providing this additional element of decision-support, the goal is for the patient to make a high-quality decision[7].

There are six minimal standard elements, or qualifying criteria, to qualify as a PtDA as defined by the International Patient Decision Aid Standards.[41] These include; 1) Discretely describing the health condition or problem, 2) An explicit statement of the decision to be made, 3) A description of the options available for the decision, 4) A description of the positive benefits or advantages of each option, 5) A description of the harms, side effects, or disadvantages of each option, and 6) A discrete description of what it is like to experience the consequences of the options as a values clarification exercise. The IPDAS has also described 10 additional certification criteria required to be certified as a PtDA, in addition to 28 quality criteria, which should be considered to minimize the risk of introducing bias to the PtDA. A standard PtDA will include evidence-based material, including probabilities of risks, benefits and harms of each potential decision option. Probabilities are presented in an easy-to-understand format, while also helping to clarify where the risks and benefits lay within an individual's values.[15] The use of PtDAs has been shown to improve patient knowledge, improve patient perceptions of treatment risks and benefits, improves patient's understanding and clarity of personal values and may lead to a more value-congruent decision.[15]

Shared Decision Making in Orthopedic Surgery

There are countless opportunities to develop, evaluate and implement PtDAs in the orthopedic surgery setting. Patients are routinely faced with challenging decisions, whether broad (undergoing surgery versus non-operative management of a fracture) or more specific (choosing between different surgical approaches for hip replacement surgery). PtDAs have previously been developed for patients with knee[16] and hip arthritis, as well as lumbar spine pathology[17]. These improve patient knowledge, participation in SDM, and overall patient experience in these populations. However, there remains a paucity of development and implementation of PtDAs within the specialty as a whole.[18]

Management Options for Acute Achilles Tendon Rupture: Decisional Conflict

The Achilles tendon is the most commonly ruptured tendon in the body.[19] These injuries were traditionally most common in the male 'weekend warrior' population aged 30-40 years.[19] However, these injuries are increasing in incidence throughout adulthood, up to those in the sixth decade of life, as the population strives to remain active for longer.[20-22]

The optimal treatment of acute ruptures has long been debated, with both surgical and non-surgical options presenting unique risks and benefits.[23] Historically, patients were immobilized for six-to-eight weeks of followed by progressive weight bearing. Due to a high tendon re-rupture rate with this approach, many surgeons have advocated for open surgical management. Surgery, however, comes with its own unique set of risks, including wound complications, infections, and nerve injury.[23] For these reasons,

alternative management strategies have been sought to minimize the risks that come with both operative and non-operative care.[24]

Many centers have replaced traditional non-operative care with alternative non-operative functional rehabilitation strategies involving early, controlled ankle mobilization.[25] These programs require significant patient engagement and access to physiotherapy for optimal results, which may present a barrier to some patient populations.[25,26] A systematic review and meta-analysis of operative versus non-operative management of Achilles tendon rupture published in 2012 by Soroceanu et al. best synthesized the risks and benefits of each of these strategies.[23] Surgery has an overall lower re-rupture rate when compared to all non-operative care. However, in their stratified analysis separating studies employing traditional non-operative care from those using functional rehabilitation, re-rupture rates were found to be equal between functional rehab and surgery. Patients undergoing surgery return to work and sport almost three weeks sooner than the non-operative patients, but unsurprisingly had a much higher complication rate. Overall, functional and clinical outcomes were equivocal between treatment arms.

Surgical care is also evolving, with minimally invasive surgical techniques being developed to negate the risk of wound complications and infections found with open surgery.[27] These techniques are more challenging that traditional open surgery, with a learning curve for surgeons, and are not yet widely used.[28] To date, no long-term functional benefit as been demonstrated over other treatment modalities,[29]. Wound complications have indeed been negated, however at the risk of increased risk of painful neuroma or sural nerve injury. Where these techniques fit in the realm of routine clinical

care has yet to be clearly defined.[27]

The most recent clinical practice guideline (CPG) for management of Achilles tendon ruptures was published in 2010 and offered management option statements of either 'weak' or 'inconclusive'.[30] This guideline was published prior to the more contemporary and modern strategies discussed above. Given the equivocal functional outcomes in treatment modalities for Achilles tendon ruptures, but vastly different complications and risk-benefit profiles, patients with these injuries regularly face a difficult decision.[31] Treatment discussions are commonly challenging with both patients and clinicians struggling to adequately articulate treatment and outcome priorities. This decision by patients requires careful consideration of their specific treatment goals based on personal values and preferences.

Summary

With several management options available, patients and clinicians must weigh risks and benefits of each approach, leading to uncertainty and decisional conflict. Furthermore, management of Achilles tendon rupture is evolving and a thorough updated literature synthesis is lacking.

Purpose of the Thesis

The primary goal of this thesis is to facilitate development a novel decision-aid for patients with Achilles tendon rupture. Due to concerns about feasibility of completion in a reasonable timeframe, the scope of the thesis has evolved over time from the initial thesis proposal. The specific objectives of the thesis are: 1) To systematically review the literature on management of acute Achilles tendon ruptures, using Network Meta-Analysis methodology to best synthesize current best-management evidence for these

injuries; and 2) To develop a comprehensive protocol for development and field-testing a novel PtDA to assist patients and clinicians managing acute Achilles tendon ruptures.

The first objective is addressed in Chapter 2, 'Treatment of Achilles Tendon Ruptures: A Systematic Review with Network Meta-Analysis'. The protocol for this study has been published[32] and registered with PROSPERO (CRD42018093033). This study synthesizes the medical literature of all relevant treatment modalities for Achilles tendon ruptures using both direct and indirect comparisons of treatment modalities. We have used NMA frameworks from the Cochrane Handbook[58], and an analysis approach previously describe in the National Institute for Health and Care Excellence (NICE) guidelines[59]. These methods have not been previously exploited for Achilles tendon rupture but offer the distinct advantage of presenting all modalities within a single methodological framework. Results of this study will be used to inform patients and clinicians of all relevant risks and benefits, as well as provide the foundational evidence for the development of the PtDA.

The second objective is addressed in in Chapter 3, entitled 'A Protocol for Development and Field-Testing a Patient Decision-Aid for Management of Acute Achilles Tendon Rupture.' This protocol was developed based on the guiding conceptual frameworks of the International Patient Decision Aid Standards (IPDAS)[33], using the Ottawa Decision Support Framework (ODSF) as a template.[34] The ODSF is based upon three foundations; decisional needs, decisional support, and decision outcomes, with the goal of providing decisional support to patients with decisional needs to improve their decision outcomes or achieve a high-quality decision. This framework has been used to guide development of more than 30 PtDAs, many of which have been evaluated in

randomized controlled trials.[15]

Chapter 4 is an integrated discussion of the findings of the NMA, implications for the PtDA development and how these studies will be used to facilitate creation and operationalization of the Ottawa Orthopedic Patient Decision Aid Program. This program represents the overarching ambition of this thesis work, with the goal of developing, evaluating, and implementing PtDAs for many realms of orthopedic pathology. With health care policy and delivery evolving to more patient-centered approach, SDM is central to its implementation.[35]

In keeping with the School of Epidemiology and Public Health's categories of theses (https://med.uottawa.ca/graduate-postdoctoral/students-hub/tac-progress-report/tac-epidemiology), this thesis has components of both 'design and 'policy' theses. The protocol for designing and evaluating the PtDA falls within the 'design thesis', while the exhaustive and comprehensive literature review with NMA will help inform clinical practice policies with the orthopedic surgery community.

Chapter 2

Management for Acute Achilles Tendon Ruptures: A Systematic Review and Network Meta-Analysis

This manuscript has been formatted for and accepted for publication in *Clinical Orthopedics and Related Research*

Authors:

1. Brad Meulenkamp MD FRCSC; Assistant Professor, Faculty of Medicine, University of Ottawa
2. Taylor Woolnough MD; Orthopaedic Surgery Resident, University of Ottawa
3. Wei Cheng PhD; Clinical Epidemiology Program, The Ottawa Hospital Research Institute
4. Risa Shorr MLIS; The Ottawa Hospital
5. Dawn Stacey PhD; Faculty of Health Sciences, University of Ottawa; Centre for Practice-Changing Research, Ottawa Hospital Research Institute
6. Megan Richards MD; Orthopaedic Surgery Resident, University of Ottawa
7. Arnav Guptua BHSc; Faculty of Medicine, University of Ottawa
8. Dean Fergusson PhD; Clinical Epidemiology Program, The Ottawa Hospital Research Institute, University of Ottawa, Department of Medicine, Centre for Practice-Changing Research
9. Ian D Graham PhD, FCAHS, FNYAM; University of Ottawa, School of Epidemiology and Public Health; Clinical Epidemiology Program, The Ottawa Hospital Research Institute, Centre for Practice-Changing Research

Disclaimer: None

Funding source: None

Abstract

Background Uncertainty exists regarding the best treatment for acute Achilles tendon ruptures. Simultaneous comparison of the multiple treatment options using traditional study designs is problematic; multiarm clinical trials often are logistically constrained to small sample sizes, and traditional meta-analyses are limited to comparisons of only two treatments that have been compared in head-to-head trials. Network meta-analyses allow for simultaneous comparison of all existing treatments utilizing both direct (head-to-head comparison) and indirect (not previously compared head-to-head) evidence.

Questions/purposes We performed a network meta-analysis of randomized controlled trials (RCTs) to answer the following questions: Considering open repair, MIS repair, functional rehabilitation, or primary immobilization for acute Achilles tendon ruptures, (1) which intervention is associated with the lowest risk of rerupture? (2) Which intervention is associated with the lowest risk of complications resulting in surgery?

Methods This study was conducted with methods guided by the Cochrane Handbook for Systematic Reviews of Interventions and is reported in adherence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement for incorporating network meta-analysis. Five databases and grey literature sources (such as major orthopaedic meeting presentation lists) were searched from inception to September 30, 2020. Included studies were RCTs comparing treatment of acute Achilles tendon ruptures using two or more of the following interventions: primary immobilization, functional rehabilitation, open surgical repair, or minimally invasive surgery (MIS) repair. We excluded studies enrolling patients with chronic ruptures,

reruptures, and preexisting Achilles tendinopathy as well as studies with more than 20% loss to follow-up or less than 6 months of follow-up. Nineteen RCTs (1316 patients) were included in the final analysis. The mean number of patients per study treatment arm was 35 ± 16, mean age was 41 ± 5 years, mean sex composition was 80% ± 10% males, and mean follow-up was 22 ± 12 months. The four treatment groups were compared for the main outcomes of rerupture and complications resulting in operation. The analysis was conducted using random-effects Bayesian network meta-analysis with vague priors. Evidence quality was evaluated using Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) methodology. We found risk of selection, attrition, and reporting bias to be low across treatments, and we found the risk of performance and detection bias to be high. Overall risk of bias between treatments appeared similar.

Results We found that treatment with primary immobilization had a greater risk of rerupture than open surgery (odds ratio 4.06 [95% credible interval {CrI} 1.47 to 11.88]; $p < 0.05$). There were no other differences between treatments for risk of rerupture. Minimally invasive surgery was ranked first for fewest complications resulting in surgery and was associated with a lower risk of complications resulting in surgery than functional rehabilitation (OR 0.16 [95% CrI 0.02 to 0.90]; $p < 0.05$), open surgery (OR 0.22 [95% CrI 0.04 to 0.93]; $p < 0.05$), and primary immobilization (OR < 0.01 [95% CrI < 0.01 to 0.01]; $p < 0.05$). Risk of complications resulting in surgery was no different between primary immobilization and open surgery (OR 1.46 [95% CrI 0.35 to 5.36]). Data for patient-reported outcome scores and return to activity were inappropriate for pooling

secondary to considerable clinical heterogeneity and imprecision associated with small sample sizes.

Conclusion Faced with acute Achilles tendon rupture, patients should be counseled that, based on the best-available evidence, the risk of rerupture likely is no different across contemporary treatments. Considering the possibly lower risk of complications resulting in surgery associated with MIS repair, patients and surgeons must balance any benefit with the potential risks of MIS techniques. As treatments continue to evolve, consistent reporting of validated patient-reported outcome measures is critically important to facilitate analysis with existing RCT evidence. Infrequent but serious complications such as rerupture and deep infection should be further explored to determine if meaningful differences exist in specific patient populations.

Level of Evidence Level I, therapeutic study.

Introduction

Achilles tendon ruptures are common and debilitating, and they are followed by intensive rehabilitation to regain function of plantarflexion strength [11]. They most commonly occur during activities that require explosive acceleration with movements such as jumping and sprinting. Typically most common in 30- to 40-year-old males, the incidence of these injuries continues to increase [11, 33, 37, 77]. Despite the rising incidence, there remains little consensus on how best to treat acute Achilles tendon ruptures [11, 37]. Further, both operative and nonoperative treatment strategies continue to evolve, increasing uncertainty for both patients and surgeons.

Nonsurgical treatment of Achilles ruptures once consisted of cast immobilization in plantarflexion with prolonged immobilization, allowing for apposition and healing of the ruptured tendon. Because of concerns of rerupture and calf atrophy, open surgical management often has been preferred over nonoperative management for active, healthy patients. However, complications largely unique to surgery such as wound dehiscence, infections, and other soft tissue issues occur in up to 10% to 15% of treated patients [63]. Functional rehabilitation protocols with early weightbearing and ankle mobilization have seen wider use in recent years, with studies reporting similar patient-reported outcome scores, return to sport, and rerupture risk compared with operative treatment but without subjecting patients to the risks of surgery [11, 22, 33, 37, 77]. With increasing evidence supporting functional rehabilitation, practice has shifted rather drastically with an associated reduction in surgical treatment by more than 50% in the past 20 years [3, 56, 57], although this trend has not been seen in the United States [67, 90]. Successful functional rehabilitation programs require substantial patient cooperation and supervision,

which may be hindered by patient and system factors, such as lack of physiotherapy access [22, 33, 37, 77]. Despite advances in nonoperative treatment, many surgeons continue to advocate for surgical management because of increased confidence in maintaining tendon apposition, length, and strength [69], as well the traditional belief that rerupture risk is lower [11, 80]. To reduce surgical site complications, minimally invasive and percutaneous repair of the Achilles tendon have been advocated [47, 69]. Although some authors report percutaneous repair is associated with an increased risk of sural nerve complications and rerupture compared with open repair, these findings have been disputed [29, 48, 52].

Numerous meta-analyses have been performed to establish the superiority of one treatment over another [22, 23, 80, 99]. Constrained by design, traditional pairwise meta-analyses can only evaluate two treatments that have been directly compared in trials. Considering the multiple treatments available for Achilles tendon ruptures, the limitations of pairwise analysis have led to pooling of treatments into heterogeneous groups (such as, operative versus nonoperative management) and numerous overlapping meta-analyses [35, 66]. A network meta-analysis addresses this issue by facilitating simultaneous comparison of multiple treatments [6, 9, 53, 63]. Further, a network meta-analysis allows for the comparison of treatments that were not evaluated in a head-to-head manner in the original RCTs. This approach facilitates the estimation of relative treatment effects for interventions that have not been directly compared in head-to-head trials and for treatments that have only been compared in a limited number of trials.

Our goal was to use network meta-analysis to answer the following questions: Considering open repair, MIS repair, functional rehabilitation, or primary immobilization

for acute Achilles tendon ruptures, (1) which intervention is associated with the lowest risk of rerupture? (2) Which intervention is associated with the lowest risk of complications resulting in surgery?

Materials and Methods

Search Strategy

We conducted a systematic review with network meta-analyses using methods guided by the Cochrane Handbook for Systematic Reviews of Interventions [31]. This review is reported in adherence with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension statement for incorporating Network Meta-Analysis [36, 77]. We published a research protocol [66] and registered this study prospectively with PROSPERO (CRD42018093033). Our electronic search of medical and rehabilitation literature related to management of acute Achilles tendon rupture was performed from database inception to the search date (September 30, 2020) using Medline, Embase, CINAHL, PEDro and Cochrane Central Register of Controlled Trials. The primary author (BM) developed the search strategy in consultation with a senior information specialist (RS). The strategy was then peer reviewed by a second medical librarian in accordance with the Peer Review of Electronic Search Strategies (PRESS) framework [76]. The search strategy may be viewed in Appendix A.1. Previously published systematic reviews were cross-referenced for any missed studies. In addition, we manually searched relevant unpublished evidence sources (grey literature), including meeting abstracts from the Orthopaedic Trauma Association, American Academy of Orthopaedic Surgery, and American Orthopaedic Foot and Ankle Society (AOFAS) annual meetings from 2014 to 2019 to identify emerging studies nearing completion.

Preprint servers and foreign-language journals not included in the specified databases were not searched. No language limits were used. The search strategy for one database is available with the published study protocol [61].

Inclusion and Exclusion Criteria

Inclusion criteria were randomized controlled trials (RCTs) directly comparing two or more interventions for the treatment of first time, acute (less than 4 weeks since injury) Achilles tendon ruptures with a minimum follow-up of 6 months. This minimum follow-up was chosen to maximize study inclusion while ensuring appropriate demonstration of return to activity and complications [98]. Interventions of interest included conventional cast immobilization with delayed weightbearing for at least 6 weeks (primary immobilization), bracing and/or splinting with ROM earlier than 6 weeks (functional rehabilitation), open surgical repair, and percutaneous or minimally open surgical repair (minimally invasive surgery [MIS]). For inclusion as a functional rehabilitation protocol, ankle ROM had to be started before 6 weeks post rupture with or without early weightbearing. Minimally invasive surgery (MIS) treatment included all surgical modalities that did not completely open and reflect the paratenon, including limited transverse incisions, suture-shuttling techniques, and device-assisted techniques. Use of primary immobilization has largely decreased in recent years in favor of functional rehabilitation; however, this treatment was included as a comparator for other treatments and therefore any expertise bias resulting from its inclusion was anticipated to have little impact on our key findings. We excluded studies investigating modifications of only one of the above treatment. For example, we did not include RCTs examining early versus

late weightbearing after open surgical repair (as both treatment arms would be considered open surgical repair).

We chose exclusion criteria based on factors that may alter the natural history of tendon repair and rehabilitation: (1) patients younger than 16 years of age, (2) chronic tendon ruptures, (3) tendon rerupture, (4) inclusion of patients with preexisting Achilles tendinopathy, and (5) musculotendinous junction tears. If two or more studies reported the same information, we included only the study with most complete data (that is, the complete reporting of outcomes of interest). Studies were excluded if nonrandom loss to follow-up was greater than 20%.

Screening

The search was conducted on September 30, 2019. Studies were screened using Covidence (Veritas Health Information Ltd). Two reviewers (BM, MR) screened all titles, abstracts, and full-text articles independently and in duplicate. Disagreements at the title and abstract stages were resolved by automatic inclusion and disagreements at the full-text stage were resolved by consensus. Study authors were contacted if eligibility criteria were unclear.

Outcomes

The primary outcomes for quantitative synthesis were (1) rerupture and (2) post-treatment complications resulting in surgery. Secondary outcomes included functional outcome score, strength, and ROM. Both outcomes were evaluated at the longest reported follow-up. Despite inclusion in the published study protocol [61], the outcomes of overall complications and return to activity were not included in the final analysis. During peer-

review, it became apparent that analyzing pooled complications, while statistically robust, resulted in an outcome of unclear clinical relevance because it would have involved pooling common but relatively mild complications (such as superficial infection) with rarer but devastating events (like complex regional pain syndrome [CRPS]). Thus, the outcome of pooled complications was excluded from the final analysis. Complications resulting in surgery were chosen partly as surrogates for serious complications as there were an insufficient number of serious complications not resulting in surgery for statistical analysis. Patients with rerupture, if treated surgically, were counted in both rerupture and complications resulting in surgery. Return to function was excluded from the final analysis because of the inconsistent and heterogeneous nature of the available evidence, which precluded appropriate application of network meta-analysis methodology.

Data Extraction

Data were abstracted in duplicate by two reviewers (MR, AG) using a standardized extraction document (Microsoft Excel 16.2), which was developed and piloted a priori. Discrepancies were resolved by consensus and input from a third reviewer (BM or WC). Study authors were contacted in cases of incomplete data. Abstracted data included study author, year, country of publication, outcome data, and participant demographics (mean age, sex, risk factors for complication such as smoking status, fluoroquinolone or steroid use, diabetes, and smoking), surgical repair method including technique and suture, surgeon experience, length of immobilization, and weightbearing status.

Quality Assessment

The Cochrane Risk of Bias version 2 (ROB 2) assessment tool was used to evaluate bias in the following domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias [83]. Two reviewers (BM, AG) evaluated all studies and assigned risk as high risk, low risk, or unclear, with disagreements resolved by consensus. Risk of bias between studies (such as, small-study effects signalling publication bias) was assessed and presented as funnel plots. The overall quality of the evidence was determined and ranked per the Grades of Recommendation, Assessment, Development and Evaluation approach for NMAs [25, 71].

Study Characteristics

The search identified 630 citations; 103 studies underwent full-text review, of which 19 RCTs (1316 patients) were included in the final analysis (Fig. 2.1). Included studies were published between 1981 and 2018 (median = 2008). Unique pairwise comparisons included open surgery versus MIS [1, 2, 21, 41, 46, 52, 73], open surgery versus functional rehabilitation [13, 49, 64, 85, 88, 96], MIS versus functional rehabilitation [60], and open surgery versus primary immobilization [10, 42, 62, 65]. One study had three treatment arms [54]. The list of included studies can be viewed in Appendix A.2. The mean number of patients per study treatment arm was 35 ± 17 patients. Across studies, the mean age was 41 ± 5 years and 80% of participants were male (Table 2.1). Mean age and sex composition were similar across treatment arms. Mean follow-up across all studies was 22 ± 12 months, which was also similar between treatment groups. Only one study had a follow-up less than 12 months [52].

Study Quality

The cumulative risk of bias was deemed low across domains (Fig. 2.2a). Of the 19 included studies, nine were deemed to be at low risk of bias in at least five domains, and 14 studies were deemed low risk in at least four domains (Fig. 2.2b). Overall, risk of selection, attrition, and reporting bias was low. However, risk of performance bias and detection bias were high, largely because of the difficulty of blinding when performing studies of surgical treatments. Risk of bias was not expected to compromise pooled results, as it appeared similar across treatment arms.

Ethical Approval

This network meta-analysis did not involve human participants and therefore was not subject to institutional review board approval.

Meta-analysis Methodology

We performed pairwise meta-analysis for all primary outcomes when direct comparisons were available. The Mantel-Haenszel random-effects model was applied to binary outcomes in the presence of sufficient clinical, methodological, and statistical homogeneity (heterogeneity $I^2 < 50\%$) [32]. Pairwise analysis results are expressed as odds ratios for dichotomous outcomes with 95% confidence intervals. Forest plots from pairwise analysis were generated using Review Manager (Version 5.3, The Cochrane Collaboration, Nordic Cochrane Centre).

Network Meta-analysis Methodology

To perform network analyses, we used the OpenBUGS software (Version 3.2.3) and the R2OpenBUGS package (Version 3.2) in R (Version 3.4.2, Open Access Online) [81, 84]. We generated network diagrams (Fig. 2.3) for each outcome to ensure well-connected

network geometry (at least one closed loop among interventions). We assessed the validity of the transitivity assumption (that is, homogeneity/similarity across studies) by thoroughly reviewing study methods, patient characteristics, and enrollment criteria using established methods [15, 16]. All treatments were assessed to be "jointly randomizable" and could reasonably be applied to any patient in the network [74]. This assumption was supported by relatively strict inclusion criteria and the similar composition of pooled treatment groups [24]. Random-effects Bayesian network meta-analysis with vague priors was performed for each outcome. Prior distributions describe information outside of the included studies used to determine the posterior distribution from which summary measures (such as, mean and SD) are calculated [39]. We used vague priors as there appeared to be sufficient data to estimate variance appropriately without introducing subjectivity into our models, which may occur with truly informative priors [97]. Adequacy of model fit was assessed by comparing the total residual deviance with the number of unconstrained data points (the number of intervention arms across studies in the analysis) and was considered adequate if these quantities were approximately equal. Model selection was based on deviance information criteria, with smaller values being preferred and a difference of five or more points representing an important difference in fit between models. Model convergence was assessed using established methods including the Gelman-Rubin diagnostics and the Potential Scale Reduction Factor [4, 20]. Validity of the consistency assumption (the agreement between direct and indirect evidence) was assessed by fitting random effects unrelated means models to the data and comparing deviance information criterion (DIC) values and posterior mean deviance contributions with the DIC values from consistency models. Deviance residuals, the

amount of deviance from each observation, were then plotted to identify inconsistency between direct and indirect evidence (Fig. 2.4). Total residual deviance values were lower than the number of unconstrained data points due to several studies with zero occurrences of the outcome of interest.

Our results are presented using odds ratios (OR) and 95% credible intervals (CrI), a measure of imprecision derived using the posterior distributions, which are akin to a Bayesian equivalent of confidence intervals. Comparisons were inferred to be significant if the 95% CrI of the OR did not cross one [17]. A Surface Under the Cumulative Ranking (SUCRA) curve, a numeric representation of treatment ranking, was calculated for each intervention. As SUCRA nears one (the maximum possible value), the greater the probability a treatment is in the top ranks of treatments [75]. Values approaching zero indicate a greater probability a treatment is in the bottom ranks. Number needed to treat (NNT) was calculated using the difference in mean patient-expected event rates [12]. Summary of findings tables are presented using open surgery as the reference treatment as it was most well connected to other interventions by direct evidence. Comparison-adjusted funnel plots were applied to assess for small-study effects as signals of publication bias. We performed a sensitivity analysis for risk of complications by excluding keloid scars as a complication. For the outcome of complications resulting in surgery, we performed a sensitivity analysis by excluding the study with follow-up duration stated to be “at least 6 months” [52].

Results

Rerupture

We found no difference between open surgical repair, MIS repair, and functional rehabilitation for risk of rerupture, and primary immobilization was associated with a greater risk of rerupture than open repair. Specifically, the network analysis for rerupture (19 RCTs, 1316 participants) demonstrated no difference between open surgical repair (reference treatment) and MIS repair (OR 0.96 [95% CrI 0.22 to 4.15]; $p > 0.05$) or functional rehabilitation (OR 2.18 [95% CrI 0.80 to 6.20]; $p > 0.05$) (Fig. 2.5). We also found no difference between functional rehabilitation and MIS (OR 0.45 [95% CrI 0.10 to 1.82]; $p > 0.05$) Compared with open surgery, primary immobilization was associated with a greater risk of rerupture (OR 4.06 [95% CrI 1.47 to 11.88]; $p < 0.05$) (Table 2.2). Open surgical repair and minimally invasive surgery were ranked most favorably for risk of rerupture (SUCRA 0.80 and 0.79, respectively) (Table 2.3). There were no differences between pairwise and network-derived estimates (Fig. 2.6).

Complications Resulting in Surgery

We found a lower risk of complications resulting in surgery with MIS repair relative to both open surgery and functional rehabilitation, and we found no difference in risk between functional rehabilitation and open surgery. The network analysis (15 RCTs, 949 patients) demonstrated that MIS repair was associated with a lower risk of complications resulting in surgery than open surgical repair (OR 0.22 [95% CrI 0.04 to 0.93]; $p < 0.05$) and functional rehabilitation (OR 0.16 [95% CrI 0.02 to 0.90]; $p < 0.05$). We found no difference in complications resulting in surgery between functional rehabilitation and open surgery (OR 1.46 [95% CrI 0.35 to 5.46]; $p > 0.05$) (Fig. 2.5). Immobilization was associated with a greater risk of complications resulting in surgery than any other treatment. Minimally invasive surgery was ranked most highly for complications

resulting in surgery (SUCRA 0.99) (Table 2.7). Consistency was present between pairwise and network comparisons (Fig. 2.7).

Discussion

Treatment of acute Achilles tendon ruptures remains an area of uncertainty, despite an abundance of RCTs and resultant meta-analyses. Our goal was to use a network meta-analysis to compare treatments for acute Achilles tendon ruptures, including treatments infrequently compared in head-to-head RCTs, in a simultaneous and comprehensive manner not otherwise possible with simple meta-analysis. We found no difference in the rerupture risk between open surgical repair, MIS repair, and functional rehabilitation; immobilization was associated with a greater risk of rerupture than open surgical repair. We found a lower risk of complications resulting in surgery after MIS repair relative to both open surgery and functional rehabilitation.

Limitations

Network meta-analysis can be a powerful tool for comparing nearly all randomized evidence for treatment of a given pathology. However, this study has several key limitations, two of which resulted from the choice of complications resulting in surgery as a primary outcome. First, rerupture was the most common complication resulting in surgery, and most reported reruptures were treated surgically. Therefore, readers must be aware that treatments with an increased risk of rerupture will be overrepresented in our study (because rerupture was counted in both study endpoints) and any conclusions should be balanced with information gathered from existing studies on complications other than rerupture [44, 66]. Specifically, following functional rehabilitation, more than 80% of complications resulting in operation were from rerupture, a greater proportion

than MIS and open surgery. Second, we settled on the outcome of complications resulting in surgery for pragmatic reasons—to facilitate robust, pooled analysis of serious complications with tangible implications for both patients and surgeons. Unfortunately, specific complications resulting in surgery other than rerupture (such as deep infection) were reported with insufficient frequency for independent network analysis [95]. Complications associated with serious morbidity not resulting in further surgery such as deep vein thrombosis and pulmonary embolism (both of which are more common after operative management) were inconsistently reported in the included studies and were therefore excluded from our analysis [70]. Readers should interpret the risk of complications resulting in surgery within the context of existing evidence that has explored serious complications not resulting in further surgery, complications that may still lead to substantial patient morbidity [59].

Another limitation of our study is we were unable to analyze both minor, more frequent complications, such as keloid scars, skin adhesions, and superficial infection, as well as other complications such as sural nerve injury (24% of all complications after MIS) and complex regional pain syndrome (CRPS). At the outset of this study, it was our goal to analyze these complications [61]; however, during the review process it became clear that pooling in this manner would have resulted in a study endpoint that grouped relatively inconsequential complications with very serious ones, which can be misleading. For example, it would not be appropriate to pool superficial skin infection resolving with a short course of oral antibiotics—the most common complication of surgical management (31% of all complications)—with permanent sural nerve dysfunction or CRPS, which are associated with substantial morbidity [43, 60]. Although independent analysis of these

complications is undoubtedly important, it was not possible to do that in the context of this network meta-analysis. For example, other than very rare instances, wound complications and infection occur only after MIS and open surgical repair and therefore a pairwise meta-analysis may be more appropriate [19]. Further, with a complication such as sural nerve injury (24% of all MIS-associated complications), analyzing a variety of MIS techniques together may be inappropriate secondary to a vastly different risk of sural nerve injury across the techniques [55]. Considering the above, our conclusions are based on only two facets of morbidity after treatment and should therefore be viewed in light of past analyses on specific complications. In addition to rerupture and complications resulting in surgery, patients should be counseled about the risks of other complications such as wound complications, infection, nerve injury, and deep vein thrombosis [44, 57, 70]

Patient-reported outcomes are increasingly important in Achilles tendon rupture literature; focus has shifted at least partly from rerupture risk to validated measures of patient function. Although described in our protocol, we were unable to perform an appropriate network meta-analysis for this outcome because of small sample sizes and heterogeneity of outcome measures, even after considering the use of standardized mean differences [14, 31, 45, 51]. Inferences would have been driven by limited direct comparisons and frequent third-order comparisons (two intermediary comparators are needed to form a network), resulting in very low confidence in network estimates [95]. Differences in treatment specifics within groups may have further limited the validity of pooling studies to perform this analysis. Recent evidence has found that distinct surgical variations and variations in postoperative protocols result in different degrees of tendon

elongation [8, 18, 27, 30, 40, 72, 86]. Further, posttreatment tendon elongation has been associated with lower patient-reported outcomes scores and reduced plantarflexion strength [28, 79, 91]. For these reasons, surgeons must largely rely on direct RCT evidence of patient-reported outcomes, rather than pooled comparisons, when putting the findings of our study into context. For reference, most included studies (6 of 7) reported no difference between MIS and open surgery, and one study reported MIS was superior to open surgery. One study reported that open surgery outperformed functional rehabilitation (Table 2.5). Only the minority of studies found differences in strength parameters (Table 2.6).

Similarly, return to work and sport analyses were not performed because of very low evidence quality and poor assessment of the endpoints in question. Inconsistency in return to sport reporting has been previously noted by other researchers [3, 44, 66], although studies have found no difference between open repair, MIS repair, and functional rehabilitation [23, 60, 66]. In our study, most included RCTs found no difference between return to work (Table 2.7); some studies also found no difference in return to sport (Table 2.8). Of great concern regarding risk of bias, nearly all studies lacked rigorous blinding and authors largely did not outline return to activity (such as work and sport) criteria in detail. Surgeons must be cautious when considering our findings in the context of existing, high risk-of-bias RCT evidence on inter-treatment differences in return to activity.

Finally, several studies did not report the presence of risk factors for complications such as smoking, diabetes, and fluoroquinolone use [5]. However, the treatment indications and inclusion criteria were very similar or identical between included studies so it is

unlikely that there was unequal distribution of effect modifiers between pooled network groups.

Rerupture

We found no difference in the risk of rerupture between open surgical repair, MIS repair, and functional rehabilitation. We also found that immobilization was associated with a greater risk of rerupture than open surgical repair, and although the quality of evidence was low, this finding is in agreement with existing evidence [66]. Although our study did not investigate the effect of early versus late weightbearing after open surgical treatment, previous analyses have demonstrated both postoperative protocols reduce rerupture risk compared with primary immobilization [66, 80]. When a functional rehabilitation protocol is used (that is, early full weightbearing with progressive ROM) our study and others, including recent meta-analyses pooling observational data from thousands of patients, have found no difference in rerupture risk between open surgery, MIS, and nonoperative treatment [60, 66, 78, 80, 89, 98]. Our findings are congruent with and further support the paradigm shift over the past decade: Although previously, operative treatment was considered the gold standard largely because of decreased rerupture risk, nonoperative treatment with functional rehabilitation has been accepted as a viable alternative with a rerupture risk that is no different from operative treatment [44, 66, 77]. However, the question of rerupture risk remains unsettled. To further inform treatment decision making, future research, both randomized and observational, should examine rerupture risk between treatments in populations that may be at higher risk for poor outcomes and rerupture such as those with increased tendon diastasis or more proximal ruptures [26, 92], and older patients or those with higher BMI [7, 50, 67, 82, 93].

Rerupture risk between treatments should also be investigated in high-demand groups such as younger patients and those engaged in athletics [38].

Reoperation

Our analysis of reoperation found that MIS was associated with a lower reoperation risk relative to open surgery, functional rehabilitation, and primary immobilization. The comparison between MIS and open surgery was informed by moderate quality evidence, and the difference between MIS and functional rehabilitation was supported by low-quality evidence. Interestingly, it appears that the risk of complications resulting in operation (or reoperation, in the case of operative management) is rarely, if ever, reported in existing meta-analyses. Our findings contrast with a recent retrospective study comparing 270 patients treated with either percutaneous or open repair that found no difference in risk of complications resulting in surgery [34]. Complications resulting in surgery, most frequently rerupture and deep infection, have been associated with poor patient-reported outcomes, and in many instances, lead to severe long-term functional deficits, particularly if repeat or extensive revision surgery is needed [58, 59, 68]. For this reason, we believe patients and surgeons should consider the moderate quality evidence that MIS may be associated with a reduced risk of complications resulting in surgery (number needed to treat = 40), particularly when compared with open surgical repair. However, patients and surgeons must balance this benefit with the potential drawbacks of MIS repair [55]. Of note, reruptures may be treated with either nonoperative management or revision surgery, though in the case of revision surgery, more involved techniques such as fascial flaps and allograft are typically used [58, 59, 68, 93]. The difference we found also calls into question the conclusions of existing cost-efficacy analyses that have

assumed equal reoperation between treatments [87, 94]. The implications of further surgery on total treatment cost are likely substantial and therefore, our findings may be of interest to policy-makers. Overall, as our study is the first to demonstrate a difference in complications resulting in surgery, future studies (including meta-analyses) should include this outcome, as it is likely of interest to patients and surgeons alike.

Conclusion

Faced with acute Achilles tendon rupture, patients should be counselled that, based on current evidence, the rerupture risk likely is no different across contemporary treatments. Considering the possibly lower risk of complications resulting in surgery associated with MIS repair, patients and surgeons must balance any benefit with the potential risks of MIS techniques. As treatments continue to evolve, consistent reporting of validated patient-reported outcome measures is critically important to facilitate analysis with existing RCT evidence. Infrequent but serious complications such as rerupture and deep infection should be further explored to determine if meaningful differences exist in specific patient populations.

References

1. Aisaiding A, Wang J, Maimaiti R, et al. A novel minimally invasive surgery combined with early exercise therapy promoting tendon regeneration in the treatment of spontaneous Achilles tendon rupture. *Injury*. 2018;49:712-719.

2. Aktas S, Kocaoglu B. Open versus minimal invasive repair with Achillon device. *Foot Ankle Int*. 2009;30:391-397.

3. Ardern CL, Glasgow P, Schneiders A, et al. 2016 Consensus statement on return to sport from the First World Congress in Sports Physical Therapy, Bern. *Br J Sports Med*. 2016;50:853-864.

4. Brooks SP, Gelman A. General methods for monitoring convergence of iterative simulations. *J Comput Graph Stat*. 1998;7:434-455.

5. Bruggeman NB, Turner NS, Dahm DL, et al. Wound complications after open Achilles tendon repair: an analysis of risk factors. *Clin Orthop Rel Res*. 2004;427:63-66.

6. Caldwell DM, Ades AE, Higgins JPT. Simultaneous comparison of multiple treatments: combining direct and indirect evidence. *BMJ*. 2005;331:897-900.

7. Cao S, Teng Z, Wang C, Zhou Q, Wang X, Ma X. Influence of Achilles tendon rupture site on surgical repair outcomes. *J Orthop Surg*. 2021;29:23094990211007616.

8. Carmont MR, Kuiper JH, Grävare Silbernagel K, Karlsson J, Nilsson-Helander K. Tendon end separation with loading in an Achilles tendon repair model: comparison of non-absorbable vs. absorbable sutures. *J Exp Orthop.* 2017;4:26

9. Catalá-López F, Tobías A, Cameron C, Moher D, Hutton B. Network meta-analysis for comparing treatment effects of multiple interventions: an introduction. *Rheumatol Int*.

2014;34:1489-1496.

10. Cetti R, Christensen SE, Ejsted R, Jensen NM, Jorgensen U. Operative versus nonoperative treatment of Achilles tendon rupture: a prospective randomized study and review of the literature. *Am J Sports Med*. 1993;21:791-799.

11. Chiodo CP, Glazebrook M, Bluman EM, et al. Diagnosis and treatment of acute Achilles tendon rupture. *J Am Acad Orthop Surg*. 2010;18:503-510.

12. Citrome L, Ketter TA. When does a difference make a difference? Interpretation of number needed to treat, number needed to harm, and likelihood to be helped or harmed. *Int J Clin*. 2013;67:407-411.

13. Costa ML, MacMillan K, Halliday D, et al. Randomised controlled trials of immediate weight-bearing mobilisation for rupture of the tendo Achillis. *J Bone Joint Surg Br*. 2006;88:69-77.

14. Demets DL. Methods for combining randomized clinical trials: strengths and limitations. *Stat Med*. 1987;6:341-350.

15. Dias S, Sutton AJ, Ades AE, Welton NJ. Evidence synthesis for decision making 2: A generalized linear modeling framework for pairwise and network meta-analysis of randomized controlled trials. *Med Decis Making*. 2013;33:607-617.

16. Dias S, Welton NJ, Sutton AJ, Ades AE. NICE DSU Technical support document 2: A generalised linear modelling framework for pairwise and network meta-analysis of randomised controlled trials. Available at: https://www.ncbi.nlm.nih.gov/books/NBK310366/. Accessed September 30, 2020.

17. Foote CJ, Chaudhry H, Bhandari M, et al. Network meta-analysis: users' guide for surgeons: part I-credibility. *Clin Orthop Rel Res*. 2015;473:2166-2171.

18. Frosch S, Buchhorn G, Hawellek T, Walde TA, Lehmann W, Hubert J. Comparison of the double loop knot stitch and Kessler stitch for Achilles tendon repair: A biomechanical cadaver study. *PLoS One*. 2020;15:e0243306.

19. Gatz M, Driessen A, Eschweiler J, Tingart M, Migliorini F. Open versus minimally-invasive surgery for Achilles tendon rupture: a meta-analysis study. *Arch Orthop Trauma Surg*. 202;141:383-401.

20. Gelman A. Inference and monitoring convergence. In: Gilks WR, Richardson S, Spiegelhalter DJ, eds. *Markov Chain Monte Carlo in Practice*. Chapman & Hall, 1996:131-143.

21. Gigante A, Moschini A, Verdenelli A, Del Torto M, Ulisse S, De Palma L. Open versus percutaneous repair in the treatment of acute Achilles tendon rupture: a randomized prospective study. *Knee Surg Sports Traumatol Arthrosc*. 2008;16:204-209.

22. Glazebrook M, Rubinger D. Functional rehabilitation for nonsurgical treatment of acute Achilles tendon rupture. *Foot Ankle Clin*. 2019;24:387-398.

23. Grassi A, Amendola A, Samuelsson K, et al. Minimally invasive versus open repair for acute Achilles tendon rupture: meta-analysis showing reduced complications, with similar outcomes, after minimally invasive surgery. *J Bone Joint Surg*. 2018;100:1969-1981.

24. Grävare Silbernagel K, Brorsson A, Olsson N, Eriksson BI, Karlsson J, Nilsson-Helander K. Sex differences in outcome after an acute Achilles tendon rupture. *Orthop J Sports Med*. 2015;3:2325967115586768.

25. Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: A new series of articles in the Journal of Clinical Epidemiology. *J Clin Epidemiol*. 2011;64:380-382.

26. Hansen MS, Vestermark MT, Hölmich P, Kristensen MT, Barfod KW. Individualized treatment for acute Achilles tendon rupture based on the Copenhagen Achilles rupture treatment algorithm (CARTA): A study protocol for a multicenter randomized controlled trial. *Trials*. 2020;21:399.

27. Hapa O, Erduran M, Havitçioğlu H, et al. Strength of different Krackow stitch configurations using high-strength suture. *J Foot Ankle Surg*. 2013;52:448-450.

28. Heikkinen J, Lantto I, Piilonen J, et al. Tendon length, calf muscle atrophy, and strength deficit after acute Achilles tendon rupture: Long-term follow-up of patients in a previous study. *J Bone Joint Surg Am*. 2017;99:1509-1515.

29. Henríquez H, Muñoz R, Carcuro G, Bastías C. Is percutaneous repair better than open repair in acute Achilles tendon rupture?. *Clin Orthop Relat Res.* 2012;470:998-1003.

30. Herbort M, Haber A, Zantop T, et al. Biomechanical comparison of the primary stability of suturing Achilles tendon rupture: a cadaver study of Bunnell and Kessler techniques under cyclic loading conditions. *Arch Orthop Trauma Surg*. 2008;128:1273-1277.

31. Higgins JPT, Thomas J, Chandler J, et al. Cochrane handbook for systematic reviews

of interventions version 6.0. Available at: www.training.cochrane.org/handbook. Accessed March 10, 2021.

32. Higgins JPT, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med*. 2002;21:1539-1558.

33. Ho G, Tantigate D, Kirschenbaum J, Greisberg JK, Vosseller JT. Increasing age in Achilles rupture patients over time. *Injury*. 2017;48:1701-1709.

34. Hsu AR, Jones CP, Cohen BE, Davis WH, Ellington JK, Anderson RB. Clinical outcomes and complications of percutaneous Achilles repair system versus open technique for acute Achilles tendon ruptures. *Foot Ankle Int*. 2015;36:1279-1286.

35. Hurley E, Yasui Y, Gianakos A, et al. Achilles tendon repair-A systematic review of overlapping meta-analyses. *Foot & Ankle Orthop.* 2017;2:2473011417S000212.

36. Hutton B, Salanti G, Caldwell DM, et al. The PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of health care interventions: checklist and explanations. *Ann Intern Med*. 2015;162:777-784.

37. Huttunen TT, Kannus P, Rolf C, Felländer-Tsai L, Mattila VM. Acute achilles tendon ruptures: incidence of injury and surgery in Sweden between 2001 and 2012. *Am J Sports Med*. 2014;42:2419-2423.

38. Jallageas R, Bordes J, Daviet JC, Mabit C, Coste C. Evaluation of surgical treatment for ruptured Achilles tendon in 31 athletes. *Orthop Traumatol Surg Res*. 2013;99:577-584.

39. Jansen JP, Crawford B, Bergman G, Stam W. Bayesian meta-analysis of multiple treatment comparisons: an introduction to mixed treatment comparisons. *Value Health*. 2008;11:956-964.

40. Kangas J, Pajala A, Ohtonen P, Leppilahti J. Achilles tendon elongation after rupture repair: a randomized comparison of 2 postoperative regimens. *Am J Sports Med*. 2007;35:59-64.

41. Karabinas PK, Benetos IS, Lampropoulou-Adamidou K, Romoudis P, Mavrogenis AF, Vlamis J. Percutaneous versus open repair of acute Achilles tendon ruptures. *Eur J Orthop Surg Traumatol*. 2014;24:607-613.

42. Keating JF, Will EM. Operative versus non-operative treatment of acute rupture of tendo Achillis: a prospective randomised evaluation of functional outcome. *J Bone Joint Surg Br*. 2011;93:1071-1078.

43. Kemler MA, de Vet HC. Health-related quality of life in chronic refractory reflex sympathetic dystrophy (complex regional pain syndrome type I). *J Pain Symptom Manage*. 2000;20:68-76.

44. Khan RJ, Smith RLC. Surgical interventions for treating acute Achilles tendon ruptures. *Cochrane Database Syst Rev*. 2010.

45. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int*. 1994;15:349-353.

46. Kołodziej Ł, Bohatyrewicz A, Kromuszczyńska J, Jezierski J, Biedroń M. Efficacy and complications of open and minimally invasive surgery in acute Achilles tendon

rupture: a prospective randomised clinical study—preliminary report. *Int Orthop*. 2013;37:625-629.

47. Kou J. AAOS clinical practice guideline: acute Achilles tendon rupture. *J Am Acad Orthop Surg*. 2010;18:511-513.

48. Kristman V, Manno M, Côté P. Loss to follow-up in cohort studies: how much is too much. *Eur J Epidemiol.* 2004;19:751-760.

49. Lantto I, Heikkinen J, Flinkkila T, et al. A prospective randomized trial comparing surgical and nonsurgical treatments of acute Achilles tendon ruptures. *Am J Sports Med*. 2016;44:2406-2414.

50. Lawrence JE, Nasr P, Fountain DM, Berman L, Robinson AH. Functional outcomes of conservatively managed acute ruptures of the Achilles tendon. *Bone Joint J*. 2017;99:87-93.

51. Leppilahti J, Forsman K, Puranen J, Orava S. Outcome and prognostic factors of Achilles rupture repair using a new scoring method. *Clin Orthop Rel Res*. 1998:152-161.

52. Lim J, Dalai R, Waseem M. Percutaneous vs. open repair of the ruptured Achilles tendon—a prospective randomized controlled study. *Foot Ankle Int*. 2001;22:559-568.

53. Lu G, Ades AE. Combination of direct and indirect evidence in mixed treatment comparisons. *Stat Med*. 2004;23:3105-3124.

54. Majewski M, Rickert M, Steinbruck K. [Achilles tendon rupture. A prospective study assessing various treatment possibilities]. [in German]. *Orthopade*. 2000;29:670-676.

55. Majewski M, Rohrbach M, Czaja S, Ochsner P. Avoiding sural nerve injuries during percutaneous Achilles tendon repair. *Am J Sports Med*. 2006;34:793-798.

56. Mattila VM, Huttunen TT, Haapasalo H, et al. Declining incidence of surgery for Achilles tendon rupture follows publication of major RCTs: evidence-influenced change evident using the Finnish registry study. *Br J Sports Med*. 2015;49:1084-1086.

57. McMahon SE, Smith TO, Hing CB. A meta-analysis of randomised controlled trials comparing conventional to minimally invasive approaches for repair of an Achilles tendon rupture. *Foot Ankle Surg*. 2011;17:211-217.

58. Metz R, van der Heijden GJ, Verleisdonk EJ, Andrlik M, van der Werken C. Persistent disability despite sufficient calf muscle strength after rerupture of surgically treated acute achilles tendon ruptures. *Foot Ankle Spec*. 2011;4:77-81.

59. Metz R, van der Heijden GJ, Verleisdonk EJ, Kolfschoten N, Verhofstad MH, van der Werken C. Effect of complications after minimally invasive surgical repair of acute Achilles tendon ruptures: report on 211 cases. *Am J Sports Med*. 2011;39:820-824.

60. Metz R, Verleisdonk EJ, van der Heijden GJ, et al. Acute Achilles tendon rupture: minimally invasive surgery versus nonoperative treatment with immediate full weightbearing—a randomized controlled trial. *Am J Sports Med*. 2008;36:1688-1694.

61. Meulenkamp B, Stacey D, Fergusson D, Hutton B, Mlis RS, Graham ID. Protocol for treatment of Achilles tendon ruptures; a systematic review with network meta-analysis. *Syst Rev*. 2018;7:247.

62. Möller M, Movin T, Granhed H, Lind K, Faxen E, Karlsson J. Acute rupture of tendo Achillis: a prospective, randomised study of comparison between surgical and non-surgical treatment. *J Bone Joint Surg Br*. 2001;83:843-848.

63. Molloy A, Wood EV. Complications of the treatment of Achilles tendon ruptures.

Foot Ankle Clin. 2009;14:745-59.

64. Nilsson-Helander K, Grävare Silbernagel K, Thomee R, et al. Acute Achilles tendon rupture: a randomized, controlled study comparing surgical and nonsurgical treatments using validated outcome measures. *Am J Sports Med*. 2010;38:2186-2193.

65. Nistor LA. Surgical and non-surgical treatment of Achilles Tendon rupture. A prospective randomized study. *J Bone Joint Surg*. 1981;63:394-399.

66. Ochen Y, Beks RB, van Heijl M, et al. Operative treatment versus nonoperative treatment of Achilles tendon ruptures: systematic review and meta-analysis. *BMJ*. 2019;7:364.

67. Olsson N, Petzold M, Brorsson A, Karlsson J, Eriksson BI, Silbernagel KG. Predictors of clinical outcome after acute Achilles tendon ruptures. *Am J Sports Med*. 2014;42:1448-1455.

68. Pajala A, Kangas J, Ohtonen P, Leppilahti J. Rerupture and deep infection following treatment of total Achilles tendon rupture. *J Bone Joint Surg*. 2002;84:2016-2021.

69. Patel MS, Kadakia AR. Minimally invasive treatments of acute Achilles tendon ruptures. *Foot Ankle Clin*. 2019;24:399-424.

70. Patel A, Ogawa B, Charlton T, Thordarson D. Incidence of deep vein thrombosis and pulmonary embolism after Achilles tendon rupture. *Clin Orthop Relat Res*. 2012;470:270-274.

71. Puhan MA, Schunemann HJ, Murad MH, et al. A GRADE working group approach for rating the quality of treatment effect estimates from network meta-analysis. *BMJ*. 2014;349:g5630-g5630.

72. Rosso C, Vavken P, Polzer C, et al. Long-term outcomes of muscle volume and Achilles tendon length after Achilles tendon ruptures. *Knee Surg Sports Traumatol Arthrosc*. 2013;21:1369-1377.

73. Rozis M, Benetos IS, Karampinas P, Polyzois V, Vlamis J, Pneumaticos SG. Outcome of percutaneous fixation of acute Achilles tendon ruptures. *Foot Ankle Int*. 2018;39:689-693.

74. Salanti G. Indirect and mixed-treatment comparison, network, or multiple-treatments meta-analysis: many names, many benefits, many concerns for the next generation evidence synthesis tool. *Res Synth Methods*. 2012;3:80-97.

75. Salanti G, Ades AE, Ioannidis JPA. Graphical methods and numerical summaries for presenting results from multiple-treatment meta-analysis: an overview and tutorial. *J Clin Epidemiol*. 2011;64:163-171.

76. Sampson M, McGowan J, Cogo E, Grimshaw J, Moher D, Lefebvre C. An evidence-based practice guideline for the peer review of electronic search strategies. *J Clin Epidemiol*. 2009;62:944-952.

77. Sheth U, Wasserstein D, Jenkinson R, Moineddin R, Kreder H, Jaglal SB. The epidemiology and trends in management of acute Achilles tendon ruptures in Ontario, Canada: a population-based study of 27 607 patients. *Bone Joint J*. 2017;99:78-86.

78. Shi F, Wu S, Cai W, Zhao Y. Multiple Comparisons of the efficacy and safety for six treatments in acute Achilles tendon rupture patients: a systematic review and network meta-analysis. *Foot Ankle Surg*. 2020:S1268-7731

79. Silbernagel KG, Steele R, Manal K. Deficits in heel-rise height and Achilles tendon

elongation occur in patients recovering from an Achilles tendon rupture. *Am J Sports Med*. 2012;40:1564-1571.

80. Soroceanu A, Sidhwa F, Aarabi S, Kaufman A, Glazebrook M. Surgical versus nonsurgical treatment of acute Achilles tendon rupture: a meta-analysis of randomized trials. *J Bone Joint Surg Am*. 2012;94:2136.

81. Spiegelhalter D, Thomas A, Best N, Dave L. OpenBUGS User Manual, version 3.2.3. Available at: http://www.openbugs.net/w/Manuals. Accessed March 10, 2020.

82. Stavenuiter XJR, Lubberts B, Prince RM 3rd, Johnson AH, DiGiovanni CW, Guss D. Postoperative complications following repair of acute Achilles tendon rupture. *Foot Ankle Int*. 2019;40:679-686.

83. Sterne JAC, Savovic J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019;2:l4898.

84. Sturtz S, Ligges U, Gelman A. R2WinBUGS: A package for running WinBUGS from R. *Stat Softw*. 2019;12:1-16.

85. Thermann H, Zwipp H, Tscherne H. Functional treatment concept of acute rupture of the Achilles tendon. 2 years results of a prospective randomized study. *Der Unfallchirurg*. 1995;98:21.

86. Tian J, Rui Y, Xu Y, et al. A biomechanical comparison of Achilles tendon suture repair techniques: Locking block modified Krackow, Kessler, and Percutaneous Achilles Repair System with the early rehabilitation program in vitro bovine model. *Arch Orthop Trauma Surg*. 2020;140:1775-1782.

87. Truntzer JN, Triana B, Harris AH, Baker L, Chou L, Kamal RN. Cost-minimization analysis of the management of acute Achilles tendon rupture. *J Am Acad Orthop Surg*. 2017;25:449-457.

88. Twaddle BC, Poon P. Early motion for Achilles tendon ruptures: Is surgery important? A randomized, prospective study. *Am J Sports Med*. 2007;35:2033-2038.

89. van der Eng DM, Schepers T, Goslings JC, Schep NW. Rerupture rate after early weightbearing in operative versus conservative treatment of Achilles tendon ruptures: a meta-analysis. *J Foot Ankle Surg*. 2013;52:622-628.

90. Wang D, Sandlin MI, Cohen JR, Lord EL, Petrigliano FA, SooHoo NF. Operative versus nonoperative treatment of acute Achilles tendon rupture: an analysis of 12,570 patients in a large healthcare database. *Foot Ankle Surg*. 2015;21:250-253.

91. Wang X, Liu H, Li D, Luo Z, Li Y, Zhang F. Modified Bunnell suture repair versus bundle-to-bundle suture repair for acute Achilles tendon rupture: a prospective comparative study of patients aged < 45 years. *BMC Musculoskelet Disord*. 2020;21:580.

92. Westin O, Nilsson Helander K, Grävare Silbernagel K, et al. Acute ultrasonography investigation to predict reruptures and outcomes in patients with an Achilles tendon rupture. *Orthop J Sports Med*. 2016;4:2325967116667920.

93. Westin O, Nilsson Helander K, Grävare Silbernagel K et al. Patients with an Achilles tendon re-rupture have long-term functional deficits in function and worse patient-reported outcome than primary ruptures. *Knee Surg Sports Traumatol Arthrosc* 2018; 26:3063-3072.

94. Westin O, Svensson M, Helander KN, et al. Cost-effectiveness analysis of surgical versus non-surgical management of acute Achilles tendon ruptures. *Knee Surg Sports Traumatol Arthrosc.* 2018;26:3074-3082.

95. White IR, Barrett JK, Jackson D, Higgins JPT. Consistency and inconsistency in network meta-analysis: model estimation using multivariate meta-regression. *Res Synth Methods*. 2012;3:111-125.

96. Willits K, Amendola A, Bryant D, et al. Operative versus nonoperative treatment of acute Achilles tendon ruptures: a multicenter randomized trial using accelerated functional rehabilitation. *J Bone Joint Surg*. 2010;92:2767-2775.

97. Woolnough T, Axelrod D, Bozzo A, et al. What is the relative effectiveness of the various surgical treatment options for distal radius fractures? A systematic review and network meta-analysis of randomized controlled trials. *Clin Orthop Relat Res*. 2021;479:348-362.

98. Wu Y, Mu Y, Yin L, Wang Z, Liu W, Wan H. Complications in the management of acute Achilles tendon rupture: a systematic review and network meta-analysis of 2060 patients. *Am J Sports Med*. 2019;47:2251-2260.

98. Zellers JA, Carmont MR, Silbernagel KG. Return to play post-Achilles tendon rupture: a systematic review and meta-analysis of rate and measures of return to play. *Br J Sports Med*. 2016;50:1325-1332.

99. Zhang H, Tang H, He Q, et al. Surgical versus conservative intervention for acute Achilles tendon rupture. *Medicine*. 2015;94:e1951.

Figures

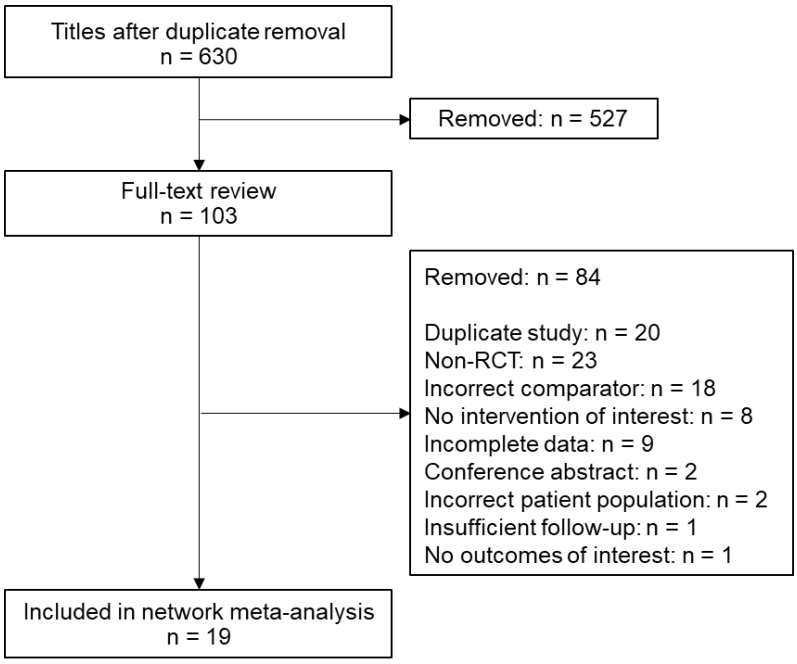

Fig. 2.1 The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for study screening

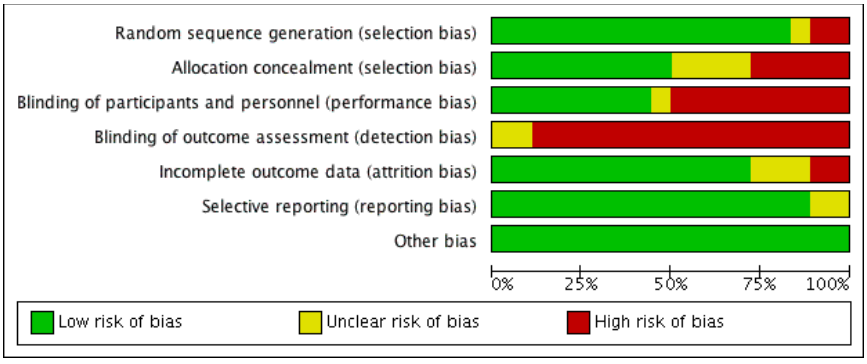

Fig. 2.2a This figure shows the cumulative risk of bias for all included studies divided by source of bias.

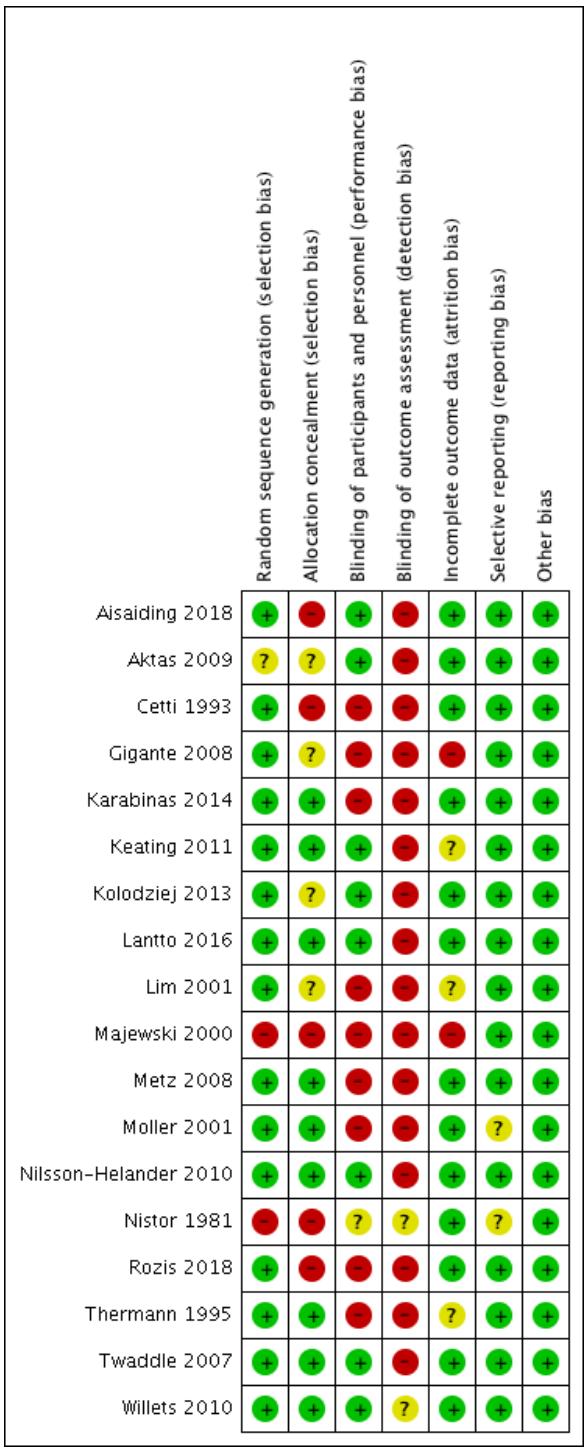

Fig. 2.2b This figure shows the summary of the risk of bias for all included studies

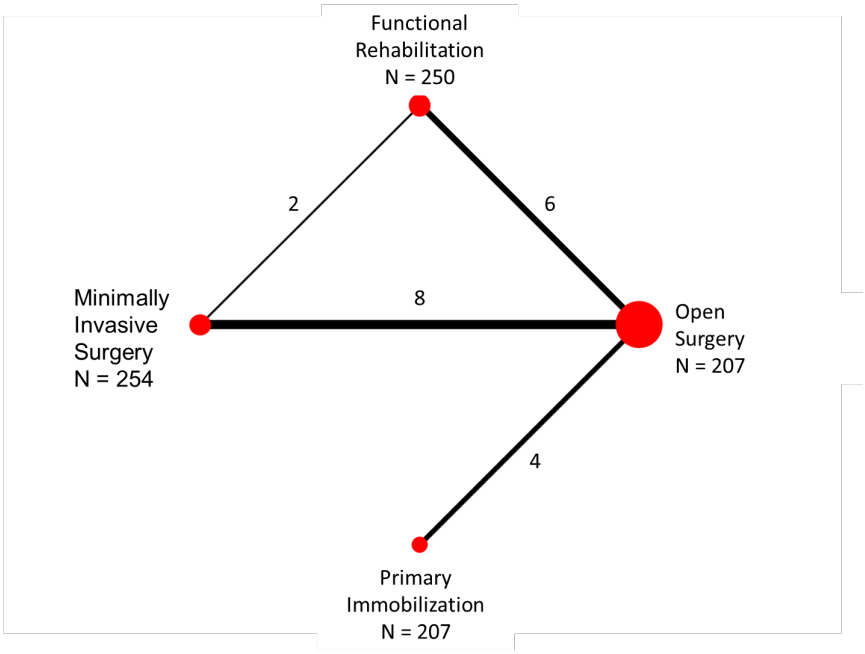

Fig. 2.3 This figure shows the network geometry for all complications. Node size is proportionate to the number of participants in the specified treatment arm and is indicated by N = below the treatment name. Edge (connecting line) thickness is proportionate to the number of studies informing an indicated comparison and is specified with the number adjacent the edge.

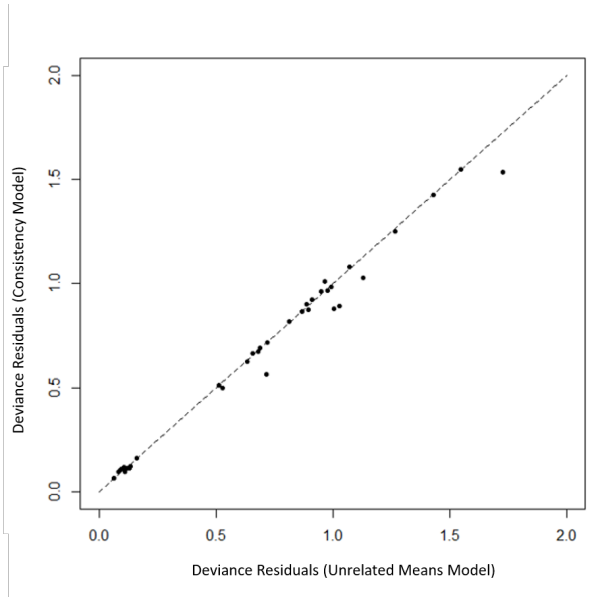

Fig. 2.4 This figure shows plots of posterior mean contributions from the random effects consistency model and unrelated means model for the assessment of the consistency assumption in the network meta-analysis of rerupture. Deviance residuals from the unrelated means relative effects model are plotted on the horizontal axis while deviance residuals from the consistency relative effects model are plotted on the vertical axis.

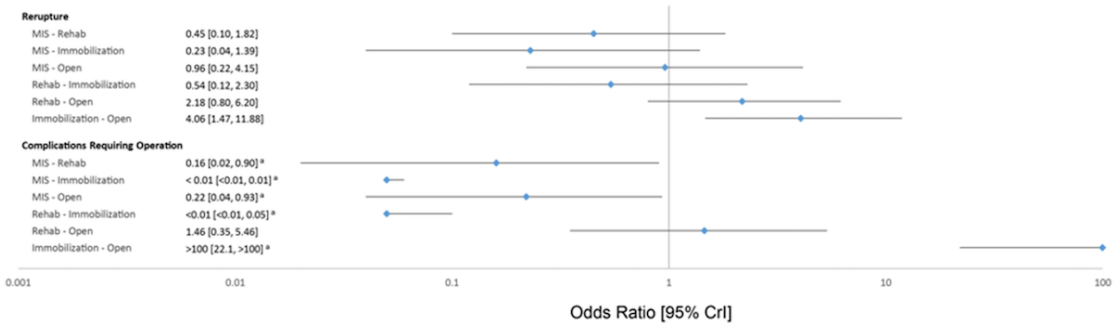

Fig. 2.5 The forest plot for all individual network comparisons. Comparison inferred to be statistically significant as the 95% credible interval does not cross the threshold for no effect. Each line describes a single network comparison including both direct and indirect evidence. The 95% confidence intervals for odds ratio are in parentheses; OR = odds ratio; CrI = credible interval; MIS = minimally invasive surgery; rehab = functional rehabilitation; open = open surgical repair.

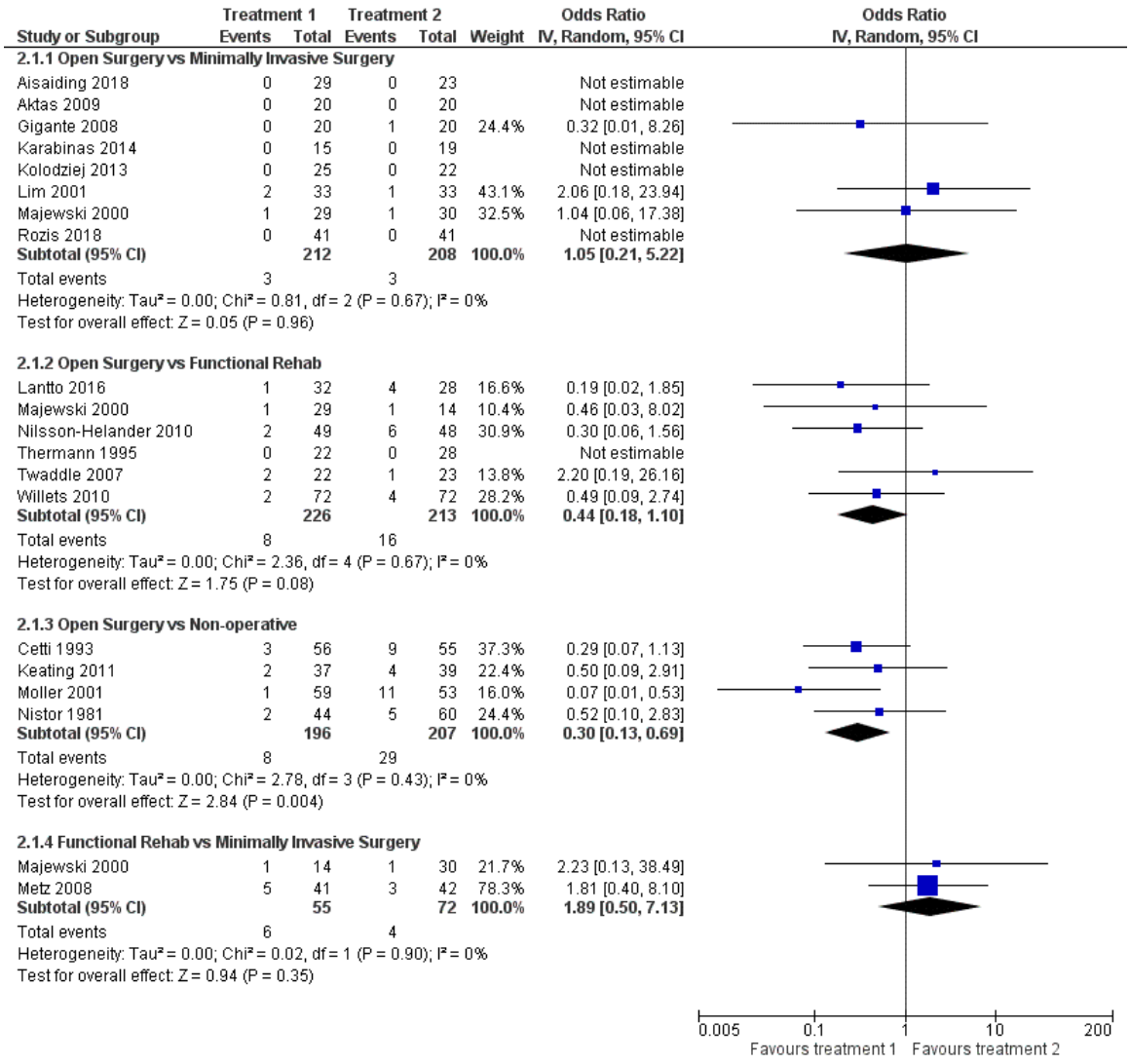

Fig. 2.6 A summary and forest plot of the pairwise analysis performed for risk of rerupture. Values were inferred to be statistically significant if the confidence interval for odds ratio did not cross one; CI = confidence interval; Df = degrees of freedom.

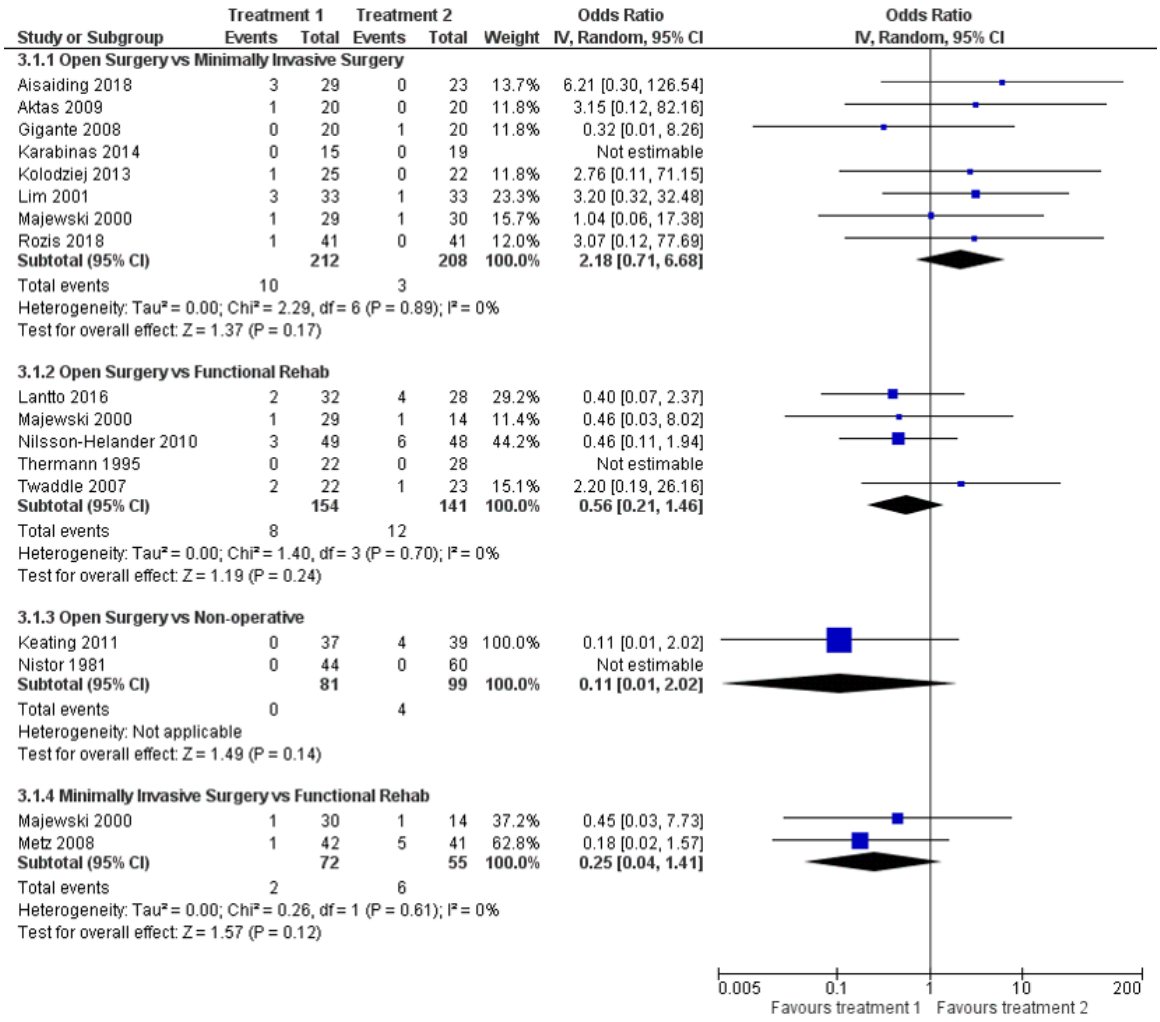

Fig. 2.7 A summary and forest plot of the pairwise analysis performed for risk of complications resulting in operation. Values were inferred to be statistically significant if the confidence interval for odds ratio did not cross one; CI = confidence interval; Df = degrees of freedom.

Tables

Table 2.1. Demographic information for included studies

Treatment	Patients	Study arms	Patients per treatment arm	Mean age	% Male	Follow-up (months)	Median publication year
Open surgery	605	17	35 ± 16	41 ± 5	81 ± 8	21 ± 12	2009 (1981-2018)
MIS	250	9	28 ± 9	43 ± 6	79 ± 11	22 ± 10	2009 (2008-2018)
Functional rehabilitation	254	7	33 ± 20	39 ± 2	75 ± 13	23 ± 11	2008 (1995-2006)
Primary immobilization	207	4	52 ± 9	39 ± 1	85 ± 5	27 ± 23	1997 (1981-2011)

For all columns but publication year, values are list as mean± SD. For publication year, the median value is given with range indicated in parentheses. The number of study arms exceeds twice the number of included studies because of studies with three treatment arms. Percent male represents the pooled value for the treatment arm calculated using weighted means for each treatment group. MIS = minimally invasive surgery.

Table 2.2 Summary of findings table for rerupture

Studies: 19[a] Participants: 1316	Minimally invasive surgery (9 RCTs[b]; 250 participants)	Functional rehabilitation (7 RCTs[b]; 254 participants)	Primary immobilization (4 RCTs[b]; 207 participants)	Open surgery (17 RCTs[b]; 605 participants)
Relative effect (95% CrI)	0.96 (0.22-4.15)[c]	2.18 (0.80-6.20)[c]	4.06[d] (1.47-11.88)	Reference
NNT	173.9	18.9[e] (Harm)	12.9[e] (Harm)	Reference
GRADE Evaluation	Low[f,g]	Moderate[g]	Low[f,g]	Reference
Mean ranking (95% CrI)	1.65 (1-4)	3.00 (2-4)	3.76 (2-4)	1.59 (1-3)
Interpretation of findings	Possibly superior	Possibly inferior	Probably inferior	Reference

Relative effect values are odds ratios relative to open surgery; harm written in parenthesis indicates the associated value is a number needed to harm; mean rank was calculated based on surface under the cumulative ranking curve (SUCRA) values; small sample sizes were considered in the evaluation of imprecision.

[a]Total number of studies across all treatments.

[b]Number of RCTs including the treatment of interest.

[c]95% CrI for odds ratio crosses one indicating no difference relative to reference treatment; $p > 0.05$.

[d]Inferred to be statistically significant with a 95% CI for odds ratio not crossing one; $p < 0.05$

[e]Treatment associated with a relative effect indicating harm. Therefore, associated value is number needed to harm.

[f]Downgraded for risk of bias.

[g]Downgraded for imprecision.

NNT = number needed to treat; GRADE = Grading of Recommendations Assessment, Development and Evaluation; CrI = credible interval.

Table 2.3. Summary of secondary network measures of effect

Outcome and treatment	Mean SUCRA	Mean Pr(best)	Mean rank
Rerupture			
Open surgery	0.803	0.462	1.59 (1 to 3)
Minimally invasive surgery	0.785	0.515	1.65 (1 to 4)
Functional rehabilitation	0.334	0.020	3.00 (2 to 4)
Primary immobilization	0.079	0.003	3.76 (2 to 4)
Complications requiring operation			
Minimally invasive surgery	0.987	0.967	1.04 (1 to 2)
Open surgery	0.582	0.016	2.25 (2 to 3)
Functional rehabilitation	0.430	0.016	2.71 (2 to 3)
Primary immobilization	0.001	< 0.001	4.00 (4 to 4)

Mean Pr(best) indicates the probability that a treatment is the top ranked treatment for that intervention; larger SUCRA values or smaller mean rank values suggest better treatments for the given outcome; mean rank is reported with 2.5% and 97.5% quantiles in parentheses; SUCRA = Surface Under the Cumulative Rank Curve

Table 2.4. Summary of findings table for complications resulting in surgery

Studies: 15[a] Participants: 949	Minimally invasive surgery (9 RCTs[b]; 250 participants)	Functional rehabilitation (6 RCTs[b]; 182 participants)	Primary immobilization (2 RCTs[b]; 99 participants)	Open surgery (14 RCTs[b]; 418 participants)
Odds ratio (95% CrI)	0.22[c] (0.04-0.93)	1.46 (0.35-5.36)[d]	> 100[c] (22.1 to > 100)	Reference
NNT	40.5	32.5[e] (Harm)	101.7[e] (Harm)	Reference
GRADE evaluation	Moderate[f]	Low[f,g]	Very low[f,h]	Reference
Mean ranking (95% CrI)	1.04 (1-2)	2.71 (2-3)	4.00 (4-4)	2.25 (2-3)
Interpretation of findings	Probably superior	Possibly inferior	Definitely inferior	Reference

Relative effect values are odds ratios relative to open surgery; harm written in parentheses indicates the associated value is a number needed to harm; mean rank was calculated based on surface under the cumulative ranking curve (SUCRA) values; small sample sizes were considered in the evaluation of imprecision.

[a]Total number of studies across all treatments.

[b]Number of RCTs including the treatment of interest.

[c]Inferred to be statistically significant with a 95% CI for mean difference not crossing one; $p < 0.05$.

[d]95% CrI for odds ratio crosses one indicating no difference relative to reference treatment; $p > 0.05$.

[e]Treatment associated with a relative effect indicating harm. Therefore, associated value is number needed to harm.

[f]Downgraded for risk of bias.

[g]Downgraded for imprecision.

[h]Downgraded two levels for imprecision; NNT = number needed to treat; GRADE = Grading of Recommendations Assessment, Development and Evaluation; CrI = Credible interval.

Table 2.5. Functional outcome measures of included studies

Author	Comparison	Outcome measure	Follow-up (months)	Finding
Aisaiding et al. [1]	MIS - Open	ATRS	3, 6	MIS superior
Keating et al. [42]	Open - PI	SMFA	3, 12	Open superior (MD 5)[b]
Lantto et al. [49]	Open - Rehab	SF-36[a]	18	Open superior
Costa et al. [13]	Open - Rehab	Return to walking		Rehabilitation superior (MD 5.5 weeks)
Karabinas et al. [41]	MIS - Open	AOFAS	24	No difference
Rozis et al. [73]	MIS - Open	AOFAS	12	No difference
Aktas et al. [2]	MIS - Open	AOFAS	6	No difference
Rozis et al. [73]	MIS - Open	ATRS	12	No difference
Gigante et al. [21]	MIS - Open	SF12	4, 12	No difference
Majewski et al. [54]	MIS - Open - PI	ATRS	30	No difference
Metz et al. [59]	MIS - Rehab	Leppilahti	12	No difference
Cetti et al. [10]	Open - PI	Abnormal gait	12	No difference
Moller et al. [62]	Open - PI	Functional index	24	No difference
Nilsson et al. [64]	Open - Rehab	ATRS	6, 12	No difference
Costa et al. [13]	Open - Rehab	EQoL	3, 6, 12	No difference
Lantto et al. [49]	Open - Rehab	Leppilahti	18	No difference
Willits et al. [96]	Open - Rehab	Leppilahti	12, 24	No difference
Twaddle et al. [88]	Open - Rehab	MFAI	8, 12, 24, 52	No difference

[a]Lantto et al. [49] describes SF-36 components of pain and physical functioning only
[b]Keating et al. [42] open surgery was only associated with superior SMFA scores at 3 but not 12 months; MIS = minimally invasive surgery; PI = primary immobilization; Rehab = functional rehabilitation; Open = open surgical repair; SMFA = short musculoskeletal functional assessment score; ATRS = Achilles tendon rupture score; SF-36 = 36-item short form survey; SF-12 = 12-item short form survey; AOFAS = American Orthopaedic Foot and Ankle Society score; EQ-5D = EuroQol Quality of Life score; MFAI = Musculoskeletal functional assessment score.

Table 2.6. Summary of ROM and strength outcomes at final follow-up for included studies

Author	Comparison	ROM	Strength
Majewski et al. [54]	MIS - Open - PI	NR	MIS superior to open and PI
Aisaiding et al. [1]	MIS - Open	NR	MIS earlier heel-rise endurance (MD 2 weeks)
Lantto et al. [49]	Open - Rehab	NR	Open surgery superior (MD 14%)[a]
Nilsson et al. [64]	Open - Rehab	NR	Open surgery superior[b]
Willits et al. [96]	Open - Rehab	Rehab superior (MD 2.21°)[c]	Open surgery superior
Keating et al. [42]	Open - PI	Rehab superior (MD 14% peak torque)	No difference
Gigante et al. [21]	MIS - Open	No difference	No difference
Kolodziej et al. [46]	MIS - Open	No difference	No difference
Karabinas et al. [41]	MIS - Open	No difference	No difference
Rozis et al. [73]	MIS - Open	No difference	No difference
Aktas et al. [2]	MIS - Open	No difference	No difference
Costa et al. [13]	Open - Rehab	No difference	No difference
Thermann et al. [85]	Open - Rehab	No difference	No difference
Twaddle et al. [88]	Open - Rehab	No difference	NR
Moller et al. [62]	Open - PI	No difference	No difference
Nistor et al. [65]	Open - PI	No difference	No difference
Metz et al. [59]	MIS - Rehab	No difference	No difference

[a]Open surgery was associated with greater mean torque at both 6 months (MD 24%) and 18 months.
[b]Open surgery was associated with greater heel-rise, power, and hopping at 6 months; there were no differences between treatments at 12 months.
[c]With reference to plantar flexion only; there were no differences in dorsiflexion.
[d]Open surgery associated with superior plantar flexion strength but only at a velocity of 240° per second; MIS = minimally invasive surgery; PI = primary immobilization; Rehab = functional rehabilitation; Open = open surgical repair; MD = mean difference; NR = not reported.

Table 2.7. Summary of time to return-to-work findings for included studies

Author	Comparison	Finding
Majewski et al. [39]	MIS - PI	MIS superior (MD 2.0 weeks)
Metz et al. [43]	MIS - Rehab	MIS superior (MD 7.0 weeks)
Aisaiding et al. [1]	MIS - Open	MIS superior (MD 3.0 weeks)[a]
Majewski et al. [39]	MIS - Open	MIS superior (MD 1.5 weeks)
Karabinas et al. [29]	MIS - Open	No difference
Kolodziej et al. [33]	MIS - Open	No difference
Lim et al. [37]	MIS - Open	No difference
Rozis et al. [53]	MIS - Open	No difference
Moller et al. [45]	Open - PI	Open repair superior (MD 4.5 weeks)[b]
Nistor et al. [48]	Open - PI	PI superior (MD 4.0 weeks)
Majewski et al. [39]	Open - PI	No difference
Cetti et al. [8]	Open - PI	No difference
Keating et al. [30]	Open - PI	No difference
Costa et al. [11]	Open - Rehab	No difference

[a]Return to heavy activity only; return to all work was not reported.
[b]Return to light work only; no difference was found for return to all work;
MIS = minimally invasive surgery; PI = primary immobilization;. Rehab = functional rehabilitation; Open = open surgical repair; MD = mean difference.

Table 2.8. Summary of return-to-sport findings for included studies

Author	Comparison	Return to same level of activity	Time to return to sport
Aisaiding et al. [1]	MIS - Open	NR	MIS superior[a] (16 vs. 18 weeks)
Aktas et al. [2]	MIS - Open	No difference[b] (90 vs. 85%)	NR
Keating et al. [42]	Open - PI	No difference (70 vs 64%)[b]	No difference[b] (34 vs 35 weeks)[b]
Kolodziej et al. [46]	MIS - Open	No difference[b]	NR
Lim et al. [52]	MIS - Open	No difference[c] (82 vs 44%)	NR
Karabinas et al. [41]	MIS - Open	NR	No difference[c] (5 months across groups)
Majewski et al. [54]	MIS - Open - PI	No difference[c] (75% across groups)	MIS 20.9 weeks, Open 26 weeks, Rehab 27.8 weeks
Metz et al. [59]	MIS - Rehab	No difference [b] (67 vs 82%)	NR
Cetti et al. [10]	Open - PI	Open superior[a] (57 vs. 29%)	NR
Moller et al. [62]	Open - PI	No difference[c] (54% across groups)	NR
Costa et al. [13]	Open - Rehab	No difference[b] (83 vs. 68%)	No difference[b]

[a] Statistically significant difference as reported by the study authors
[b] No difference reported with appropriate statistical analysis described by the study authors
[c] No difference reported but statistical analysis for the outcome of return to sport were not described
NR = not reported; MIS = minimally invasive surgery; PI = primary immobilization; Rehab = functional rehabilitation; Open = open surgical repair

Chapter 3:

Development and Field-Testing a Patient Decision Aid for Management of Acute Achilles Tendon Rupture: A Protocol

This manuscript is formatted for: *BMC Medical Informatics and Decision Making* (not submitted)

Authors

1. Brad Meulenkamp MD FRCSC; Assistant Professor, Faculty of Medicine, University of Ottawa

2. Dean Fergusson PhD; Clinical Epidemiology Program, The Ottawa Hospital Research Institute, University of Ottawa, Department of Medicine, Centre for Practice-Changing Research

3. Ian D Graham PhD, FCAHS, FNYAM; University of Ottawa, School of Epidemiology and Public Health; Clinical Epidemiology Program, The Ottawa Hospital Research Institute, Centre for Practice-Changing Research

4. Dawn Stacey RN, PhD, FAAN, FCAHS; Faculty of Health Sciences, University of Ottawa; Centre for Practice-Changing Research, Ottawa Hospital Research Institute

Funding Source: Canadian Orthopedic Research Legacy (CORL) Grant

Abstract:

Background: Achilles tendon ruptures are common injuries in an otherwise healthy, active population. Several treatment options exist, with both surgical and non-surgical options. Each treatment option has a unique set of risks and harms, which may present patients with decisional conflict. The aim of the proposed study is to develop, alpha test and field-test a patient decision aid for patients presenting with acute Achilles tendon ruptures.

Methods: This is a three-stage study protocol. First we will assemble a multi-disciplinary steering group including patients, clinicians, educators, and researchers to develop the patient decision aid prototype using the Ottawa Decision Support Framework.
Second, a mixed-methods alpha-test of the decision aid prototype will be performed with patients and clinicians with experience in acute Achilles tendon ruptures. Outcomes measured will include acceptability and usability of the patient decision aid measured using validated outcome scales and semi-structured interviews. A minimum of three rounds of feedback will be obtained. Results will be analyzed using descriptive statistics, reviewed by the steering group to guide revisions to decision aid prototype at each round. The third stage will be field-testing the revised decision aid prototype in usual clinical care. A pre/post study will performed with patients with acute Achilles tendon ruptures. Eligibility criteria will include adult patients over 18 years with clinical or radiographic confirmed Achilles tendon rupture. Patients will be recruited from the emergency department and complete the pre-consultation decision aid prior to a one-week follow up with their surgeon. The primary outcome of field-testing is feasibility of implementing the decision aid in the clinical setting and will be measured with recruitment and

completion metrics. Secondary outcomes include acceptability of the decision aid, knowledge, preparedness for decision making and decisional conflict, measured using validated outcome measures. Statistical analysis will be performed using descriptive analysis for primary outcomes and student t-test and Wilcoxon Rank-Sum test for secondary outcomes.

Discussion: This comprehensive study protocol outlines the development, alpha and field-testing of a patient decision aid for patients with acute Achilles tendon rupture. Systematic and transparent development and testing of patient decision aids is critical to improve decision aid quality.

Funding: This study has received funding through the Canadian Orthopedic Research Legacy (CORL) fund.

Keywords: Achilles tendon rupture, decision aid, shared decision-making

Background

Patients presenting to hospital with an acute Achilles tendon rupture are faced with an important decision regarding treatment management; to have surgery or conservative management. There are harms and benefits to each approach. Historically, non-operative care has been associated with a higher tendon re-rupture rate, and surgery has the risk of surgical complications including infections, wound healing problems, and subsequent surgery.**[1]**

The decision is made more complex as there are now varying non-operative and surgical treatment options.**[1,2]** Non-operative management has evolved from a period of prolonged immobilization in a cast to allow tendon healing, to early motion and functional rehabilitation protocols. Use of these protocols has led to decrease re-rupture rates, but require early patient enrollment, high patient engagement in following the protocol and ideally access to physiotherapy to provide optimal outcomes.**[1]** Surgical care is also evolving from traditional open surgery to more percutaneous and minimally invasive options being used in an attempt to decrease wound healing problems. These surgical techniques, however, come with increased risk of other harms including nerve injury.**[3]** Given the evolution in the benefit-to-harm ratio, practice trends in Scandinavia**[4]** and Canada**[5]** have shifted towards non-operative functional rehabilitation with declining rates of surgery.

When several reasonable treatment options exist with varying harms and benefits, patients often experience decisional conflict.**[6]** Decisional conflict is uncertainty over a course of action, and may result in, worry, questioning of personal values, physical stress and ultimately decision delay.**[7]**

Meanwhile, the delivery of patient care is in the midst of a paradigm shift.**[8]** The patient-clinician relationship is evolving from a paternalistic, unilateral discussion and advice from clinician to more of a patient-centered approach. The concept of shared decision-making (SDM) is the crux of this approach.**[9,10]** SDM involves an exchange of information around health-care decisions, supplementing the patient-clinician discussion, allowing patients to make a more personal, value-based decision.**[11]** Decision support tools are methods that facilitate this process. **[11,12]**

Patient Decision-Aids (PtDAs) are tools that may be used by patients either in preparation for or within a consultation with their physician. They explicitly state the decision to be made, and provide patient-friendly information on decision options, harms and benefits in a format that allows the patient to clarify what matters most to them.**[13]** The utility of PtDAs has been widely studied with demonstrated effectiveness in improving patient knowledge, decreasing decisional conflict, and increasing patient participation in decision-making **[14]**. As facilitators of SDM, PtDAs may also lead to improved satisfaction with their patient experience.**[15]**

There are no known PtDAs in the published literature to assist patients making treatment decisions regarding acute Achilles tendon ruptures. The aim of this study protocol is to develop and test a PtDA to help patients make a more informed, value-based decision when considering treatment options for acute Achilles tendon rupture. Specific objectives are: a) to develop a PtDA for patients to use in preparation for the consultation; and b) field test the patient decision aid with patients and clinicians making this treatment.

Methods

Guiding Conceptual Frameworks

The PtDA will be developed using the Ottawa Decision Support Framework (ODSF)**[16]** and in accordance with the International Patient Decision Aids Standards (IPDAS) quality criteria.**[17]** The ODSF is a theory-based model for helping guide patients making health decisions. It is grounded on cognitive, socioeconomic and psychology theories and has been used in the creation dozens of PtDAs,**[16,18]** 24 of which have been evaluated in randomized controlled trials.**[18]** The IPDAS criteria were developed to systematically guide the PtDA development, content and evaluation of PtDAs, with agreement from over 100 stakeholders including patients, policy makers, clinicians and researchers.**[19]**

1. Development of the Patient Decision Aid

The IPDAS criteria specific to development have subsequently been updated and expanded to include steps to help guide the PtDA development process.**[20]** These steps include; (1) defining the purpose, scope and audience of the decision aid, (2) collecting and synthesizing the data for inclusion, (3) developing the PtDA prototype, (4) alpha testing by end-users to ensure usability of the PtDA, (5) field-testing feasibility with end-users in the clinical setting and (6) producing the final version (figure 3.1).**[20]**

1.1 Steering Group

In keeping with an integrated knowledge translation (iKT) approach**[21]** and as recommended by the IPDAS,**[20]** a steering group will be assembled to guide the PtDA development process. Central to the iKT approach is the involvement of and feedback from end-users as part of the research team longitudinally throughout the research processes.**[21]** This approach has demonstrated benefits in terms of development of a

more useful tool with increased end-user knowledge buy-in, uptake and impact.**[22-26]** For this protocol and subsequent study, the knowledge end-users include patients, physiotherapists and orthopedic surgeons. The steering group will be inter-disciplinary and will include end-users with content expertise, two members with methodological expertise in shared decision-making and PtDAs, patient educators, and a web-developer to facilitate creation of a web-based tool.

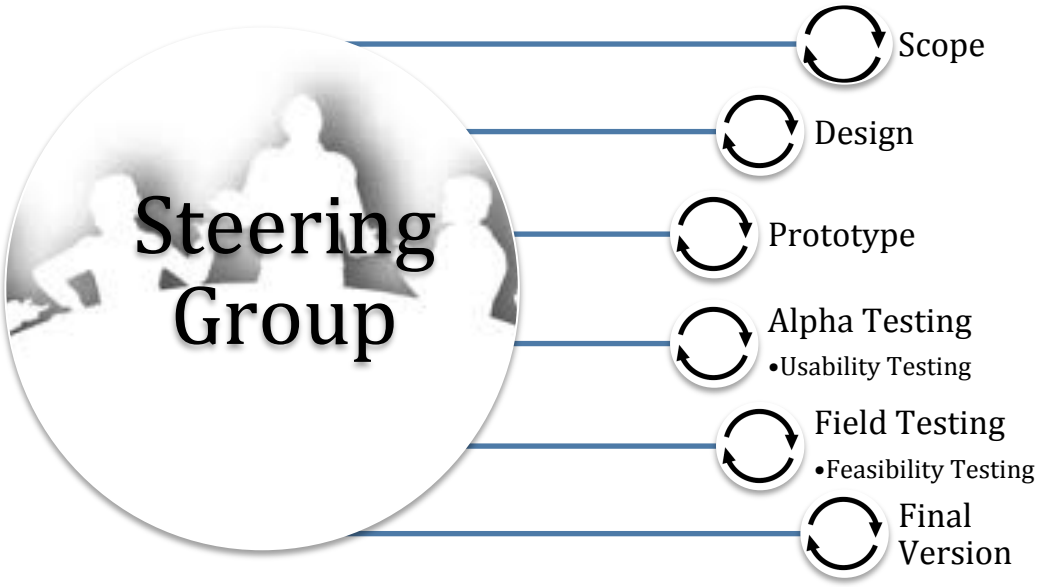

Figure 3.1: The IPDAS development model for Patient Decision Aids

1.2 Establishing the scope of the PtDA

According to IPDAS, the scope of the PtDA involves establishing the specific decision, the target audience, and the purpose of the PtDA.**[20]** The purpose of this pre-consultation PtDA is to inform patients with acute Achilles tendon rupture about treatment options, as well as harms and benefits of each of the options. The goal is to assist patients in deciding on a course of treatment. Specifically, the decision to be made is 'Should I have surgery or non-operative management for my Achilles tendon rupture?'

1.3 Design of the PtDA

The steps in designing the PtDA prototype include an assessment of decisional needs of patients and clinicians, formulating a format and distribution plan, and reviewing and synthesizing the evidence for inclusion as content**[20]**. Recent literature demonstrates conflicting clinician opinions on how to advise patients with an Achilles tendon rupture,**[60, 61]** and the first steering group agenda item will be a discussion with clinician and patient members to identify patients' decisional needs. The steering group will develop and revise the PtDA through an iterative process until consensus is reached on content and structure. The prototype design will be based on the ODSF template**[62]** and it meets the IPDAS minimal development standards recommended for minimizing risk of bias in PtDAs.**[27]**

The initial prototype will paper-based and drafted in English, with plans for final distribution electronically and printable paper versions available in clinical practice in both English and French translations. Treatment initiation for Achilles tendon rupture is time sensitive thus it is essential that the PtDA be administered to patients soon following injury. With accessibility being a key aspect of PtDA usability, offering both paper and electronic formats will facilitate and maximize patient uptake.**[28]** It will be designed knowing that the most common points of first patient contact will be in the emergency room or outpatient orthopedic clinic.

The prototype will be written in plain language appropriate for an 8th grade reading level or lower as determined by the Flesh-Kincaid Readability Test Tool.**[29]** Following, the ODSF template, the PtDA will ask the specific question 'should I have surgery or non-operative management for my Achilles tendon rupture?' It will be

formatted to include (a) information on Achilles tendon ruptures and specify which patients are eligible for the PtDA; (b) treatment options to consider; (c) summarized evidence on benefits and harms of each approach; (d) a values clarification exercise; (e) space to indicate a preferred treatment option; and (f) the SURE test.**[30]** The SURE test is a 4-item questionnaire validated for screening for decisional conflict. The clinical data on options, benefits and harms will be provided primarily by the network meta-analysis in chapter 2. Probabilities will be presented numerically and in words, with links to graphical representation to facilitate patients' understanding and adhering to the IPDAS criteria specific to presenting probabilities.**[31]** There will also be links included for additional information about Achilles tendon ruptures, literature used to develop the PtDA and treatment specifics including rehabilitation protocols.

2. Alpha Testing

Alpha testing is a necessary next step in the PtDA development process to evaluate the acceptability and usability of the decision tool from the perspective of patients and clinicians**[20]**. The steering group will discuss results and feedback from this step in an iterative fashion until consensus is reached on required revisions to the PtDA prototype and field-testing outcomes of interest.

2.1 Methods

A mixed-methods study will be performed with both acceptability and usability questionnaires, as well as qualitative descriptive methods used to optimize stakeholder feedback**[32,33]** This approach has the advantage of allowing evaluation of the outcomes of interest, while also allowing for participants to go beyond explicit questioning, expressing their thoughts and perspectives on the PtDA. This type of qualitative data

collection and analysis allows ‘low inference’ discussion and analysis of participant’s responses without manipulation. Specifically, the primary data collection methods will be semi-structured interviews (SSI) with patients and clinicians. This will allow for each participant to elaborate and clarify responses.

Participants

Participants for alpha testing will be end-users of PtDA, consisting of both clinicians and patients who have previously made this decision.

Clinician participants

Clinician participants will include emergency room physicians, orthopedic surgeons, and physiotherapists, all members of the care team typically involved in the diagnosis and care of these patients. Convenience sampling**[34,35]** will be used to recruit clinicians participants through professional networks. Members of the Division of Orthopedic Surgery and Department of Emergency Medicine at the Ottawa Hospital, in addition to physiotherapists from the Riverside Hospital (Ottawa, Ontario) will be invited to participate in the study through e-mail. An information letter explaining the purpose of the PtDA and of alpha testing will be included. We will also invite orthopedic surgeons from across Canada to participate. This will increase the diversity of participants, as well as raise awareness of the PtDA for future dissemination. We will attempt to include both male and female surgeons to maintain diversity of the sample. Recruitment external to Ottawa will be done through email lists of Canadian Orthopedic Foot and Ankle Society (COFAS) members.

Patient Participants

A convenience sample of patients will be recruited for participation if they have been or are actively being treated for an acute, first-time Achilles tendon rupture at TOH. Although this is predominantly a male compared to female injury (6:1)**[2],** we will strive to include both men and women patients that have been treated both with and without surgery. A study poster will be placed both in the orthopedic clinic waiting area and eligible patients will be approached by a member of the clinical team to provide a description of the purpose and structure of alpha testing for the PtDA. Patients will be excluded if they are unable to understand the PtDA due to language barrier or visual impairment.

The target sample size for alpha testing will be 20 participants, with 10 patients and 10 clinicians. This is derived from the work of Faulkner,**[36]** who demonstrated that problem identification was substantially decreased in usability testing with increasing participant size. With participant sizes of five, 10 and 20, the lowest percentage of problem identification increased from 55% to 80% and finally 95%, respectively.**[36]**

Intervention

The intervention of interest is the PtDA prototype developed in part one of this study. Alpha testing will be performed exclusively with the English version of the PtDA prototype.

Procedure

Alpha testing will be an iterative process of revising and redrafting the PtDA**[20]** using a minimum of three rounds with five participants in each round (Figure 3.2). Further

rounds will be added at the discretion of the steering group based on ongoing feedback from participants.

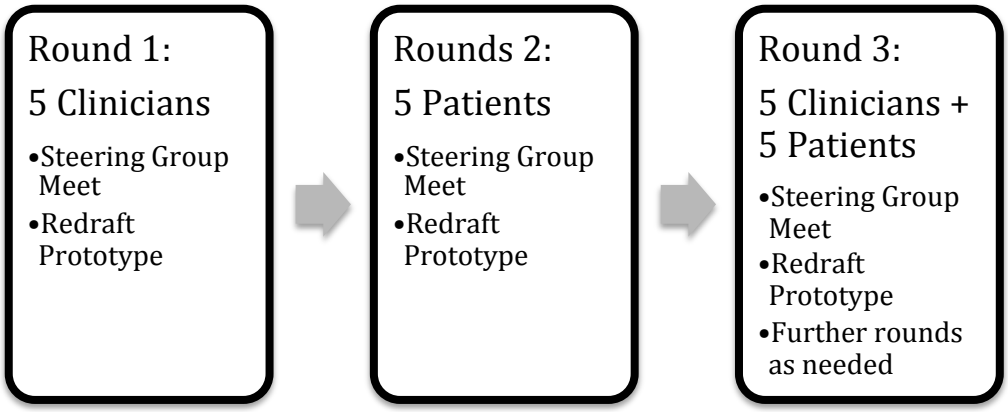

Figure 3.2: Alpha testing process

The first round of testing will be with five clinician participants who are routinely part of the care team of Achilles tendon rupture patients. This will include three orthopedic surgeons, an emergency medicine physician, and a physiotherapist. Those who agree to participate will be sent a study package with consent form, a copy of the updated PtDA prototype, and alpha testing clinician outcome questionnaires. They will be contacted by the RA either in person or on the phone depending on geographic location and preference. Following an explanation of the purpose of the study, participants will be asked to sign consent (appendix B.1) for participation. They will then review the PtDA, complete the outcome instruments and participate in the SSI with the RA. The steering group will meet to review outcome measures and interview feedback and decide on revisions to the PtDA prototype.

The second round of testing will be with five patients recruited from the Ottawa Hospital Foot and Ankle clinic. Patients will meet with the RA who will review the study goals and provide consent. To simulate the intended setting of the PtDA, they will take

the PtDA home with instructions to review it and complete the alpha test patient outcome questionnaires. They will then be invited for a SSI either on the phone or in person depending on their comfort and preferences. Recruited patients will be given a $20 gift voucher for compensation for their time as well as a hospital-parking pass. Once again, results and feedback will be brought to the steering group for review and revisions to the prototype made as needed. Despite being a predominant male injury,**[2]** we will aim to two female participants for each block of five so as not to miss potential important differences between genders.

The third round of testing will be concurrently performed five additional clinicians and five additional patients, with the structure of the encounter as described above. If the steering group deems further prototype revisions necessary, subsequent recruitment will be performed in blocks of 3-5 participants.

Outcomes and Instruments

Baseline clinician and patient demographics will be collected. For clinicians this will include profession, sex, gender, years in practice, number of Achilles tendon rupture patients treated monthly, and clinical subspecialty training for surgeons. Baseline patient demographics collected will include age, sex, gender, level of education, occupation and treatment status

The primary outcomes of interest are acceptability and usability of the PtDA, which will be evaluated quantitatively and qualitatively. For measuring PtDA acceptability with both patients and clinicians, we will adapt the Ottawa Acceptability Tool (OAT) from the ODSF website**[62]**. For patients, this 10-item survey evaluates user perception of the PtDA using a combination of closed and open-ended questions,

specifically asking about length, perceived usefulness for decision support, amount of and balance of information presented (appendix B.2). This tool has strong face validity and has been used extensively in PtDA evaluation with a wide range of conditions.**[37-39]** The OAT has also been adapted for use with clinicians with a 15-question format (appendix B.3), and will be used

as the primary quantitative measure of acceptability for clinician participants.

Usability will be evaluated both quantitatively using the System Usability Scale (SUS) **[40,41]** and qualitatively through feedback from the semi-structured interviews. The SUS is a validated,**[42]** 10-item survey using a five-point Likert scale response categories, with a score over 68 indicating higher than average usability (appendix B.4). It has been previously used in usability testing of PtDAs**[43]**

Semi-Structured Interviews

Semi-structured interviews will be conducted with separate interview guides for clinician and patient participants. Draft interview guides are attached in appendix B.5, and will be reviewed and adapted as needed by the steering group. For clinicians, a series of open and closed-ended questions will be asked about process usability, mode of delivery in the clinical setting, and feedback on content (length, language, information and balance). For patients, the focus of the interview will be on presentation (layout and format) and content (length, language, information and balance) to help ensure the end product is optimized for the end user. Interviews will be recorded and transcribed.

Data Analysis

Data will be analyzed iteratively following each round of testing. Quantitative data will be coded and stored in an encrypted Microsoft Excel spreadsheet. Descriptive statistics

will be used to summarize data from the OAT and SUS. Response frequencies from the patient OAT will be reported and dichotomized into positive and negative responses. Given the small sample size, we will use medians and ranges for the practitioner OAT and SUS. Qualitative data, including feedback from the OAT and SSIs will be compiled and analyzed using thematic analysis**[44,45]**. This will be performed in 6-phases, beginning with 1) transcription and initial data review, 2) broad generation of initial codes, 3) collating codes into themes, 4) reviewing the themes to either further collapse or expansion, 5) defining and naming the themes and 6) generating a final report.

The steering group will perform iterative data review following each round of testing. Revisions will be discussed and suggested when negative responses are encountered on the patient OAT or SUS, median scores less than three on the clinician OAT when further suggestions are found through qualitative descriptive analysis.

3. Field-Testing the revised PtDA prototype

Field-testing by end users is a critical component of PtDA development as identified by IPDAS.**[20]** As opposed to the alpha testing, field-testing solicits feedback on the PtDA from patients within the typical clinical setting. The primary outcome of the field-testing is to evaluate the feasibility of using the PtDA at the point-of-care and to guide any final revisions, with secondary outcomes including acceptability, and potential of the PtDA to have the desired impact without adverse consequence.

3.1 Methods

We will perform a field-test of the revised PtDA prototype using a pre/post test study design and embedded qualitative feedback. A pre/post test design has been chosen as it allows for evaluation of the secondary outcomes of the PtDA having the desired impact,

which will provide us with baseline data to calculate a sample size for a larger evaluation study.**[46]**

Participants

Patient recruitment will take place at The Ottawa Hospital Emergency Department (ED). The Ottawa Hospital serves a population of 1.2 million people for orthopedic care in Eastern Ontario, Canada and sees an average of 60 acute Achilles tendon rupture annually, or an average of 5 per month.

Eligibility for participation will include 1) adult patients over 18 years, 2) clinical or radiographically confirmed Achilles tendon rupture, 3) presentation and immobilization within 72 hours of injury, 4) willingness to consent to the study, and 5) ability to speak and read English. Patients will be excluded for 1) re-rupture of the Achilles tendon, 2) musclotendinous junction tears and 3) delayed presentation over 72 hours as this limits the ability to optimally treat with non-surgical methods.

Intervention

The intervention is the revised paper-based, pre-consultation PtDA prototype resulting from the alpha testing phase. This will be given to the patient following initial presentation with the injury in the emergency department, and self-administered by the patient at home prior to final treatment consultation with the orthopedic surgeon.

Procedure

The procedure flow for patient recruitment is summarized in figure 3.3. Upon consultation from the ED physician, a member of the orthopedic team (resident, staff physician or physician assistant) will meet patients presenting with an acute Achilles tendon rupture. The orthopedic team will confirm the diagnosis, discuss the diagnosis

and management options with the patient. Concurrently, they will verify if the patient meets inclusion criteria, discuss the study procedures, answer patients' questions, and obtain the patients' signed consent to participate. The patient will be asked to complete a baseline questionnaire including questions about their demographics (age, sex, gender, occupation, highest level of education) and secondary outcome measures. The patient will be splinted in plantarflexion in keeping with standard practice and given a copy of the PtDA to review and complete in preparation for their follow-up appointment in the orthopedic clinic.

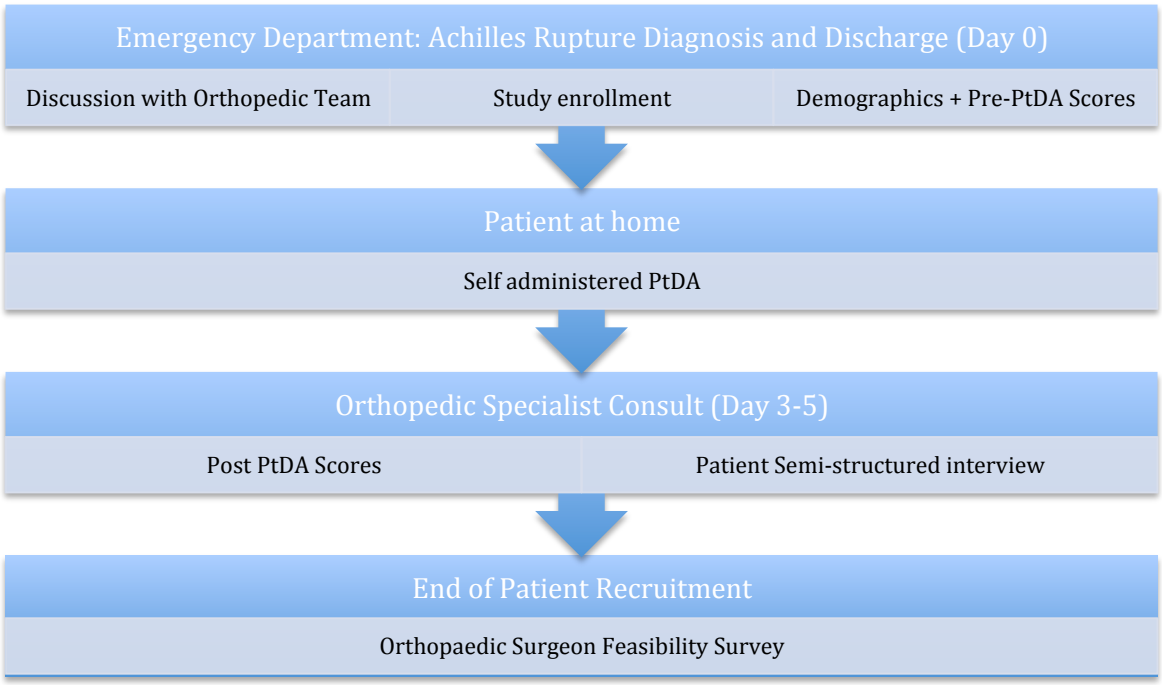

Figure 3.3: Patient participant study procedure

As per usual clinical practice, patients will be given a follow-up appointment in the orthopedic plaster room 3-5 days following their ED visit. At the plaster room, the orthopedic resident or surgeon will discuss the treatment options, answer patients' questions and make the treatment decision with the patient. Either immediately following

or within 2 weeks of the, the RA will ask the patient to complete a questionnaire including the secondary outcome measures and conduct the semi-structured interview.

We will also obtain feedback from orthopedic residents and surgeons who consulted with patients in the study to determine the clinician experience with patients using the PtDA. After the last patient is recruited, these orthopedic surgeons will be sent a link to an online survey using the SurveyMonkey (San Mateo CA) platform to elicit feedback on the PtDA.

Outcomes and Instruments

Field test outcomes of interest have been chosen based on those recommended by IPDAS.**[19]** Field test outcomes are summarized in Table 3.1 and include 1) feasibility of PtDA administration and use by patients, 2) barriers to PtDA use among patients and clinicians 3) patients' acceptability of the PtDA, and 4) potential of the PtDA to have the desired impact without adverse consequence.

Specific patient feasibility metrics will include the 1) percent of screened eligible patients recruited, 2) reasons for ineligibility, 3) percentage of recruited patients that completed the PtDA prior to the follow-up appointment and the 4) percentage of missing data on follow up outcome questionnaires. We will set a level of success at 80% participant recruitment of those meeting eligibility, 80% participant completion of the PtDA, and 80% minimal completed data on follow up questionnaires, in keeping with levels set in previously performed field-tests.**[47]**

The semi-structured interview with the patients will ask them to share their experiences on using the PtDA, their experiences discussing the decision with the

orthopedic surgeon, suggestions to improve the process of using the PtDA, formatting, and any barriers to use.

Acceptability of the PtDA, will be evaluated using the OAT**[63]** previously used in the alpha test phase. This validated instrument measures key outcomes including; amount of information, length, clarity and balanced presentation, which is important for avoiding biased presentation of information on options.

To evaluate whether the PtDA potential to have the desired impact without adverse consequence, patients will complete a knowledge test**[64]** and the SURE test**[30]** as a pre/post outcome and the Preparation for Decision Making Scale (PDMS)**[65]** as a post PtDA outcome measure.

Patient knowledge will be measured using a knowledge test developed by the steering group and embedded within the PtDA. The test will be adapted from the template available on the Ottawa Decision Support Group website**[64]** and will consist of 4-6 questions about key content important to know when making this decision. This format has been adapted for several clinical conditions and been shown to have high internal consistency and validity. Patient knowledge of their specific pathology and treatment options underlies one of the pillars of informed consent,**[48]** and improved decision quality is based on patients making an informed, value-based decision.**[14]**

The SURE test will be used to screen patients' for decisional conflict**[30]**. It has four questions with 'yes' or 'no' responses in the domains of certainty, knowledge, values and support. Any 'no' answer is indicative of clinically significant decisional conflict. This test has been validated in a range of clinical settings.**[49,50]**

Outcome	Instruments	Measure of Success
1. Feasibility a. Patients	Metrics of Use	At least 80% recruitment At least 80% PtDA completion At least 80% data completion
	Patient Semi-structured Interview	Identifying resolvable barriers to PtDA use
	Metrics of use	At least 80% use for eligible patients
b. Surgeons	Surgeon Survey	Identifying resolvable barriers to PtDA use
2. Acceptability • Amount of information • Length • Clarity • Balance of presentation	**Post PtDA** Patient acceptability questionnaire	At least 66% perceive as acceptable
3. Potential for PtDA to have desired effect without adverse consequence	**Post PtDA** Patient Preparation for Decision Making Scale (PDMS)	Score of at least 66/100
	Practitioner Preparation for Decision Making Scale (PDMS)	Score of at least 66/100
	Pre and Post PtDA Knowledge test	At least 66% demonstrate improvement from pre to post PtDA administration
	SURE Test	66% demonstrate improvement from pre to post PtDA administration And/Or > 66% Score 4/4 on post PtDA SURE Test

Table 3.1 – Summary of field test outcome measures

We will use the Preparation for Decision Making Scale (PDMS) **[65]** to measure patients' perceived usefulness of a PtDA in preparing for a medical consultation (appendix 6). This specifically measures the IPDAS criteria for the quality of the decision process. This instrument consists of 10 questions to be ranked on a 5-point Likert scale, has both high reliability and internal consistency with a Chronbach's alpha of 0.92-0.96.**[51]**

The survey of orthopedic surgeons will ask questions about how the PtDA influenced the patient-surgeon encounter. Data collected will aim to quantify experience with the PtDA including 1) number of times and reasons the PtDA was used or not used for eligible patients, 2) if they plan to continue to use the PtDA and 3) barriers and facilitators to implementation in usual clinical care. Specific feedback will be sought with respect on how and when the PtDA can best be administered in the patient journey to optimize uptake by both clinicians and patients. As part of the survery, we will also use the 11-question practitioner version of the PDMS to evaluate clinician views on how effective the PtDA was on the patient encounter**[65]** (appendix B.6).

Sample Size

There is a paucity of guidance for sample size justification for field-test methods. With the primary objectives being feasibility of use in the clinical setting, we will aim to recruit a sample of 30 patient participants. This sample size is consistent with minimum numbers required to demonstrate adequate feasibility in pilot studies,**[53]** and consistent with other pre/post studies testing PtDAs with patients facing the decision.**[54-56]** Based on usual referral volumes, we expect to recruit 3 patients per month and complete study recruitment after 10-12 months.

Data management and Analysis

Quantitative data will be uploaded and stored in an encrypted Microsoft Excel spreadsheet. As the focus of the field test is on feasibility rather than efficacy outcomes, analysis will be primarily descriptive with baseline participant characteristics and feasibility data presented using frequencies and percentages. Tests for data normality will be performed and summarized using means and standard deviation if normally distributed, and medians and ranges if not. For post-test only outcomes (acceptability, PDMS), patients' responses will be summarized and described. For pre/post test outcomes (knowledge and SURE test) questionnaires will be compared using student t-test if normally distributed and using the Wilcoxon rank-sum test if not. Data will be disaggregated by sex and gender to examine how these variables may affect patient and clinician experience with the PtDA and associated outcome measures. Qualitative data from the semi-structured interviews will be transcribed verbatim and analyzed using thematic analysis as described for alpha testing.

There are no known defined standards for determining success of field-testing measures. As such, we have determined the following a-priori criteria as determinants for success of the field test; 1) no insurmountable barriers identified from semi-structured interviews or open-ended feedback based on review from the steering group, 2) minimum of 80% targets for feasibility outcomes, 3) minimum of 66% of participants find the PtDA acceptable and balanced, 4) minimum score of 66 on the PDMS 5) 66% demonstrate nominal improvement on pre/post test outcomes for desired impact (knowledge and SURE). For the SURE test, an overall finding of >66% participants responding with a 4/4 score will also be deemed a measure of success. If the cutoffs for

determining success of the field test are not reached, revisions to the PtDA will be discussed and implemented by the steering group with further recruitment and testing at the discretion of the steering group

Discussion

This is a multi-faceted study protocol outlining the development, alpha and field-testing of a pre-consultation PtDA for patients presenting with an acute Achilles tendon rupture. The need for a decision support tool for this treatment decision is evident due to longstanding controversy in the orthopaedic community about the effectiveness of surgery versus conservative management**[60,61]** and important differences in the benefit:harm profile offered by the varying treatment methods. The treatment decision for patients with acute Achilles tendon rupture is time-sensitive, and so feasibility testing with patients presenting to the ED with these injuries is imperative to ensure the PtDA can be effectively administered in a timely fashion.

Strengths and Limitations

The strengths of the protocol are the use of an iKT approach to develop the PtDA. This approach has been demonstrated to maximize knowledge users input, increase use and improve impact.**[23]**. Additionally, we have adhered to a rigorous methodology guided by the ODSF and the IPDAS to ensure the PtDA is developed to a high quality standard. **[57]** Additionally, engaging stakeholders from multiple disciplines and cities in development and alpha testing of the PtDA will ensure that the end product is usable and optimized to better meet the needs of both patients and clinicians. It will also raise early awareness of its existence, with goals for public availability and national dissemination. Finally, the inclusion of qualitative methods allows for collection of deeper stakeholder

insights, perceptions and opinions,**[58]** all of which are critical in designing a PtDA that will optimize user uptake.

Limitations of this study protocol include the arbitrary success endpoints for both alpha and field-testing outcomes. Discrete success endpoints have not been previously described to our knowledge, remain largely qualitative and to the discretion of the steering committee. Despite this, we are using methods recommended by IPDAS**[20]**, and will have steering committee members with expertise in PtDA development and evaluation. Further work and study on better defining these endpoints is required. Additionally, we may not identify sex and gender-specific differences from either patients or clinicians as Achilles tendon ruptures occur far more frequently in men,**[2]** and the majority of surveyed orthopaedic surgeons in field-testing will be men due to a gender bias in the profession. Nonetheless, we have made efforts to capture and analyze these potentially important differences in our analysis plan. Finally, there are inherent limitations of the before-after study design, including the lack of a control arm. This makes it difficult to control for confounding factors that may affect patient outcomes, such as independent research into treatment options. This design has, however, been previously used in the evaluating PtDAs**[59]** and offers the advantage of facilitating patient recruitment.

Conclusion

Patient decision aids are meant to improve patient preparation for decision-making. By providing foundational information and encouraging patients to reflect on relevant personal values for outcomes of options, these tools may facilitate the patient-physician decision making interaction and enhancing patient-centered care. Our aim is to develop,

alpha and field-test this pre-consultation Achilles tendon rupture decision aid as the first of a series of orthopaedic PtDAs, under a quality improvement initiative for facilitating shared decision making for patients receiving musculoskeletal care.

References

1. Soroceanu A, Sidhwa F, Aarabi S, Kaufman A, Glazebrook M. Surgical Versus Nonsurgical Treatment of Acute Achilles Tendon Rupture. J Bone Joint Surg Am. 2012;94:2136.

2. Kadakia AR, Dekker RG II, Ho BS. Acute Achilles Tendon Ruptures. J Am Acad Orthop Surg. 2017;25:23–31.

3. Patel MS, Kadakia AR. Minimally Invasive Treatments of Acute Achilles Tendon Ruptures. Foot and Ankle Clinics. 2019;24:399–424.

4. Mattila VM, Huttunen TT, Haapasalo H, Sillanpää P, Malmivaara A, Pihlajamäki H. Declining incidence of surgery for Achilles tendon rupture follows publication of major RCTs: evidence-influenced change evident using the Finnish registry study. British Journal of Sports Medicine. 2015;49:1084–6.

5. Sheth U, Wasserstein D, Jenkinson R, Moineddin R, Kreder H, Jaglal SB. The epidemiology and trends in management of acute Achilles tendon ruptures in Ontario, Canada: a population-based study of 27 607 patients. Bone Joint J. 2017;99-B:78–86.

6. Garvelink MM, Boland L, Klein K, Nguyen DV, Menear M, Bekker HL, et al. Decisional Conflict Scale Use over 20 Years: The Anniversary Review. Med Decis Making. 2019;39:301–14.

7. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995;15:25–30.

8. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. N Engl J Med. 2012;366:780–1.

9. Scholl I, Zill JM, Härter M, Dirmaier J. An integrative model of patient-centeredness - a systematic review and concept analysis. PLoS ONE. 2014;9:e107828.

10. Weston WW. Informed and shared decision-making: the crux of patient-centered care. CMAJ. 2001;165:438–9.

11. Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. Soc Sci Med. 1999;49:651–61.

12. Stacey D, Hill S, McCaffery K, Boland L, Lewis KB, Horvat L. Shared Decision Making Interventions: Theoretical and Empirical Evidence with Implications for Health Literacy. Stud Health Technol Inform. 2017;240:263–83.

13. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Consumers and Communication Group, editor. Cochrane Database of Systematic Reviews.

2017;19:2172.

14. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2017;4:CD001431.

15. Shay LA, Lafata JE. Where Is the Evidence? A Systematic Review of Shared Decision Making and Patient Outcomes. Med Decis Making. 2014;35:114–31.

16. O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingworth G, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. Patient Educ Couns. 1998;33:267–79.

17. Joseph-Williams N, Newcombe R, Politi M, Durand M-A, Sivell S, Stacey D, et al. Toward Minimum Standards for Certifying Patient Decision Aids. Med Decis Making. 2014;34:699–710.

18. Stacey D, Légaré F, Boland L, Lewis KB, Loiselle M-C, Hoefel L, et al. 20th Anniversary Ottawa Decision Support Framework: Part 3 Overview of Systematic Reviews and Updated Framework. Med Decis Making. 3rd ed. 2020;40:379–98.

19. Elwyn G. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ. 2006;333:417–0.

20. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. BMC Medical Informatics and Decision Making. BioMed Central Ltd; 2013;13:S2.

21. Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge. Implementation Science; 2017;:1–9.

22. Cargo M, Mercer SL. The Value and Challenges of Participatory Research: Strengthening Its Practice. Annu. Rev. Public Health. 2008;29:325–50.

23. Walter I, Davies H, Nutley S. Increasing research impact through partnerships: evidence from outside health care. J Health Serv Res Policy. 2003;8 Suppl 2:58–61.

24. Golden-Biddle K, Reay T, Petz S, Witt C, Casebeer A, Pablo A, et al. Toward a communicative perspective of collaborating in research: the case of the researcher-decision-maker partnership. J Health Serv Res Policy. 2003;8 Suppl 2:20–5.

25. Bartunek J, Trullen J, Bonet E, Sauquet A. Sharing and expanding academic and practitioner knowledge in health care. J Health Serv Res Policy. 2003;8 Suppl 2:62–8.

26. Kujala S. User involvement: A review of the benefits and challenges. Behaviour & Information Technology. 2nd ed. 2003;22:1–16.

27. Joseph-Williams N, Newcombe R, Politi M, Durand M-A, Sivell S, Stacey D, et al. Toward Minimum Standards for Certifying Patient Decision Aids. Med Decis Making. 2014;34:699–710.

28. Edwards A, Evans R, Elwyn G. Manufactured but not imported: new directions for research in shared decision making support and skills. Patient Educ Couns. 2003;50:33–8.

29. FLESCH R. A new readability yardstick. J Appl Psychol. 1948;32:221–33.

30. Légaré F, Kearing S, Clay K, Gagnon S, D'Amours D, Rousseau M, et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. Can Fam Physician. 2010;56:e308–14.

31. Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PK, et al. Presenting quantitative information aboutdecision outcomes: a risk communication primerfor patient decision aid developers. BMC Medical Informatics and Decision Making. BioMed Central Ltd; 2013;13:S7.

32. Sandelowski M. What's in a name? Qualitative description revisited. Res. Nurs. Health. 10:n/a–n/a.

33. Colorafi KJ, Evans B. Qualitative Descriptive Methods in Health Science Research. HERD. 4 ed. 2016;9:16–25.

34. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Administration and Policy in Mental Health and Mental Health Services Research. Springer US; 2015;:1–12.

35. Sandelowski M. Sample size in qualitative research. Res. Nurs. Health. 1995;18:179–83.

36. Faulkner L. Beyond the five-user assumption: benefits of increased sample sizes in usability testing. Behav Res Methods Instrum Comput. 2003;35:379–83.

37. Drake ER, Engler-Todd L, O'Connor AM, Surh LC, Hunter A. Development and Evaluation of a Decision Aid About Prenatal Testing for Women of Advanced Maternal Age. J Genet Couns. 1999;8:217–33.

38. Man-Son-Hing M, Laupacis A, O'Connor A, Wells G, Lemelin J, Wood W, et al. Warfarin for atrial fibrillation. The patient's perspective. Arch. Intern. Med. 1996;156:1841–8.

39. Fiset V, O'Connor AM, Evans W, Graham I, Degrasse C, Logan J. Development and evaluation of a decision aid for patients with stage IV non-small cell lung cancer. Health Expect. 2000;3:125–36.

40. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. International Journal of Human-Computer Interaction. 2008;24:574–94.

41. Determining What Individual SUSScores Mean. 2009;:1–10.

42. Sauro J. A Practical Guide to the System Usability Scale. CreateSpace; 2011.

43. Bansback N, Chiu JA, Carruthers R, Metcalfe R, Lapointe E, Schabas A, et al. Development and usability testing of apatient decision aid for newly diagnosedrelapsing multiple sclerosis patients. BMC Neurology; 2019;:1–11.

44. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nurs Health Sci. 2013;15:398–405.

45. Graneheim UH, Lindgren B-M, Lundman B. Nurse Education Today. Nurse Education Today. Elsevier; 2017;56:29–34.

46. O'Connor AM, Fiset V, DeGrasse C, Graham ID, Evans W, Stacey D, et al. Decision aids for patients considering options affecting cancer outcomes: evidence of efficacy and policy implications. J. Natl. Cancer Inst. Monographs. 1999;:67–80.

47. Carroll SL, Stacey D, McGillion M, Healey JS, Foster G, Hutchings S, et al. Evaluating the feasibility of conducting a trial using a patient decision aid in implantable cardioverter defibrillator candidates: a randomized controlled feasibility trial. Pilot and Feasibility Studies; 2017;:1–12.

48. Berger K. Informed consent: information or knowledge? Med Law. 2003;22:743–50.

49. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. Patient Educ Couns. 2010;78:130–3.

50. Ferron Parayre A, Labrecque M, Rousseau M, Turcotte S, Légaré F. Validation of SURE, a Four-Item Clinical Checklist for Detecting Decisional Conflict in Patients. Med Decis Making. 2013;34:54–62.

51. Boland L, Légaré F, McIsaac DI, Graham ID, Taljaard M, Dècary S, et al. SURE Test Accuracy for Decisional Conflict Screening among Parents Making Decisions for Their Child. Med Decis Making. 2nd ed. 2019;39:1010–8.

52. Hertzog MA. Considerations in determining sample size for pilot studies. Res. Nurs. Health. 2008;31:180–91.

53. Hoffman AS, Bateman DR, Ganoe C, Punjasthitkul S, Das AK, Hoffman DB, et al. Development and Field Testing of a Long-Term Care Decision Aid Website for Older Adults: Engaging Patients and Caregivers in User-Centered Design. Bowers BJ, editor. The Gerontologist. 2019;60:935–46.

54. Sivell S, Marsh W, Edwards A, Manstead ASR, Clements A, Elwyn G, et al. Patient Education and Counseling. Patient Educ Couns. Elsevier Ireland Ltd; 2012;86:179–88.

55. Hooiveld T, Molenaar JM, van der Heijde CM, Meijman FJ, Groen TP, Vonk P. End-user involvement in developing and field testing an online contraceptive decision aid. SAGE Open Medicine. 2018;6:205031211880946.

56. Sepucha KR, Abhyankar P, Hoffman AS, Bekker HL, LeBlanc A, Levin CA, et al. Standards for UNiversal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist. BMJ Qual Saf. 2018;27:380–8.

57. Rahman MS. The Advantages and Disadvantages of Using Qualitative and Quantitative Approaches and Methods in Language "Testing and Assessment" Research: A Literature Review. JEL. 2016;6:102.

58. O'Connor AM, Fiset V, DeGrasse C, Graham ID, Evans W, Stacey D, et al. Decision aids for patients considering options affecting cancer outcomes: evidence of efficacy and policy implications. J. Natl. Cancer Inst. Monographs. 1999;:67–80.

60. Cohen D. What do the Experts Say? Achilles Tendon Treatment Options Debate. COA Bulletin. Accessed on May 10, 2020

61. Erad MAJ. Acute Achilles Tendon Injuries. JBJS Clinical Summary. Accessed May 10, 2020. https://www.jbjs.org/summary.php?id=284&native=1

62. Ottawa Patient Decision Aid eTraining. Ottawa: 2019. Accessed on May12, 2020. https://decisionaid.ohri.ca/eTraining/

63. O'Connor AM & Cranney A. User Manual – Acceptability. Ottawa: Ottawa Hospital Research Institute; © 1996 [modified 2002; cited 2020 05 20]. 5 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Acceptability.pdf

64. O'Connor AM. User Manual – Knowledge. Ottawa: Ottawa Hospital Research Institute; © 2000 [modified 2004; cited 2020 08 14]. 4 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Knowledge.pdf .

65. Graham ID & O'Connor AM. User Manual – Preparation for Decision Making Scale. Ottawa: Ottawa Hospital Research Institute; © 1995 [modified 2010; cited 2020 08 14]. 3 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_PrepDM.pdf.

Chapter 4:

Integrative Discussion

This chapter will elaborate on the findings of this thesis, with elaboration and discussion on the implications of using Network Meta Analysis (NMA) data in the development process of patient decision aids (PtDAs). The focus will be on strengths and limitations of their use, implications for clinicians and patients. It will include reflections on furthering the development and testing of PtDAs in clinical practice. Finally, future directions will be discussed including plans for furthering the development and evaluation of orthopaedic-specific PtDAs at the University of Ottawa. This thesis contributed to partial fulfillment of the requirements of the Master of Science in Clinical Epidemiology at the University of Ottawa, with many overarching principles acquired through this degree applied within (Appendix C.1).

The optimal treatment decision following Achilles tendon ruptures is widely seen to be controversial[60,61]. As treatment strategies have evolved and changed over time, there are several options available to patients with unique sets of benefits and harms. When there is more than one acceptable treatment option, it is known that clinicians, and surgeons specifically, struggle to accurately predict a patient's treatment goals[36,37] The purpose of this thesis was to 1. provide the most inclusive and up-to-date information on Achilles tendon ruptures using network meta-analysis (NMA) methods and 2. develop a comprehensive protocol for developing and testing and novel patient decision aid for patients with acute Achilles tendon ruptures using the results of the NMA as the primary data source.

The division of orthopaedic surgery at the University of Ottawa is committed to improving the patient experience through its Continuous Quality Improvement program,[1] focusing on high-value, patient-centered care. As described by Weston, shared decision making (SDM) should be seen as the 'crux of patient-centered care'.[11] Management of Achilles tendon ruptures is just one example of a preference-sensitive decision faced by orthopaedic surgery patients. Patients, clinicians and policymakers agree that there is abundant opportunity to further improve patient engagement in SDM strategies such as patient decision-aids within the field of orthopaedic surgery.[18] Through the creation and operationalization of the Ottawa Orthopaedic Decision Aid Program we aim to improve the delivery of patient-centered musculoskeletal care locally, nationally, and beyond. To begin this program, we chose management of acute Achilles tendon rupture, a common, patient preference-sensitive decision as the foundational PtDA. This pathology required an updated literature synthesis to guide creation of the PtDA, which we performed with the NMA. The subsequent protocol to create and test a novel PtDA will serve as a template for further PtDA development for the decision aid program.

Management for Acute Achilles Tendon Ruptures: A Systematic Review and Network Meta-Analysis

This NMA is to our knowledge the first to report on all management treatment options for patients with an acute Achilles tendon rupture. We focused on reporting important and relevant outcomes for patients and clinicians facing this decision. These outcomes included overall complications, re-ruptures, re-operation, and return to sport and work, with minimally invasive surgery (MIS) ranking best for avoiding overall complications, complications associated with a secondary operation, and at least

equivalent return to activity. We anticipate these results to stimulate further interest in surgeons learning and adopting MIS techniques for Achilles tendon repair. Additionally, these results will facilitate the clinician-patient discussion, allowing patients to weigh the risks with potential benefits when choosing their optimal treatment.

Use of Network Meta-Analysis in Patient Decision Aid Development

The use of NMA data offers a unique opportunity for PtDA development. It has been well established by the International Patient Decision Aid Standards (IPDAS) collaboration that a thorough literature review and synthesis is requisite to the creation and population of data within the PtDA, whether this be by systematic reviews, meta-analysis or use of clinical practice guidelines.[33] When multiple treatment options exist, and particularly when more than one option may be a reasonable choice for a patient, this entails combining data from multiple head-to-head trials. In the case of Achilles tendon ruptures, pairwise comparison of just four reasonable management strategies entails six different pairwise comparisons (A vs. B, A vs. C, A vs. D, B vs. C, B vs. D, C vs. D). This number of pairwise comparisons increases exponentially as further options exist. This can be problematic for several reasons. First, head to head trials may not exist for all competing options in which case pairwise comparisons cannot be performed. Second, when pairwise comparisons do exist, trials sizes must be sufficiently large enough to allow for precise risk estimates to drive decision-making[62]. NMA methods address both of these issues by facilitating the generation and interpretation of indirect comparisons when head-to head data does not exist, and allows combining of direct and indirect evidence, thereby increasing the pooled sampling which may improve the precision of risk estimates.[38]

A multi-national survey of medical students demonstrated that basic knowledge of SDM principles is increasing in medical students as further emphasis on SDM is placed in medical school curriculums.[39] Yet despite student attitudes being overwhelmingly positive towards the practice of SDM with patients, barriers to SDM implementations still exist. In particular, effective risk communication with patients is lacking.[39,40] When utilizing a Bayesian framework, as we have done, results of a NMA may facilitate risk communication by knowledge users. In contrast to frequentist methods, where analysis results are presented as fixed estimates without a probability distribution, Bayesian frameworks allow for more intuitive data interpretation using probabilities of relative effectiveness and ranking of individual outcome variables.[38,41,42] This has obvious relevance to stakeholders engaged in creation of decision support tools such as PtDAs, allowing for critical appraisal, interpretation and translation of data to patients in an efficient format that has direct significant to the decision-maker.

Limitations to use of NMA Data

Nonetheless, knowledge users should take a cautious approach when interpreting in the results of NMA data. As a relatively novel statistical technique, many clinicians do not have the background for accurate interpretation of results.[43] Ranking of data with both numeric and graphical techniques has been advocated,[38] including the surface under the cumulative ranking (SUCRA) curve as we have done. SUCRA values represent the percent likelihood that a given treatment will be ranked highest with respect to a particular outcome. This is an attractive and easy way to present results, but it must be taken in the full context of the data including the quality of the evidence from which it is based, and each of the other relevant reported outcomes must be considered

concomitantly. Perhaps most importantly, the magnitude of differences between subsequent ranked data may be very small, and the clinical relevance of these differences must be scrutinized carefully before drawing firm conclusions based on ranking. For these reasons, it would be prudent to include a researcher with knowledge or expertise in PtDA creation as part of the steering group overseeing development.

Development and Field-Testing a Patient Decision Aid for Management of Acute Achilles Tendon Rupture: A Protocol

This research protocol details the comprehensive process of creating and testing a novel PtDA for patients with acute Achilles tendon ruptures. It was created using guidance from the Ottawa Decision Support Framework (ODSF)[34] and in accordance with PtDA qualifying criteria from the International Patient Decision Aid Standards (IPDAS).[44] The use of a systematic development and evaluation process for PtDAs has been a cornerstone for the IPDAS, from their original published version[7] and more recent revisions.[33] This protocol will provide a framework for further PtDA development within the Ottawa Orthopedic Decision Aid

Strengths of Protocol

Despite the recommendation from the IPDAS, evaluative studies of PtDAs infrequently report on key developmental stages such as who was involved in development of PtDA (patients, clinicians, or both), how the prototype was developed, how clinical evidence is appraised and selected for inclusion, and whether there was any user-testing of the prototype. [33,45] The goal with this protocol and subsequent studies is to add transparency to this process in order to limit the potential to bias the future implementation of the PtDA.

The end goal for any PtDA is not to use it in an evaluative study, but to have a high-impact tool that empowers patients to discuss options freely and openly with their medical team. For a PtDA to have impact, it must be accepted and used by the target knowledge-user. The use of integrated knowledge transition (iKT), or collaborative research with knowledge-users, is based on the premise that the research team and knowledge-users will identify and eliminate barriers to real-world application of research findings.[46] Involving the knowledge-user in the research process should support and ease the integration and impact of research into practice.[47] It is with these principles in mind that we engage both Achilles tendon rupture patients and clinicians central to the care team throughout the development and evaluative stages of the PtDA.

Limitations of protocol

As always, there are limitations to be considered as well. There remains a paucity of guidance for methods to perform rigorous field-testing of PtDAs. In keeping with the goal of having PtDA uptake for use in routine care, beyond the study phase, we have carefully designed the field test to mimic the patient journey in real-life conditions. The results of the feasibility metrics will allow for scrutiny and trouble-shooting of the delivery methods of the PtDA and further refinement as to how best optimize it for clinical use. Nonetheless, there is no known 'road-map' for field-tests of PtDA and further work should be done to explore and optimize these methods.

Ottawa Orthopedic Decision Aid Program

Surgeons, and orthopedic surgeons in particular, struggle to incorporate SDM strategies with their patients[48] despite generally positive attitudes towards the practice.[49,50] Systematically developed PtDAs smooth the SDM process between patients

and clinicians. They explicitly state the decision needed to be made, communicate risks in language that has been validated to facilitate understanding by patients, and perhaps most importantly allow patients to weigh how they value the outcomes or features of the options available. Wider creation and dissemination of musculoskeletal pathology-specific PtDAs is one mechanism that may help bridge this important gap in SDM participation.

Future Research Opportunities

While creating PtDAs may facilitate the practice of SDM, future research must include methods to improve PtDA uptake in the clinical setting. Improving uptake may be looked upon from both 'orthopedic specific strategies' and 'system strategies' point of view.

Orthopedic surgery-specific strategies to increasing PtDA uptake and use can be viewed from barriers analysis performed by Bunzli et al.[50] Using the Theoretical Domains Framework, their group identified surgeon barriers and facilitators in their study on the uptake of PtDA for patients with end stage knee osteoarthritis. Concern about disruption or slowing of workflow was noted, consistent with prior studies on barriers to implementation of SDM strategies.[51] Also noted was the tendency to distrust evidence on surgical outcomes and how it generalizes to their individual practice.

Disruption of clinical workflow is an important aspect to consider if PtDAs are to be more widely used in busy surgical practices. The envisioned PtDA for Achilles tendon ruptures is to be used pre-consultation with the goal of minimal disruption in the actual consultation process. It is important to note that while pre-consultation PtDAs may work well for elective and semi-elective decisions, this is less likely to be possible for more

urgent or time-sensitive decisions such as acute trauma. Feedback from surgeons during field-testing will specifically ask for reflection on how PtDA use affected the clinical flow process. Direct and indirect time-saving impacts of PtDA will be explored, such as quality of patient questions, need for increased follow-up visits or phone calls due to unanswered questions and increased time spent with patients who may not be satisfied with their treatment choice. Further study on PtDA impact, and specifically positive impact on clinical efficiency are needed to help alleviate this barrier.

General system strategies for increasing uptake and use of PtDAs must include improving patient awareness and access to the PtDAs. Directly recruiting patients in the study setting as aligned in the Chapter 3 protocol may work for the research purposes, but it is less likely that this method of recruitment is sustainable long term.[52] Leveraging partner providers in musculoskeletal care is an important strategy that should be further investigated. Family physicians, physiotherapists and sports medicine physicians are often involved in early evaluation and screening of orthopedic pathologies either independently or as part of screening or triage clinics. A PtDA for patients with hip or knee arthritis has previously been studied in the a screening clinic, demonstrating benefits in decreasing wait times and improved decision quality.[53] Screening and triage clinics for orthopedic pathology are expanding locally and nationally in efforts to improve access to care, and substantial opportunity exists to engage patients with PtDAs as part of the triage process.

Patients also have easier access to their electronic medical record (EMR) through patient portals as EMR technology and security features improve. Previous studies have demonstrated high rates of patient access to their patient portal for health information

access.[54] A patient's EMR portal may be linked to a pathology-specific PtDA, accessible to the patient pre-consultation as part of the consult screening process offers a unique and potentially powerful translational strategy to investigate. This also has the potential to address the barrier of surgeon or clinician engagement in offering the PtDA for use.

Implications for Health Policy

The adoption of SDM practices is medicine is being increasing encouraged and promoted by policymakers in North America and globally.[55] For example, in the United States, the Affordable Care act urges physicians and other health care providers to engage patients in their medical decisions by providing clear, evidence-based guidance on outcomes, risks, harms, and options for their medical decisions[63]. While not currently legislated in Canada, there is increasing federal funding garnered to support research initiatives aimed at progressing the science of decision support tools and interventions.[56] Much of this research is centered locally at the Ottawa Hospital Research Institute (OHRI).

A central consideration for healthcare policymakers is the costs of healthcare delivery. This is perhaps most relevant in the publically funded healthcare systems such as we have in Canada. There is some evidence to suggest that the use of PtDAs in orthopaedic surgery may be associated with less practice variation. Sepucha et al. reported on a comparative cohort of patients who received either usual care or a PtDA intervention tailored to their orthopaedic pathology (hip or knee osteoarthritis, lumbar disc herniation or lumbar spinal stenosis).[57] In addition to improved knowledge and decision quality scores, patients in the intervention group were less likely to choose a surgical intervention (42.3% vs. 55.7%) with a direct effect on lowering health care costs.

This has been corroborated locally with a cost-effectiveness study of a randomized controlled trial (RCT) for patients referred to a screening clinic for evaluation of hip or knee arthritis.[16] In the RCT, 343 patients were randomized to either usual care of a video-based PtDA tailored to their pathology.[53] Over the two-year course of the study, patients who accessed the PtDA reported similar quality of life scores yet had fewer surgeries with obvious cost savings incurred.

While it is not yet known what the impact of a PtDA for Achilles tendon ruptures will have on a patient's treatment decision, it is conceivable that based on the data presented in our NMA that it may translate to even fewer surgeries for this injury. Alternatively, as MIS surgery increases in popularity with mounting evidence that it helps avoid complications, primary repair rate may in fact increase. The cost implications of PtDA use must be explored further, particularly when treatment options may incur radically different systemic and societal costs such a surgical procedure over a conservative alternative, or the systemic costs of incurring complications requiring costly secondary procedures.

Conclusion

Treatment of Achilles tendon ruptures is a preference-sensitive decision dependent on patient's functional goals and risk tolerance for undergoing an invasive procedure. Our network meta-analysis demonstrates that newer MIS strategies may mitigate the risk of post-operative complications when compared to open surgery, and also decrease the need for secondary surgical procedures compared to all treatments. Using this data to help create a PtDA is hoped to assist patients make a more informed, value-based decision congruent with their preferences. Our protocol will act as a template

to further develop and test PtDAs with a spectrum of musculoskeletal pathologies with a vision to improve shared decision making within orthopedic surgery.

References (Chapters 1 + 4)

1. Beaulé PE, Roffey DM, Poitras S. Continuous quality improvement in orthopedic surgery: changes and implications with health system funding reform. *Can J Surg*. 2016;59(3):149–150. doi:10.1503/cjs.005416.

2. Leclercq WKG, Keulers BJ, Scheltinga MRM, Spauwen PHM, van der Wilt G-J. A Review of Surgical Informed Consent: Past, Present, and Future. A Quest to Help Patients Make Better Decisions. *World J Surg*. 2010;34(7):1406–1415. doi:10.1007/s00104-004-0917-6.

3. Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand? *AJS*. 2009;198(3):420–435. doi:10.1016/j.amjsurg.2009.02.010.

4. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. *JAMA*. 1992;267(16):2221–2226.

5. Weinstein JN, Clay K, Morgan TS. Informed patient choice: patient-centered valuing of surgical risks and benefits. *Health Aff (Millwood)*. 2007;26(3):726–730. doi:10.1377/hlthaff.26.3.726.

6. Sepucha KR, Fowler FJ Jr., Mulley AG Jr. Policy Support For Patient-Centered Care: The Need For Measurable Improvements In Decision Quality. *Health Aff (Millwood)*. 2004;23(Suppl2):VAR–54–VAR–62. doi:10.1097/00019514-200008020-00003.

7. Elwyn G. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333(7565):417–0. doi:10.1136/bmj.38926.629329.AE.

8. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ*. 2012;345(nov07 6):e6572–e6572. doi:10.1136/bmj.e6572.

9. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood)*. 2013;32(2):207–214. doi:10.1377/hlthaff.2012.1061.

10. Kiesler DJ, Auerbach SM. Optimal matches of patient preferences for information, decision-making and interpersonal behavior: evidence, models and interventions. *Patient Educ Couns*. 2006;61(3):319–341. doi:10.1016/j.pec.2005.08.002.

11. Weston WW. Informed and shared decision-making: the crux of patient-centered care. *CMAJ*. 2001;165(4):438–439.

12. Salzburg Global Seminar. Salzburg statement on shared decision making. *BMJ*. 2011;342:d1745. doi:10.1136/bmj.d1745.

13. Merchant FM, Dickert NW Jr, Howard DH. Mandatory Shared Decision Making by the Centers for Medicare & Medicaid Services for Cardiovascular Procedures and Other Tests. *JAMA*. 2018;320(7):641. doi:10.1001/jama.2018.6617.

14. Stacey D, Hill S, McCaffery K, Boland L, Lewis KB, Horvat L. Shared Decision Making Interventions: Theoretical and Empirical Evidence with Implications for Health Literacy. *Stud Health Technol Inform*. 2017;240:263–283. doi:10.3233/978-1-61499-790-0-263.

15. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2017;4:CD001431. doi:10.1002/14651858.CD001431.pub5.

16. Trenaman L, Stacey D, Bryan S, et al. Decision aids for patients considering total joint replacement: a cost- effectiveness analysis alongside a randomised controlled trial. *Osteoarthritis and Cartilage*. 2017;25(10):1615–1622. doi:10.1016/j.joca.2017.05.022.

17. Sepucha K, Atlas SJ, Chang Y, et al. Patient Decision Aids Improve Decision Quality and Patient Experience and Reduce Surgical Rates in Routine Orthopaedic Care. *J Bone Joint Surg Am*. 2017;99(15):1253–1260. doi:10.2106/JBJS.16.01045.

18. Bozic KJ, Chenok KE, Schindel J, et al. Patient, surgeon, and healthcare purchaser views on the use of decision and communication aids in orthopaedic surgery: a mixed methods study. *BMC Health Serv Res*. 2014;14(1):281. doi:10.1038/oby.2011.65.

19. Chiodo CP, Glazebrook M, Bluman EM, et al. Diagnosis and treatment of acute Achilles tendon rupture. *J Am Acad Orthop Surg*. 2010;18(8):503–510.

20. Huttunen TT, Kannus P, Rolf C, Felländer-Tsai L, Mattila VM. Acute achilles tendon ruptures: incidence of injury and surgery in Sweden between 2001 and 2012. *Am J Sports Med*. 2014;42(10):2419–2423. doi:10.1177/0363546514540599.

21. Sheth U, Wasserstein D, Jenkinson R, Moineddin R, Kreder H, Jaglal SB. The epidemiology and trends in management of acute Achilles tendon ruptures in Ontario, Canada: a population-based study of 27 607 patients. *Bone Joint J*. 2017;99-B(1):78–86. doi:10.1302/0301-620X.99B1.BJJ-2016-0434.R1.

22. Ho G, Tantigate D, Kirschenbaum J, Greisberg JK, Vosseller JT. Increasing age in Achilles rupture patients over time. *Injury*. 2017;48(7):1701–1709. doi:10.1016/j.injury.2017.04.007.

23. Soroceanu A, Sidhwa F, Aarabi S, Kaufman A, Glazebrook M. Surgical Versus Nonsurgical Treatment of Acute Achilles Tendon Rupture. *J Bone Joint Surg Am*. 2012;94(23):2136. doi:10.2106/JBJS.K.00917.

24. Kadakia AR, Dekker RG II, Ho BS. Acute Achilles Tendon Ruptures. *J Am Acad Orthop Surg*. 2017;25(1):23–31. doi:10.5435/JAAOS-D-15-00187.

25. Glazebrook M, Rubinger D. Functional Rehabilitation for Nonsurgical Treatment of Acute Achilles Tendon Rupture. *Foot and Ankle Clinics*. 2019;24(3):387–398. doi:10.1016/j.fcl.2019.05.001.

26. Willits K, Amendola A, Bryant D, et al. Operative versus nonoperative treatment of acute Achilles tendon ruptures: a multicenter randomized trial using accelerated functional rehabilitation. *The Journal of Bone & Joint Surgery*. 2010;92(17):2767–2775. doi:10.2106/JBJS.I.01401.

27. Patel MS, Kadakia AR. Minimally Invasive Treatments of Acute Achilles Tendon Ruptures. *Foot and Ankle Clinics*. 2019;24(3):399–424. doi:10.1016/j.fcl.2019.05.002.

28. Hsu AR, Jones CP, Cohen BE, Davis WH, Ellington JK, Anderson RB. Clinical Outcomes and Complications of Percutaneous Achilles Repair System Versus Open Technique for Acute Achilles Tendon Ruptures. *Foot Ankle Int*. 2015;36(11):1279–1286. doi:10.1177/1071100715589632.

29. Grassi A, Amendola A, Samuelsson K, et al. Minimally Invasive Versus Open Repair for Acute Achilles Tendon Rupture: Meta-Analysis Showing Reduced Complications, with Similar Outcomes, After Minimally Invasive Surgery. *The Journal of Bone & Joint Surgery*. 2018;100(22):1969–1981. doi:10.2106/JBJS.17.01364.

30. Kou J. AAOS Clinical Practice Guideline: acute Achilles tendon rupture. *J Am Acad Orthop Surg*. 2010;18(8):511–513.

31. MD PP. PrefaceUpdates in the Management of Acute and Chronic Lesions of the Achilles Tendon. *Foot and Ankle Clinics of NA*. 2019;24(3):xv–xvi. doi:10.1016/j.fcl.2019.05.003.

32. Meulenkamp B, Stacey D, Fergusson D, Hutton B, MLIS RS, Graham ID. Protocol for treatment of Achilles tendon ruptures; a systematic review with network meta-analysis. December 2018:1–7. doi:10.1186/s13643-018-0912-5.

33. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S2. doi:10.1186/1472-6947-13-S2-S2.

34. O'Connor AM, Drake ER, Fiset V, Graham ID, Laupacis A, Tugwell P. The Ottawa patient decision aids. *Eff Clin Pract*. 1999;2(4):163–170.

35. Barry MJ, Edgman-Levitan S. Shared decision making--pinnacle of patient-centered care. *N Engl J Med*. 2012;366(9):780–781. doi:10.1056/NEJMp1109283.

36. McNair AGK, MacKichan F, Donovan JL, et al. What surgeons tell patients and whatpatients want to know before major cancersurgery: a qualitative study. *BMC Cancer*. March 2016:1–8. doi:10.1186/s12885-016-2292-3.

37. Levinson W, Hudak P, Tricco AC. Patient Education and Counseling. *Patient Educ Couns*. 2013;93(1):3–17. doi:10.1016/j.pec.2013.03.023.

38. Jansen JP, Fleurence R, Devine B, et al. Interpreting Indirect Treatment Comparisons and Network Meta-Analysis forHealth-Care Decision Making: Report of the ISPOR Task Force on IndirectTreatment Comparisons Good Research Practices: Part 1. *JVAL*. 2011;14(4):417–428. doi:10.1016/j.jval.2011.04.002.

39. Yen RW, Barr PJ, Cochran N, et al. Medical Students' Knowledge and Attitudes Toward Shared Decision Making: Results From a Multinational, Cross-Sectional Survey. *MDM Policy & Practice*. 2019;4(2):238146831988587. doi:10.1177/0272989X14551638.

40. Trevena LJ, Zikmund-Fisher BJ, Edwards A, et al. Presenting quantitative information aboutdecision outcomes: a risk communication primerfor patient decision aid developers. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S7. doi:10.1186/1472-6947-13-S2-S7.

41. Mills EJ, Thorlund K, Ioannidis JPA. Demystifying trial networks and network meta-analysis. *BMJ*. 2013;346(may14 2):f2914–f2914. doi:10.1136/bmj.f2914.

42. Salanti G, Ades AE, Ioannidis JPA. Graphical methods and numerical summaries for presenting results from multiple-treatment meta-analysis: an overview and tutorial. *Journal of Clinical Epidemiology*. 2011;64(2):163–171. doi:10.1016/j.jclinepi.2010.03.016.

43. Aïda Bafeta LTRSPR. Reporting of results from network meta-analyses: methodological systematic review. March 2014:1–9. doi:10.1136/bmj.g1741.

44. Joseph-Williams N, Newcombe R, Politi M, et al. Toward Minimum Standards for Certifying Patient Decision Aids. *Med Decis Making*. 2014;34(6):699–710. doi:10.1093/acprof:oso/9780198723448.003.0001.

45. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Consumers and Communication Group, ed. *Cochrane Database of Systematic Reviews*. 2017;19(9):2172. doi:10.1002/14651858.CD001431.pub4.

46. Wehrens R. Beyond two communities. *Public Health*. May 2014:1–7. doi:10.1016/j.puhe.2014.02.004.

47. Jull J, Giles A, Graham ID. Community-based participatory research and integrated knowledge translation: advancing the co-creation of knowledge.

December 2017:1–9. doi:10.1186/s13012-017-0696-3.

48. Braddock C III, Hudak PL, Feldman JJ, Bereknyei S, Frankel RM, Levinson W. "Surgery Is Certainly One Good Option": Quality and Time-Efficiency of Informed Decision-Making in Surgery. *J Bone Joint Surg Am*. 2008;90(9):1830–1838. doi:10.2106/JBJS.G.00840.

49. Adam JA, Khaw F-M, Thomson RG, Gregg PJ, Llewellyn-Thomas HA. Patient decision aids in joint replacement surgery: a literature review and an opinion survey of consultant orthopaedic surgeons. *Ann R Coll Surg Engl*. 2008;90(3):198–207. doi:10.1016/j.pec.2005.02.003.

50. Bunzli S, Nelson E, Scott A, French S, Choong P, Dowsey M. Barriers and facilitators to orthopaedic surgeons' uptake of decision aids for total knee arthroplasty: a qualitative study. *BMJ Open*. 2017;7(11):e018614. doi:10.1136/bmjopen-2017-018614.supp1.

51. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: Update of a systematic review of health professionals' perceptions. *Patient Educ Couns*. 2008;73(3):526–535. doi:10.1016/j.pec.2008.07.018.

52. Elwyn G, Scholl I, Tierbohl C, Mann M, Edwards AGK, Clay C, Légaré F , van de Weijden T, Lewis CL, Wexler RM, Frosch DL. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision Making*. November 2013:1–10. doi:10.1186/1472-6947-13-S2-S14.

53. Stacey D, Taljaard M, Dervin G, et al. Impact of patient decision aids on appropriate and timely access to hip or knee arthroplasty for osteoarthritis: a randomized controlled trial *Osteoarthritis and Cartilage*. August 2015:1–36. doi:10.1016/j.joca.2015.07.024.

54. Redmond P Burke AFRBRWRLHJAZJAW. Original Article. *https://doiorg/101017/S1047951110000363*. August 2010:1–8. doi:10.1017/S1047951110000363.

55. Martin HÃ rter Dipl Psych MP, Trudy van der Weijden PhD MD, PhD GEBMBMF. Policy and practice developments in the implementation of shared decision-making: an international perspective. *Theriogenology*. 2011;105(4):229–233. doi:10.1016/j.zefq.2011.04.018.

56. Lagare FL, Stacey D, Forest P-G, Coutu M-F. Moving SDM forward in Canada: milestones, public involvement, and barriers that remain. *Theriogenology*. 2011;105(4):245–253. doi:10.1016/j.zefq.2011.04.011.

57. Sepucha K, Atlas SJ, Chang Y, et al. Patient Decision Aids Improve Decision Quality and Patient Experience and Reduce Surgical Rates in Routine Orthopaedic

Care. *J Bone Joint Surg Am*. 2017;99(15):1253–1260. doi:10.2106/JBJS.16.01045.

58. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated July 2019). Cochrane, 2019. Available from www.training.cochrane.org/handbook.

59. Dias S, Welton NJ, Sutton AJ, Ades AE. NICE DSU Technical Support Document 2: A generalised linear modelling framework for pairwise and network meta-analysis of randomised controlled trials. URL: https://www.ncbi.nlm.nih.gov/books/NBK310366/. Accessed September 30, 2020.

60. Cohen D. What do the Experts Say? Achilles Tendon Treatment Options Debate. COA Bulletin. Accessed on May 10, 2020

61. Erad MAJ. Acute Achilles Tendon Injuries. JBJS Clinical Summary. Accessed May 10, 2020. https://www.jbjs.org/summary.php?id=284&native=1

62. Norman GR, Streiner DL. Biostatistics: The Bare Essentials. 3rd Ed. Hamilton, Canada: BC Decker Inc. 2008

63. The Affordable Care Act. US Department of Health and Human Services 2010. http://www.hhs.gov/healthcare/rights/law/index.html.!!Accessed!on!Nov.20 2020

Appendix A

A.1 Ovid MEDLINE search strategy

Database: Ovid MEDLINE(R) ALL <1946 to September 30, 2020>

Search Strategy:

1 achilles tendon/ (16990)

2 (achill* or tendoachill* or calcaneal).tw. (37844)

3 1 or 2 (41306)

4 rupture/ or ruptur*.tw. (290970)

5 3 and 4 (6677)

6 ((achill* or tendoachill* or calcaneal) and (ruptur* or tear* or damag* or injur*)).kf. (389)

7 ((achill* or tendoachill* or calcaneal) adj3 repair*).tw. (1834)

8 ((achill* or tendoachill* or calcaneal) adj5 (tear* or damage* or injur*)).tw. (2010)

9 or/5-8 (8399)

10 randomized controlled trial.pt. (917562)

11 controlled clinical trial.pt. (182870)

12 random*.tw. or placebo.ab. (3209251)

13 clinical trials as topic.sh. (217426)

14 trial*.ti. (829576)

15 or/10-14 (3894307)

16 9 and 15 (886)

17 exp animals/ not humans/ (16581887)

18 16 not 17 (600)

19 18 use medall (267)

20 achilles tendon rupture/ (2444)

21 achilles tendon/ (16990)

22 tendon rupture/ (4380)

23 21 and 22 (299)

24 ((achill* or tendoachill* or calcaneal) and ruptur*).tw. (6062)

25 ((achill* or tendoachill* or calcaneal) adj3 repair*).tw. (1834)

26 ((achill* or tendoachill* or calcaneal) adj5 (tear* or damage* or injur*)).tw. (2010)

27 20 or 23 or 24 or 25 or 26 (8547)

28 double-blind*.mp. or placebo*.tw. or blind*.tw. (1300956)

29 random*.tw. (2991078)

30 randomized controlled trial/ (976028)

31 28 or 29 or 30 (3730276)

32 27 and 31 (913)

33 (exp animal/ or nonhuman/) not exp human/ (11143609)

34 32 not 33 (719)

35 34 use emczd (307)

36 achilles tendon/ (16990)

37 (achill* or tendoachill* or calcaneal).tw. (37844)

38 36 or 37 (41306)

39 rupture/ or ruptur*.tw. (290970)

40 38 and 39 (6677)

41 ((achill* or tendoachill* or calcaneal) adj3 repair*).tw. (1834)

42 ((achill* or tendoachill* or calcaneal) adj5 (tear* or damage* or injur*)).tw. (2010)

43 40 or 41 or 42 (8346)

44 43 use cctr (280)

45 19 or 35 or 44 (854)

46 remove duplicates from 45 (512)

Appendix A.2. Individual study demographics

Study information	Criteria	Intervention	Comparator
Aisaiding et al. [1]			
Year: 2018	Treatment	Minimally invasive surgery	Open surgery
Country: China	Patients (n)	23	29
Mean age: 57 years	Treatment details	Achillon, #2 Ethibond	Achillon, #2 Ethibond
Percent male: 81%	Time to full weight bearing (weeks)	3	3
Follow-up (months): 24	Time to ROM (weeks)	3	3
Excluded comorbidities:		Diabetes, preexisting tendinopathy	
Risk factor prevalence:		Fluoroquinolone use (10.3%), steroid use (30.4%)	
Not reported:		Smoking status	
Aktas et al. [2]			
Year: 2009	Treatment	Minimally invasive surgery	Open surgical repair
Country: Poland	Patients (n)	20	20
Mean age: 40 years	Treatment details	Tenolig	Modified Ma & Griffith
Percent male: 88%	Time to full weight bearing (weeks)	6-7	6-7

Follow-up (months): 23	Time to ROM (weeks)	4	3
Excluded comorbidities:		Preexisting tendinopathy	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use, steroid use, diabetes status	
Cetti et al. [10]			
Year: 1993	Treatment	Primary immobilization	Open surgical repair
Country: Denmark	Patients (n)	55	56
Mean age: 37 years	Treatment details	Plantar flexion plaster of Paris cast	End-to-end Bunnell technique
Percent male: 83%	Time to full weight bearing (weeks)	6-7	6-7
Follow-up (months): 12	Time to ROM (weeks)	4	3
Excluded comorbidities:		Preexisting tendinopathy	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use, steroid use, diabetes status	
Gigante et al. [21]			
Year: 2008	Treatment	Minimally invasive surgery	Open surgical repair
Country: Italy	Patients (n)	20	19
Mean age: NR	Treatment details	Platar flexion plaster of paris cast	with #1 PDS

Percent male: NR	Time to full weight bearing (weeks)	6-7	6-7
Follow-up (months): 24	Time to ROM (weeks)	4-5	4-5
Excluded comorbidities:		Preexisting tendinopathy, steroid use	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use, diabetes status	
Karabinas et al. [41]			
Year: 2014	Treatment	Minimally invasive surgery	Open surgical repair
Country: France	Patients (n)	19	15
Mean age: 41 years	Treatment details	Modified Ma and Griffith technique	Krakow technique with #1 Ethibond
Percent male: 80%	Time to full weight bearing (weeks)	6-7	6-7
Follow-up (months): 22	Time to ROM (weeks)	3	3
Excluded comorbidities:		Preexisting tendinopathy, steroid use	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use, diabetes status	
Keating et al. [30]			
Year: 2011	Treat	Primary immobilization	Open surgical repair

	ment		
Country: UK	Patients (n)	39	37
Mean age: 40 years	Treatment details	Casting 4 weeks plantarflexion, 4 weeks some plantarflexion, 2 weeks in neutral	Kessler technique using PDS and vicryl
Percent male: 79%	Time to full weight bearing (weeks)	8	NR
Follow-up (months): 12	Time to ROM (weeks)	10	NR
Excluded comorbidities:		Preexisting tendinopathy	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use, steroid use, diabetes status	
Kolodziej et al. [46]			
Year: 2013	Treatment	Minimally invasive surgery	Open surgical repair
Country: Poland	Patients (n)	22	25
Mean age: 46 years	Treatment details	Krakow technique, absorbable suture	Achillon, absorbable suture
Percent male: 96%	Time to full weight bearing (weeks)	6	6
Follow-up (months): 24	Time to ROM (weeks)	NR	NR
Excluded comorbidities:		Preexisting tendinopathy, fluoroquinolone use, steroid use, diabetes status	

Risk factor prevalence:			
Not reported:		Smoking status	
Lantto et al. [49]			
Year: 2016	Treatment	Open surgical repair	Functional rehabilitation
Country: Finland	Patients (n)	32	28
Mean age: 40 years	Treatment details	Krakow technique with #2 FiberWire	Maximal plantar flexion and nonweightbearing week 1, orthosis with weekly reduction in plantarflexion until no orthosis by week 7
Percent male: 91%	Time to full weight bearing (weeks)	1	1
Follow-up (months): 18	Time to ROM (weeks)	1	1
Excluded comorbidities:		Preexisting tendinopathy, diabetes, steroid use	
Risk factor prevalence:			
Not reported:		Smoking status, fluoroquinolone use	
Lim et al. [52]			
Year: 2001	Treatment	Minimally invasive surgery	Open surgical repair
Country: UK	Patients (n)	33	33
Mean age: 38 years	Treatment details	Modified Ma & Griffith technique	Modified Kessler technique with PDS
Percent male: 59%	Time to full	NR	NR

	weight bearing (weeks)		
Follow-up (months): 6	Time to ROM (weeks)	NR	NR
Excluded comorbidities:		Fluoroquinolone use	
Risk factor prevalence			
Not reported:		Preexisting tendinopathy, diabetes, steroid use, smoking status	
Majewski et al. [54]			
Year: 2000	Treatment	Minimally invasive surgery	Open surgical repair
Country: Germany	Patients (n)	30	29
Mean age: 38 years	Treatment details	NR	NR
Percent male: 81%	Time to full weight bearing (weeks)	NR	NR
Follow-up (months): 31	Time to ROM (weeks)	NR	NR
	Treatment	Functional rehabilitation	
	Patients (n)	14	
	Treatment details	NR	
	Time to full weight	NR	

	bearing (weeks)		
	Time to ROM (weeks)	NR	
Excluded comorbidities:		Steroid use, preexisting tendinopathy	
Risk factor prevalence:			
Not reported:		Fluoroquinolone use, smoking status, diabetes	
Metz et al. [59]			
Year: 2008	Treatment	Functional rehabilitation	Minimally invasive surgery
Country: Netherlands	Patients (n)	41	42
Mean age: 41 years	Treatment details	Plantar flexion cast week 1 then progressively less plantar flexion in a custom orthosis	Bunell technique with #1 PDS
Percent male: 62%	Time to full weight bearing (weeks)	1	1
Follow-up (months): 42	Time to ROM (weeks)	3	1
Excluded comorbidities:			
Risk factor prevalence:		Fluoroquinolone use (10%)	
Not reported:		Preexisting tendinopathy, diabetes, steroid use, smoking status	
Möller et al. [62]			
Year: 2001	Treatment	Primary immobilzation	Open surgical repair
Country:	Patient	53	59

Sweden	s (n)		
Mean age: 39	Treatment details	Below knee cast	Modified Kessler technique
Percent male: 89%	Time to full weight bearing (weeks)	4	8
Follow-up (months): 24	Time to ROM (weeks)	8	3
Excluded comorbidities:		Preexisting tendinopathy, diabetes	
Risk factor prevalence:			
Not reported:		Fluoroquinolone use, steroid use, smoking status	
Nilsson-Helander et al. [64]			
Year: 2010	Treatment	Open surgical repair	Functional rehabilitation
Country: Sweden	Patients (n)	49	48
Mean age: 41	Treatment details	Kessler technique with #1 PDS	
Percent male: 81%	Time to full weight bearing (weeks)	6-8	6-8
Follow-up (months): 12	Time to ROM (weeks)	2	2
Excluded comorbidities:		Steroid use, preexisting tendinopathy, diabetes	
Risk factor			

prevalence:			
Not reported:		Fluoroquinolone use, smoking status	
Nistor et al. [65]			
Year: 1981	Treatment	Open surgical repair	Primary immobilization
Country: Sweden	Patients (n)	44	60
Mean age: 41	Treatment details	Bunnell technique	Plantarflexion cast then shoe with heel lift
Percent male: NR	Time to full weight bearing (weeks)	4	4
Follow-up (months): 60	Time to ROM (weeks)	2	4
Excluded comorbidities:			
Risk factor prevalence:			
Not reported:		Steroid use, preexisting tendinopathy, diabetes, fluoroquinolone use, smoking status	
Rozis et al. [73]			
Year: 2018	Treatment	Minimally invasive surgery	Open surgical repair
Country:	Patients (n)	41	41
Mean age: 41 years	Treatment details	Ma and Griffith technique	Krakow technique
Percent male: NR	Time to full weight bearing (weeks)	6	6

Follow-up (months): 12	Time to ROM (weeks)	6	6
Excluded comorbidities:		Steroid use, preexisting tendinopathy, diabetes	
Risk factor prevalence:			
Not reported:		Fluoroquinolone use, smoking status	
Thermann et al. [85]			
Year: 1995	Treatment	Open surgical repair	Functional rehabilitation
Country: Germany	Patients (n)	22	28
Mean age: 37 years	Treatment details	Kessler technique with #1 PDS	Custom orthosis
Percent male: 78	Time to full weight bearing (weeks)	1	1
Follow-up (months): 12	Time to ROM (weeks)	8	8
Excluded comorbidities:			
Risk factor prevalence:			
Not reported:		Steroid use, preexisting tendinopathy, diabetes, fluoroquinolone use, smoking status	
Twaddle et al. [88]			
Year: 2007	Treatment	Open surgical repair	Functional rehabilitation
Country: New Zealand	Patients (n)	20	22
Mean age: 41 years	Treatment	Krakow technique, #1	

	details		
Percent male: 67%	Time to full weight bearing (weeks)	6	6
Follow-up (months): 12	Time to ROM (weeks)	NR	NR
Excluded comorbidities:		Smoking status	
Risk factor prevalence:			
Not reported:		Fluoroquinolone use, diabetes, steroid use	
Willits et al. [96]			
Year: 2010	Treatment	Open surgical repair	Functional rehabilitation
Country: Canada	Patients (n)	72	72
Mean age: 41 years	Treatment details	Krakow technique, #2	
Percent male: 82%	Time to full weight bearing (weeks)	2	2
Follow-up (months): 24	Time to ROM (weeks)	Standard accelerated protocol	Standard accelerated protocol
Excluded comorbidities:		Fluoroquinolone use, preexisting tendinopathy	
Risk factor prevalence:			
Not reported:		Smoking status	

Appendix B

B.1 Consent Form – Patient Decision Aid Development and Alpha Testing

Minimal Risk Informed Consent Form for Participation in a Research Study

Study Title: Development and Field-Testing a Patient Decision-Aid for Management of Acute Achilles Tendon Rupture – Part 1 – Development and Alpha Testing

OHSN-REB Number: REB PENDING

Study Doctor: Dr. Brad Meulenkamp, Division of Orthopaedic Surgery, 613-798-5555 ext. 18596

Sponsor/Funder(s): Canadian Orthopaedic Research Legacy

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you have had an acute Achilles tendon rupture. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

The hospital is receiving financial payment from the Canadian Orthopaedic Research Legacy to cover the cost of conducting this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to develop and test a patient decision-aid for the management of acute Achilles tendon ruptures.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about *20* people will take part in this study, in 3 rounds of alpha testing.

This study should take 30 minutes to complete and the decision-aid should be finalized in approximately 18 months.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to participate in a semi-structured interview. During this interview, you will meet with a member of the research team. The interview will be about 10 minutes in length and will take place at your standard of care follow-up appointment in the Plaster Room or Orthopaedic Clinic at the Civic Campus. You will be asked to share your feedback on the patient decision-aid.

You will be provided with two questionnaires. The purpose of these questionnaires is to collect your feedback on the length, perceived usefulness, amount of and balance of information presented and usability of the decision-aid. Each questionnaire will take 5-10 minutes to complete.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Complete the semi-structure interview
- Complete the questionnaires

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation on this study will last for one visit.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no risks to you from participating in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no benefits to you for taking part in this study. We hope the information learned from this study will help other people with acute Achilles tendon ruptures in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
- Ottawa Hospital Research Institute or Ottawa Heart Institute Research Corporation, to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your age, sex, level of education, occupation and date of Achilles tendon rupture.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you decide to participate in this study, you will receive a $20 gift voucher as compensation for your time as well as a hospital-parking pass

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the study doctor know.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor, or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. Brad Meulenkamp	613-798-5555 ext. 18596
Principal Investigator Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

Study Title: Development and Field-Testing a Patient Decision-Aid for Management of Acute Achilles Tendon Rupture – Part 1 – Development and Alpha Testing

SIGNATURES

- All my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree to take part in this study.

Signature of Participant	**Printed Name**	**Date**

Signature of Person Conducting the Consent Discussion	**Printed Name and Role**	**Date**

Appendix B.2: Ottawa Acceptability Tool (Patient Version)

My thoughts on the education package on Achilles Tendon Rupture Management

We would like to know what you think about the education package you have just received.

1. Please rate each section, by circling 'poor', 'fair', 'good', or 'excellent' to show what you think about the way the information was presented on:

Impact of an Achilles Tendon Rupture	Poor	Fair	Good	Excellent
Risk Factors for Complications	Poor	Fair	Good	Excellent
Types of Research Studies	Poor	Fair	Good	Excellent
Non Surgical Options	Poor	Fair	Good	Excellent
Evidence About Non Surgical Options	Poor	Fair	Good	Excellent
Surgery Options	Poor	Fair	Good	Excellent
Evidence About Surgery	Poor	Fair	Good	Excellent
Stories About Others	Poor	Fair	Good	Excellent

2. The length of presentation was (*check one)*

|__| too long

|__| too short

|__| just right

3. The amount of information was (*check one*)

|__| too much information

|__| too little information

|__| just right

4. I found the presentation (*check one*)

|__| slanted towards choosing non-operative treatment

|__| slanted towards choosing surgery

|__| balanced

5. Would you have found this decision aid useful when you were making your decision about treatment for your Achilles tendon rupture?

|__| Yes

|__| No

Comments:

7. What did you think of the rest of the personal worksheet? Did it make the decision

|__| easy

|__| more difficult?

Comments:

_____
_____
_____

8. Do you think we included enough information to help a patient decide on treatment for Achilles tendon rupture?

|__| Yes

|__| No

Comments:

_____
_____
_____

9. What did you like about the decision aid and worksheet?

_____
_____
_____
_____
_____

10. What suggestions do you have to improve the decision aid or worksheet?

_____
_____
_____
_____
_____
_____

Appendix B.3: Ottawa Acceptability Tool (Clinician Version)

My thoughts on the education package on Achilles Tendon Rupture Management

The following set of questions asks about your perceptions of the decision support strategy you have been assigned. We are interested in your reactions to the strategy so please try to answer these questions in the same way you would if you had not agreed to take part in this study and were seeing the strategy for the first time. Please indicate how strongly you agree or disagree with each statement by *circling* the appropriate number

In General:	**Strongly Disagree**		**Neutral**		**Strongly Agree**
It will be easy for me to use with my patients	1	2	3	4	5
It is easy for me to understand how it can be used with my patients	1	2	3	4	5
It will be easy for me to experiment with using the strategy before making a final decision to adopt it.	1	2	3	4	5
The results of using the strategy will be easy to see.	1	2	3	4	5
This strategy is better than how I usually go about helping patients decide about Achilles tendon rupture management.	1	2	3	4	5
This strategy is compatible with the way I think things should be done.	1	2	3	4	5
The use of this strategy is a more cost-effective than my usual approach to helping patients decide about Achilles tendon rupture management	1	2	3	4	5
Compared with my usual approach, this strategy will result in my patients making more informed decisions.	1	2	3	4	5
Using this strategy will save me time.	1	2	3	4	5
This strategy is a reliable method of helping patients make decisions about Achilles tendon rupture management	1	2	3	4	5

Pieces or components of the strategy can be used by themselves.	1	2	3	4	5
This type of strategy is suitable for helping patients make value laden choices.	1	2	3	4	5
This strategy complements my usual approach.	1	2	3	4	5
Using this strategy does not involve making major changes to the way I usually do things	1	2	3	4	5
There is a high probability that using this strategy may cause/result in more benefit than harm	1	2	3	4	5

Practitioner Opinion (Acceptability) Survey © ID Graham 1996

Appendix B.4: System Usability Scale

	Strongly Disagree		Neutral		Strongly Agree
I think that I would like to use this tool.	1	2	3	4	5
I found the tool unnecessarily complex	1	2	3	4	5
I think that I would need support to be able to use this system.	1	2	3	4	5
I found the various parts in this tool were well integrated.	1	2	3	4	5
I thought there was too much inconsistency in this tool.	1	2	3	4	5
I would imagine that most people would learn to use this tool very quickly.	1	2	3	4	5
I found the tool very cumbersome to use.	1	2	3	4	5
I felt very confident using the tool.	1	2	3	4	5
I needed to learn a lot of things before I could get going with this tool.	1	2	3	4	5

Appendix B.5 Alpha Testing Semi-Structured Interview Guide

Patient Guide

Section 1: Presentation of the Patient Decision Aid

1. Tell me about your overall view of the decision aid?

Section 2: Content of the Patient Decision Aid

1. What did you think about content in the decision aid?

Further probing questions as required

a. What do you think about the layout of the decision aid?
b. What do you think about the design?
c. Should any sections be added or removed?
d. Did you find the order or sections appropriate? What, if any, flow problems did you identify?
e. Were there any areas of concern as you read through the decision aid?
f. What did you think about the length of the decision aid? Did you find you find it too long or too short?
g. Did you feel there was enough information presented? Was there too much or too little?
h. Was the information easy to understand?
i. How did you find the language? Would you suggest any wording changes?
j. Did you find that information was slanted towards one of the treatment options? If so, which way and why?

2. Do you think the Patient Decision Aid will allow others facing this treatment decision to reflect on what aspects of each treatment are most important to them?
    a. Are there any other important aspects that have not been considered or are missing?

Section 3: General Feedback

1. What did you like most about the decision aid?
2. What did you like least about the decision aid?
3. Do you have any suggestions about how the decision aid could be improved?
4. Would you recommend this decision aid to others?

Alpha Testing Semi-Structured Interview Guide

Clinician Guide

Section 1: Content of the Patient Decision Aid

1. What was your overall view of the decision aid?

Further probing questions as required

   b. Were there any areas of concern as you read through the decision aid?
   c. What did you think about the length of the decision aid? Did you find you find it too long or too short?
   d. Did you feel there was enough information presented? Was there too much or too little?
   e. Was the information easy to understand?
   f. How did you find the language? Would you suggest any wording changes?
   g. Did you find that information was slanted towards one of the treatment options? If so, which way and why?

Section 2: Usability

1. What do you think about the usability of the decision too in the clinical setting?

Further probing questions as required

   a. How do you foresee this too being implemented in the clinical setting?
   b. How would you foresee delivery of the decision aid to the patient?
   c. Is it best administered prior to or during consultation? Why?
   d. What format of delivery would be most useful for the patient?

Section 3: General Feedback

2. What did you like most about the decision aid?
3. What did you like least about the decision aid?
4. Do you have any suggestions about how the decision aid could be improved?
5. Would you use this decision aid with you patients?
   a. Yes
   b. No
   c. Maybe

Appendix B.6: Preparation for Decision Making Scale

Patient Version

Please show your opinion of the patient decision aid by circling the number to show how much you agree with each statement.

Did this educational material . . .	**Not at all**	**A Little**	**Some-what**	**Quite a bit**	**A great deal**
5. Help you recognize that a decision needs to be made?	1	2	3	4	5
6. Prepare you to make a better decision?	1	2	3	4	5
7. Help you think about the pros and cons of each option?	1	2	3	4	5
8. Help you think about which pros and cons are most important?	1	2	3	4	5
9. Help you know that the decision depends on what matters most to you?	1	2	3	4	5
10. Help you organize your own thoughts about the decision?	1	2	3	4	5
11. Help you think about how involved you want to be in this decision?	1	2	3	4	5
12. Help you identify questions you want to ask your doctor?	1	2	3	4	5
13. Prepare you to talk to your doctor about what matters most to you?	1	2	3	4	5
10. Prepare you for a follow-up visit with your doctor?	1	2	3	4	5

Practitioner Version

The following questions refer to the patient decision aid that was given to your patient prior to the follow-up consultation visit.

To what extent did the use of the Patient Decision Aid by your patient:	**Not at all**	**A Little**	**Some-what**	**Quite a bit**	**A great deal**
1. Help them to fully understand the risks and benefits of Achilles tendon rupture management options	1	2	3	4	5
2. Help them identify the importance they place on the risks and benefits of Achilles tendon rupture management options?	1	2	3	4	5
3. Prepare them for the follow-up consultation visit?	1	2	3	4	5
4. Help them be as involved in the decision making process as they desired?	1	2	3	4	5
5. Help them to make a more informed decision?	1	2	3	4	5
6. Help you to more fully understand the issues that are most important to [her]?	1	2	3	4	5
7. Help you tailor your counseling to their preference for decision participation?	1	2	3	4	5
8. Facilitate the follow-up consultation visit?	1	2	3	4	5
9. Affect the patient-physician relationship?	1	2	3	4	5
10. Improve the way time was spent during the follow- up consultation visit?	1	2	3	4	5
11. Improve the quality of the follow-up consultation visit?	1	2	3	4	5

Appendix C

C.1 Program Learning Outcomes for Graduate Programs in Epidemiology

<table>
<tr><td>Attribute</td><td colspan="2">Learning Outcomes</td></tr>
<tr><td></td><td>Master's Program</td><td></td></tr>
<tr><td></td><td colspan="2">Graduating students will be able to:</td></tr>
<tr><td>Depth and breadth of knowledge</td><td>1. Define concepts, terms and methods used in epidemiology and public health to describe the health of a population.</td><td>1. Achieved throughout course work and applied throughout thesis development
<u>Relevant Courses</u>
EPI 5240 EPIDEMIOLOGY I - INTRO EPIDEM.
EPI 5242 BIOSTATISTICS I
EPI 5189 HEALTH ECONOMIC EVALUATION
EPI 6178 INTER STUDIES HEALTH RESEARCH
EPI 6188 SYSTEMATIC REVIEW AND META-ANA
EPI 6278 ADVANCED CLINICAL TRIALS</td></tr>
<tr><td></td><td>2. Summarize basic facts concerning the health of populations and health determinants.</td><td>2. This is well demonstrated throughout the thesis chapters with respect to Achilles tendon ruptures, and will be central to decision aid development</td></tr>
<tr><td></td><td>3. Describe and compare features of observational and interventional study designs commonly used in epidemiology.</td><td>3. This was performed throughout several courses, including Interventional Studies and Advanced Interventional Studies, as well as Systematic Reviews and Meta-Analyis. This was also demonstrated</td></tr>
</table>

		throughout Chapter 2 of the thesis work Relevant Courses EPI 5240 EPIDEMIOLOGY I - INTRO EPIDEM. EPI 6178 INTER STUDIES HEALTH RESEARCH EPI 6188 SYSTEMATIC REVIEW AND META-ANA EPI 6278 ADVANCED CLINICAL TRIALS
	4. Describe the principles of causal reasoning in epidemiology.	4. Achieved through course work and small group sessions, as well as elaboration in thesis discussion Relevant Courses EPI 5240 EPIDEMIOLOGY I - INTRO EPIDEM.
	5. Identify and classify common primary and secondary sources of data for epidemiologic research. 6. Define core terms and concepts used in descriptive and inferential biostatistics.	5. Central component to the performance of the network meta-analysis in Chapter 2 of thesis 6. This was central to the course work and heavily involved in the performance of the network meta-analyis in chapter 2 of the thesis. Relevant Courses EPI 5242 BIOSTATISTICS I EPI 6188 SYSTEMATIC REVIEW AND META-ANA
		7. This is central to the mixed methods alpha and field

	7. Describe methods used in qualitative health research and ways in which qualitative and quantitative methods can complement each other. 8. Develop specialized knowledge about a health research topic or method.	tests described in the Chapter 3 protocol. 8. This is best exemplified in the performance of the network meta-analysis, using advanced statistical techniques and methods for data summary
Application of knowledge	9. Evaluate and critically appraise the strengths and limitations of an epidemiologic study from its design to the conclusions drawn. 10. Critically and systematically synthesize existing knowledge about a health topic. 11. Evaluate whether conclusions about causality are appropriate in particular examples of epidemiologic studies. 12. Design feasible studies with appropriate study designs to address health research questions. 13. Choose, apply, and interpret	9. This was performed in the Chapter 2 meta-analyisis, in particular with risk of bias assessments and use of the GRADE criteria for ranking evidence 10. This was central to my meta-analyis on calcaneus fractures in the SR/MA class, as well as with the Network meta-analysis in chapter 2 of the thesis. 11. This was the focus of small group sessions in the Intro to epidemiology course and also regularly performed in the critical appraisal of studies 12. This was the focus of bother Interventional Studies courses taken, and was a central focus of the study protocol design in Chapter 3 of the thesis Relevant Courses EPI 6188 SYSTEMATIC REVIEW AND META-ANA 13. Exemplified throughout my thesis as well as in prior

	appropriate biostatistical methods. 14. Proficiently use statistical software to analyze epidemiologic data.	coursework, particularly in Introduction to biostatistics Relevant Courses EPI 6188 SYSTEMATIC REVIEW AND META-ANA EPI 5242 BIOSTATISTICS I 14. Became proficient with SAS in Introduction to Biostatistics. Proficient with RevMan systematic review software, as well as Winbugs and R for performance of the network meta-analysis Relevant Courses EPI 6188 SYSTEMATIC REVIEW AND META-ANA EPI 5242 BIOSTATISTICS I
Engaged scholarship, knowledge translation, and communication	15. Define the core components of engaged scholarship 16. Describe best practices for facilitating uptake of evidence into policy, programs, patient care, and/or the design or analysis of	15. The principles of 'engaged scholarship' are at the core of my thesis work. The goal is for me to gain expertise in the field of patient decision aids and shared decision making, and engaging colleagues to better integrate these practices into their clinical practices. Specifically, I have lectured the local orthopedic community about the importance and implications of shared decision making in orthopedic surgery. Relevant Courses EPI 5244 SPECIAL TOPICS IN EPIDEMIOLOGY (KNOWLEDGE TRANSLATION 16. Again a key component of my thesis work, with focus

	future research. 17. Prepare a clearly written and logically argued report from epidemiologic analyses. 18. Effectively disseminate and communicate epidemiologic evidence to academic and non-academic audiences in written and oral formats. 19. Describe the implications of epidemiologic evidence for policy, programs, patient care, and/or future research	on future strategies for dissemination of patient decision aids. Relevant Courses EPI 5244 SPECIAL TOPICS IN EPIDEMIOLOGY (KNOWLEDGE TRANSLATION 17. Performed throughout epi classes with multiple assignments as well as with thesis work 18. Multiple presentations performed throughout masters coursework and will culminate in a thesis defence 19. This was exemplified in coursework, specifically in Health Cost Analysis, as well as within the integrated discussion of the thesis EPI 5189 HEALTH ECONOMIC EVALUATION
Autonomy, professional capacity, leadership and mentorship	20. Identify and adhere to ethical principles relevant to epidemiologic research that apply locally, nationally, and internationally, including the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). 21. Adhere to principles of academic integrity according to the policies of the University of Ottawa.	20. Exemplified throughout the MSc experience and also in my clinical research with adherence to ethical principles throughout the conduct of research 21. I certify that my work represents independent thought and always adheres to the principles of academic integrity

	22. Appreciate the value of and participate in an interdisciplinary research community in their chosen field of health research. 23. Commit to proactively seeking new knowledge and being aware of current issues of debate in their chosen field of health research.	22. This is once again exemplified in the protocol in chapter 3, with specific consideration for interdisciplinary contributions to the patient decision aid 23. This is central to my academic medical practice, and encompassed by the theme of my thesis to further develop the field of shared decision making within the orthopedic surgery subspecialty