# Outcome measurement in articular cartilage repair: exploring the patient

perspective

A critical appraisal submitted to London Metropolitan University in fulfillment of the requirements for the degree of PhD by Prior Output.

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### DECLARATION AND COLLABORATIVE WORK

I declare that this work is not substantially the same as any that I have previously submitted or am currently submitting in any form or for any qualification at any university or other institution.

No parts of this work have previously been submitted for any similar qualification.

Statements from Griva for Hambly and Griva (2008) and Hambly and Griva (2010) and from Bobić, Van Assche, Wondrasch and Marlovits for Hambly et al. (2006) are attached in Appendix 9.

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#### LIST OF PAPERS

- Paper I Hambly K, Bobić V, Wondrasch B, Van Assche D, Marlovits S. (2006).
  Autologous chondrocyte implantation postoperative care and rehabilitation: science and practice. *Am J Sports Med.* 34(6), 1020-1038.
- Paper II Hambly K, Griva K. (2008). IKDC or KOOS? Which measures symptoms and disabilities most important to postoperative articular cartilage repair patients? *Am J Sports Med.* 36(9), 1695-1704.
- Paper III Hambly K, Griva K. (2010). IKDC or KOOS: which one captures symptoms and disabilities most important to patients who have undergone initial anterior cruciate ligament reconstruction? *Am J Sports Med.* 38(7), 1395-1404.
- Paper IV Hambly K. (2011). The use of the Tegner activity scale for articular cartilage repair of the knee: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 19(4), 604-614.
- Paper V Hambly K. (2011). Activity profile of members of an online health community after articular cartilage repair of the knee. Sports Health.
  3(3), 275-282.

# LIST OF ABBREVIATIONS

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ACI	Autologous chondrocyte implantation
ACR	Articular cartilage repair
ACL	Anterior cruciate ligament
ACLR	Anterior cruciate ligament reconstruction
ADL	Activities/Function in Daily Living
AMED	Allied and complimentary Medicine Database
BNI	British Nursing Index
CINAHL	Cumulative Index for Nursing and Allied Health Literature
FIP	Frequency importance product
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ICF	International Classification of Functioning, Disability and Health
IKDC	International Knee Documentation Committee
IBM	Interactive Biopsychosocial Model
IPR	Individual patient ranking
IQR	Inter quartile range
KOOS	Knee injury and Osteoarthritis Outcome Score
MIR	Mean importance ranking
MSF	Musculoskeletal Services Framework
MWU	Mann-Whitney U
NHS	National Health Service
OA	Osteoarthritis
OHC	Online health community
PEDro	Physiotherapy Evidence Database
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement
PRO	Patient reported outcome
RCT	Randomised controlled trial
SORT	Strength Of Recommendation Taxonomy
TAS	Tegner activity scale
TKA	Total knee arthroplasty
WHO	World Health Organisation

# LIST OF FIGURES

Figure 1: The World Health Organisation's International Classification of Functioning, Disability and Health framework (WHO 2001)

## ABSTRACT

This critical appraisal provides an overview of five published research papers that collectively make an original and significant contribution to the patients' perspective of outcome measurement after articular cartilage repair (ACR) of the knee. The work represents the evolution and development of the author's coherent research programme in this field over a period of 8 years.

In 2003 the author conducted a comparative analysis of rehabilitative guidelines of 11 international ACR centres that identified large variations in practice. This work was significant as it resulted in the publication of the first evaluation of the evidence base for postoperative care after autologous chondrocyte implantation. The evidence base for postoperative care that was elucidated in this work served to uphold the biomedical model as being the dominant paradigm. Concurrently, the concept of patient-centred medicine was being actively promoted within primary care in the UK and patient-reported outcomes (PRO) were being adopted as primary endpoints in new ACR clinical trials across Europe and in the USA. This gap between PRO evidence and practice prompted this researcher to evaluate patient's and orthopaedic surgeon's perspectives of the rehabilitation process using a mixed methods approach incorporating grounded theory and content analysis. These inductive pilot works were noteworthy as they indicated that not only were ACR service users willing to allow their views to be captured for research purposes but they were prepared to do so using web-based tools.

Two key research questions emerged: what are the symptoms and disabilities most important to ACR patients and are current PRO measures capturing this information? To explore these questions, two commonly used knee-specific PRO measures were evaluated for item importance to ACR patients from an online health

community (OHC) using a clinical impact methodology. The emergent pattern was one of function in sports and recreation activities being important for people who had undergone ACR, more than an anterior cruciate ligament reconstruction (ACLR) cohort from the same OHC knee population. This work led to the formulation of a further research question: what is the postoperative physical activity profile of this OHC ACR population?

The Tegner activity scale (TAS) is frequently used to assess physical activity level within ACR studies but this use had not previously been evaluated. The first systematic review of the TAS for ACR raised important methodological issues relating to the use and reporting of the outcome. The key findings from this review were utilised by the researcher to inform the reporting of cross-sectional TAS data for the ACR and ACLR groups from this OHC. The postoperative physical activity profile of this ACR population was one where activity levels increased with postoperative time but remained lower than expected compared with then-current clinical and normative data.

The main body of this critical appraisal reviews and evaluates the papers within this research programme and the conceptual links between them. The methodological approaches used in the studies are reflected upon and the significance of the work and future directions for research are discussed.

### **SYNOPSIS**

This programme of research evaluates the patient perspective of outcome measurement in articular cartilage repair of the knee. The programme of research has five specific objectives:

i. To establish and evaluate the evidence based for current autologous chondrocyte implantation postoperative practice.

ii. To identify which instrument as between the Knee Osteoarthritis Outcome Score (KOOS) and the International Knee Documentation Centre (IKDC) subjective knee form measures symptoms and disabilities most important to postoperative articular cartilage repair (ACR) patients.

iii. To identify which instrument as between the KOOS and the IKDC subjective knee form captures symptoms and disabilities most important to patients who have undergone initial anterior cruciate ligament reconstruction (ACLR).

iv. To review the use of the Tegner activity scale (TAS) for ACR of the knee.

v. To establish a postoperative profile of users of an online health community (OHC) who have undergone ACR of the knee and to compare this profile with individuals from the same OHC who have undergone initial ACLR.

The critical appraisal that follows reviews and evaluates the research programme and the resultant five published papers that collectively serve to meet the programme objectives. The methodological approaches used in the studies are reflected upon and the significance of the work and future directions for research are discussed.

### INTRODUCTION

The 21<sup>st</sup> century is already one of significant change for global healthcare. The biomedical model of health and illness is a mechanistic view of medicine that focuses on the absence of disease or dysfunction (Lindau et al. 2003) and adopts a reductionist approach based on reducing illness and symptoms to a pathology (McKee & Rivard 2011, Wade & Halligan 2004). The introduction of the biopsychosocial model in 1977 endeavoured to facilitate a shift to a more patientcentred approach to medicine (Wade & Halligan 2004, Engel, G. 1977). The concept of patients being active participants at the centre of healthcare decision-making has been increasingly promoted in health interventions (Frydman 2009, Staley 2009, Swan 2009, INVOLVE 2007). This presents significant challenges for the clinician especially within insurance-based systems where case management processes may influence the range and extent of options available to clinicians.

The endorsement of the WHO's International Classification of Functioning, Disability and Health (ICF) framework in 2001 facilitated the global recognition of patients as key stakeholders in healthcare (WHO 2001). The WHO ICF reinforced the need for recognition of the importance of the individual's judgement of limitations in function and promoted the consideration of disability in a wider societal context (Jette 2006, WHO 2001). However, the implementation of the WHO ICF framework for musculoskeletal conditions is complex and multi-levelled especially in chronic conditions (Harding et al. 2010) and has resulted in the biomedical model remaining the dominant paradigm in orthopaedics.

#### The importance of patient reported outcome measures

The process of assessing change in healthcare status of an individual is complex due to interactions between self-identity, social functioning and impairment. However, despite the inherent difficulties, the measurement of change in health status is critical to improving quality; optimising patient satisfaction; increasing costeffectiveness of healthcare spending; facilitating research; and improving provider performance (Appleby & Devlin 2004).

Musculoskeletal medicine, in particular, has been identified as one of the fields of medicine where there has been a heavy bias towards the use of a biomedical model (Appleby & Devlin 2004). Historically, clinical trials have adopted clinician-assessed endpoints using standardised instruments with accepted psychometric properties. Traditionally, these endpoints have been biomedical measures of health status such as clinician-assessed musculoskeletal measures of impairment (Suk et al. 2005, Appleby & Devlin 2004) that have been developed with limited or no patient involvement (Wright, Rudicel & Feinstein 1994). This practice assumed that clinicians knew what guestions to pose to elucidate responses that reflected issues the patient themselves perceived to be of the greatest importance (Pollard, Johnston & Dixon 2007, Bayley et al. 1995, Ruta et al. 1994, Wright, Rudicel & Feinstein 1994). Although this assumption has previously been implicit in healthcare outcomes research, when it has been put to the test concordance between clinician and patient ratings of importance has been found to be highly variable (Pollard, Johnston & Dixon 2007, Carr et al. 2003, Hewlett 2003, Amadio 1993). For an outcome measure to be valid it should capture the patient's perceptions by reflecting the effect of a health condition on those aspects of a patient's life that they consider to be of importance (Appleby & Devlin 2004, Ruta et

al. 1994). This is in accordance with the recognition of the patient as a key stakeholder in healthcare (Department of Health 2005, Appleby & Devlin 2004) and a reflection of the WHO ICF framework (WHO 2001). Biomedical measures of health status are often unable to capture the perspective of what matters most to the individual patient (Haywood 2006) and often correlate poorly with patient reported outcomes (PRO) (Pollard, Johnston & Dixon 2007). Consequently, PROs are increasingly used to support claims of treatment efficacy (Haywood 2007, Bradley 2006) and are being adopted as the primary and co-primary endpoints in clinical trials within European regulatory frameworks (Breckenridge 2004, 2001). From a service delivery perspective, under the new Standard NHS Contract for Acute Services, providers in England have been required to report PROs from April 2009 (Department of Health 2009b).

Patients are increasingly being asked to describe their individual perceptions and experiences of health, illness and quality of life. PROs offer a way to incorporate the patient's individual perspective into the planning, implementation and evaluation of healthcare provision. Salmon et al. (2001) reviewed the patient perspective of recovery from hip and knee arthroplasty and found that clinician assumptions about recovery were often inaccurate. To date no one has reviewed the patient perspective of recovery following ACR. In spite of the increasing accessibility and use of PROs there is a paucity of research on the evaluation of PRO health status measures on clinical decision-making (Greenhalgh, Long & Flynn 2005). In the musculoskeletal arena the increased use of PROs and greater insight into patient experience might lead to improved patient outcomes but evidence of the impact of using PROs is limited (Dawson et al. 2010, Timmins 2008). Currently, most of the literature has focused on chronic disease or mental health management (Marshall, Haywood &

Fitzpatrick 2006) where communication and satisfaction with clinical decisions have been positively impacted by the use of PROs (Marshall, Haywood & Fitzpatrick 2005). The internet is now being seen as an important platform for PRO data collection (Jones, Snyder & Wu 2007) and dedicated web-sites have already been established to facilitate this process (Patient Reported Outcomes Measurement System, Unit of Health-Care Epidemiology).

## The emergence of online health communities

Health information-seeking behaviour is recognised as a key coping strategy in patient engagement with health problems (Lambert & Loiselle 2007). Whilst the medical profession still remains the most trusted source of health information for orthopaedic patients (Cutilli 2010) the internet is a growing source of supplemental information on health related issues (Kummervold et al. 2008, Rice 2006, Greenberg, D'Andrea & Lorence 2004, Shuyler & Knight 2003, Cline & Haynes 2001). The internet is increasingly being viewed as a vehicle for empowering people to become more involved in decisions regarding their health care (van Uden-Kraan et al. 2009, Powell & Clarke 2002). Individuals are often keen to be in contact with others with similar health conditions (Lambert & Loiselle 2007) and this has played an important role in the development of online health communities (OHCs) (Armstrong & Powell 2009).

OHCs experienced a rapid period of growth following the introduction of the world wide web in 1991 and the subsequent new technologies that provided opportunities for interaction (Frydman 2009). The percentage of the population who have used the internet for health information has risen in the UK from 37% in 2005 to 68% in 2007 (Dutton & Helsper 2007) and across Europe from 42% in 2005 to an

estimated 52% in 2007 (Kummervold et al. 2008). This growth is occurring across all ages with young women (15-25 years) having been found to be some of the most active internet health users (Kummervold et al. 2008). A key finding of a survey by Kummervold et al. (2008) was that the second generation of internet users were using the internet in a health context for more than just reading information. In particular, the authors found that as new dynamic and interactive sociable technologies such as Web 2.0 (Kamel Boulos & Wheeler 2007, Giustini 2006) became available there was a parallel increase in the communication channels amongst patients and, to a more limited extent between, patients and clinicians (Kummervold et al. 2008, Kamel Boulos & Wheeler 2007). This marked a significant change in health information-seeking behaviour and contributed to the growth of OHCs (Demiris 2006, Eysenbach et al. 2004).

The upsurge of OHCs provides opportunities for online health service users to influence their own and their peers' healthcare expectations, perspectives, decisions and ultimately outcomes. In this way OHCs are facilitating the emergence of a more patient-driven model of health care. There is now a transition from patients being the recipients of health information from clinicians to patients being collaborative partners in their healthcare decision-making. Clinicians are now engaging with patients who are more confident discussing management options as a result of their information seeking (Swan 2009) and who are supportive of shared decision-making (Mazur et al. 2005).

The increased use of the internet for health information gathering has not been mirrored by the assessment of the completeness, accuracy or timeliness of the information that is being gathered (Starman et al. 2010). In addition there is insufficient evidence of the influence that OHCs have on clinical outcomes or patient

empowerment (Demiris 2006, Eysenbach et al. 2004). In 2004 Eysenbach et al. published a systematic review of the evidence on the effects on health and social outcomes of computer based peer-to-peer communities and concluded that no robust evidence existed at that time. In the last five years research into OHCs has begun to catch up with the speed of development of the technology. Although not comprehensive, there is now increasing evidence to support participation in OHCs for the empowerment of patients especially in the areas of 'being better informed' and 'enhanced social well-being' (van Uden-Kraan et al. 2009, Donnelly, Shaw & van den Akker 2008, van Uden-Kraan et al. 2008, Demiris 2006). There is recognition that further research is needed in the use of the internet in healthcare. However, the majority of the calls for research in orthopaedic and musculoskeletal fields have focused on the evaluation of how the online consumer searches for health information on the internet and the quality and content of such information (Starman et al. 2010, Powell et al. 2005, Greenberg, D'Andrea & Lorence 2004, Shuyler & Knight 2003). There is a paucity of research looking at the interactions of OHC participation on expectations and outcomes. Because of the growing body of patients involving themselves with OHCs there is a need for further research to develop an understanding of the profile of the online health consumer and ultimately, whether and how OHCs might add value for patients, clinicians and researchers (Demiris 2006, Powell & Clarke 2002).

The KNEEguru is an OHC specifically for people with knee problems and currently has over 29,000 registered members. A published analysis of patient information about knee arthroscopy on the internet identified KNEEguru as one of only 16 websites to provide patient information that was of sufficient quality for the website to be recommended by orthopaedic surgeons to patients (Sambandam et al.

2007). The KNEEguru OHC is based around a dynamic bulletin board to which individuals over the age of 18 must register in order to allow interactivity. The bulletin board is an active OHC with an average of 407 new topics and 7125 new posts per month (Strover 2010).

#### The impact of patient expectations on physical activity

Mondloch et al. (2001: 174) state, "most clinicians would probably agree that what patients think will happen can influence what does happen over the clinical course". However, the knowledge of the relationship between patient expectations and outcomes is limited (Mannion et al. 2009, Janzen et al. 2006). It is only in the last decade that patient expectations have been identified as being important predictors of functional outcome and satisfaction in knee surgery populations (Noble et al. 2006, Mahomed et al. 2002). Consequently, the inclusion of patient expectations in the planning and subsequent evaluation of knee surgical interventions is a relatively new concept. Patients' expectations of knee surgery are multiple and encompass both symptom relief as well as improvements in physical functioning (Mancuso et al. 2001). These improvements in physical function are frequently linked to participation in sports and exercise activities with returning to sports and exercise activity being one of the main reasons given for individuals to elect to undergo knee surgery (Hambly 2006a, Hambly, Bobic et al. 2006). Brewer et al. (2007) identified that return to sport was one of the most frequent question themes posted on two internet message boards relating to knee problems. This focus on participation in sports and exercise activities is not surprising as the promotion of physical activity is now a major worldwide public health initiative (Haskell et al. 2007, Department of Health 2005).



Figure 1: The World Health Organisation's International Classification of Functioning, Disability and Health framework (World Health Organisation 2001)

## The relationship between the WHO ICF and physical activity

The WHO ICF framework stresses the importance of the interaction of the biological, social and personal factors in determining health status as shown in Figure 1 (World Health Organisation 2001). Activities and participation are two of the main domains within the WHO ICF. The WHO ICF framework defines activity as 'the execution of a task or action by an individual' and participation as 'involvement in a life situation' (Jette 2006, World Health Organisation 2001). In this context physical activity is inextricably linked to both activity and participation domains.

## The global burden of physical inactivity

Physical inactivity has been cited as being the biggest public health problem of the 21<sup>st</sup> century (Blair 2009) and in the UK there is a considerable public health burden due to physical inactivity (Weiler & Stamatakis 2010, Allender et al. 2007). Physical inactivity has been found to be directly responsible for 3% of disability adjusted life years lost in the UK in 2002 with an estimated direct cost to the NHS of £1.06 billion (Allender et al. 2007). A dose-response relationship has been established between physical activity and health and the promotion of physical activity is now a major public health initiative (Department of Health 2009a, Haskell et al. 2007, Department of Health 2005).

Physical inactivity is associated with negative health outcomes for all ages and is consequently being actively promoted throughout the lifespan within the NHS (Department of Health 2009a, Foster, Thompson & Harkin 2009, Sari 2009, Haskell et al. 2007, Department of Health 2005). The Department of Health's current 'Lets Get Moving' scheme provides a framework for the promotion of physical activity by primary care trusts and practice-based commissioners (Foster, Thompson & Harkin 2009).

The global burden of physical inactivity and associated policy changes encouraging participation in physical activity are impacting on participation and expectations of participation in sport and exercise activities. Sport England's Active People Survey for 2008/9 indicated increases in sports participation across both the 16-34 and the 35-54 age groups (Sport England 2009). This is a trend that is likely to continue with the increasing encouragement for the recognition of the health benefits of participation in physical activity (Department of Health 2009a, Allender, Cowburn & Foster 2006). The relationship between the stages in the life course and

perceptions and expectations regarding participation in physical activity is changing. The notion of the 'active aging exerciser' is now not only one that is more socially and culturally acceptable (Haskell et al. 2007) but it is also increasingly being perceived as an expectation as chronological age becomes increasingly irrelevant (Mason 2008). The collective effect of the recognition of the health burden of physical inactivity and the proactive promotion of physical activity in the UK are resulting in changes in healthcare needs that have been recognised in the 2006 NHS Musculoskeletal Services Framework (MSF) (Department of Health 2006).

## The global burden of osteoarthritis

The global burden of osteoarthritis (OA) is increasing (Khaltaev et al. 2003, World Health Organisation 2003) and it is expected to be the 4<sup>th</sup> leading cause of disability by 2020 (Woolf & Pfleger 2003). In the UK 1 million adults under the age of 45 have arthritis (Department of Health 2006). The prevalence of OA and rate of joint replacement in the UK has significantly increased between 1991 and 2006 with total knee arthroplasty (TKA) rising at the greatest rate (Culliford et al. 2010). The 2010 National Joint Registry Annual Report showed a 27% increase in the number of primary knee replacements performed in England and Wales compared to 2005/6 figures (National Joint Registry 2010, 2005). However, there has only been a small decrease in the mean age for TKA (Culliford et al. 2010) with an average age of 67.5 years (lower 25% quartile 62.9 years) for primary TKA in England and Wales in 2009/10 (National Joint Registry 2010) compared with 70 years (lower 25% quartile 64 years) in 2004/5 (National Joint Registry 2010). The proportion of individuals who are under 55 at the time of primary TKA has remained static at 6% (National Joint Registry 2010, 2005). In addition, the percentage of patients classified as fit and

healthy at the time of primary knee replacement has actually decreased from 20% in 2004/5 (National Joint Registry 2005) to 13% in 2009/10 (National Joint Registry 2010). This is highly relevant as injuries that have arisen from participation in sport and exercise are major risk factors for the development of OA. A substantial proportion of the overall OA population are individuals who sustain post-traumatic OA following participation in sport and exercise activities (Arthritis Research UK 2010a, Ratzlaff & Liang 2010, Zhang & Jordan 2008, Lohmander et al. 2007, Thelin, Holmberg & Thelin 2006, Conaghan 2002, Gelber et al. 2000). It has been estimated that one in 6 people engaged in the recommended amount of physical activity will be injured each year equating to 1.5 million musculoskeletal injuries per annum (Batt 2009). The knee is the most commonly injured site accounting for between 15-50% of all sports injuries (de Loes, Dahlstedt & Thomee 2000). There is a 50% increased risk of post-traumatic OA after patellar dislocation (Engebretsen et al. 2009), anterior cruciate ligament (ACL) tear (Lohmander et al. 2004) or meniscus tear (Lohmander et al. 2007). An individual who sustains these injuries is frequently considered to be "the young patient with an old knee" (Lohmander et al. 2007). Interestingly, the health benefits of an active lifestyle were considered more valuable than the potential risks associated with injuries by keen amateur sports participants in a recent market survey (Arthritis Research UK 2010b). These individuals are often not willing to relinquish participation in sports and exercise activities and tend to be proactive in seeking treatment options that have the potential to meet their higher functional treatment options frequently include surgical demands. These interventions. Improvement in physical functioning is one of the main expectations of individuals undergoing knee surgery and is frequently linked to participation in sport and exercise activities (Mancuso et al. 2001). Clinicians are increasingly confronted

with patients who have the desire to continue participation in sports and exercise activities after knee surgery (Naal et al. 2007, Seyler et al. 2006, Mancuso et al. 2001). This concurs with current public health policy promoting active ageing (Department of Health 2010). There is consequently an increasing demand from these 'active aging exercisers' for musculoskeletal treatment options that will meet their needs and help to maintain their ability to participate in physical activity.

Activity level scales provide a measure of 'what patients are doing'. Consequently, the evaluation of activity levels is not only pertinent to individual patients in terms of expectations of function but also to clinicians and researchers as activity limitation and participation restriction are key elements of the ICF framework. However, the linking of the adoption of a disability model such as the ICF to the assessment of sports and exercise participation is currently in its infancy (Parsons et al. 2008, Snyder et al. 2008, Valovich McLeod et al. 2008).

# Why are articular cartilage defects a problem?

A person-orientated definition of OA is "a painful, functionally limiting joint condition that impairs quality of life" (Conaghan 2010). Focal cartilage defects in the knee are a problem as they have been shown to impair quality of life as much as severe OA (Heir et al. 2010). The aetiology of focal cartilage defects is frequently a result of a single impact or repeated micro trauma, often linked to sports and exercise. There is evidence to indicate that focal articular cartilage defects is still largely unknown (Safran & Seiber 2010, Wluka et al. 2009, Davies-Tuck et al. 2008, Wang, Y. et al. 2006, Smith, G. D., Knutsen & Richardson 2005, Messner & Maletius 1996,

Drongowski, Coran & Wojtys 1994). In 1743 William Hunter reported that "an ulcerated cartilage is universally allowed to be a very troublesome disease and that, when destroyed, it is never recovered" (Hunter 1743:516). This still holds true as articular cartilage has a low intrinsic capacity for repair and there is increasing evidence that senescent chondrocytes accumulate with age (Loeser 2009, Martin, J. et al. 2004, Martin, J. & Buckwalter 2003). Until the 1980's treatment of chondral defects could be considered to be predominantly palliative. There were limited surgical options and management mainly focused on the patient's acceptance of early arthrosis and the need for modification of activities with the prospect of TKA in later years. The treatment of articular cartilage damage therefore posed a significant challenge for the medical profession, especially in the middle-aged knee (Cooper 2003).

The treatment of articular cartilage damage has undergone a rapid and exciting evolution in recent years, most notably in the field of advanced cell-based orthobiologic technologies. Articular cartilage repair (ACR) is an umbrella grouping for a range of surgical interventions developed to address the problem of articular cartilage defects. The aim of ACR is to restore the joint surface with a durable tissue that accepts functional loading and has the potential to prevent or significantly delay the requirement for knee joint replacement (Davies-Tuck et al. 2008). Articular cartilage defects are an increasing social problem (Widuchowski et al. 2006). In terms of the scale of the problem, there were 30,000 knee arthroscopies performed in England in 2004 (Hawker et al. 2008). The incidence of articular cartilage defects on knee arthroscopy has been reported as being between 11 and 66% (Engen, Engebretsen & Aroen 2010, Widuchowski, Widuchowski & Trzaska 2007, Aroen et al. 2004, Hjelle et al. 2002, Curl, Krome & Gordon 1997) of which 4-11% may be

suitable for ACR (Aroen et al. 2004, Curl, Krome & Gordon 1997). In 2005 it was estimated that 10,000 patients each year might warrant ACR in the UK (National Institute for Health and Clinical Excellence 2005). ACR reduces absenteeism and disability (Lindahl 2001), has an acceptable cost per additional quality-adjusted life year (Minas 1998) and is potentially cost-effective as it is more likely to prevent osteoarthritis in the longer term (Clar et al. 2005). One of the more promising tissue engineered therapies is autologous chondrocyte implantation (ACI) (Brittberg et al. 1994, Peterson, Menche & Grande 1984). The results of the first human trial using ACI were published in 1994 (Brittberg et al. 1994) and good clinical results have now been shown to be maintained even 10 to 20 years after implantation (Peterson et al. 2010). The general research about treatment of chondral lesions was found to have increased by 11% from 2002 to 2007 (Benthien, Schwaninger & Behrens 2011). The level of interest in ACR is exemplified by the fact that Peterson et al.'s study reporting the 2 to 9 year outcome data from ACI (Peterson et al. 2000) in is already the 51<sup>st</sup> most cited paper in the orthopaedic surgery literature (Kelly et al. 2010).

## Who are the people who have ACR?

Over the last few decades patients have become more demanding and now have higher expectations of continued function, mobility and activity levels (Mason 2008). Coverage of new orthobiologic technologies in the popular press and on the internet has led to a greater awareness of the availability of these procedures and consequently patient-demand is on the rise. This is exemplified by the coverage of a new cell-based technique in the UK's national daily press in 2006 with the headline "woman has first 'grow your own knee' transplant" and the interviewee saying she was "hoping to get back to a sporting life again" (Hope 2006). Initial pilot work by the author has identified that reduction in pain; participation in sports and exercise activities; and the prevention or delay of knee replacement are the main reasons for individuals to choose to have ACR surgery (Hambly 2008, 2006a, 2005). Individuals who undergo ACR tend to be under 55 years of age who want to be active but are not necessarily competitive sports participants and have symptoms that are impacting on their function and ability to exercise that are impairing their quality of life. This is highly relevant in the context of the WHO ICF.

## ACR rehabilitation and postoperative care

In the first published clinical study the ACI rehabilitation methodology was very limited and the outcome measures were solely clinician-reported (Brittberg et al. 1994). Rehabilitation has been identified as a key factor in determining clinical outcome following ACR (Steadman et al. 2003, Peterson et al. 2002, Peterson et al. 2000), yet in the 9 years from 1994 to 2003 only 3 papers were published that focused on ACI rehabilitation (Bailey et al. 2003, Blackburn 2003, Gillogly, Voight & Blackburn 1998). Although detailed regarding the practical content of the rehabilitation these papers were descriptive and did not thoroughly review the clinical evidence base. Rehabilitation was identified within academic and scientific communities as a priority area for strengthening methodological quality within ACR studies (Jakobsen, Engebretsen & Slauterbeck 2005).

## Patient reported outcomes and activity scales in ACR

There is currently no consensus regarding a gold standard PRO for ACR and a disease-specific PRO has not been developed for ACR. Consequently, kneespecific PROs are frequently used to assess ACR outcome. These PROs often ask about difficulty in functional activities and symptoms but they do not explicitly question the importance of each item to the patient. Tanner et al. (2007) found that in terms of general knee instruments the International Knee Documentation Committee (IKDC) Standard Evaluation Form and the Knee Injury and Osteoarthritis Outcome Score (KOOS) scored favorably for ACL, meniscal and osteoarthritic populations (Tanner et al. 2007). This raises the issue of whether current knee-specific PROs adequately serve ACR patients.

In the last decade, seven different activity level scales have been identified as being potentially applicable to outcome studies in sports medicine (Marx 2003, Weitzel & Richmond 2002, Marx et al. 2001). The Tegner activity scale (TAS) was developed in 1984 as a score to assess activity level (Tegner 1985). The TAS scores a person's activity level between 0 and 10 where 0 is 'on sick leave/disability due to knee problems' and 10 is 'participation in competitive sports such as soccer at a national or international elite level'. The TAS has been cited as being the most widely used activity scoring system for patients with knee disorders (Briggs et al. 2006, Halasi et al. 2004). The TAS has a high clinical utility (Suk et al. 2005) and has demonstrated acceptable psychometric parameters for a range of knee disorders (Briggs, K. K. et al. 2009, Smith, T. O. et al. 2008, Briggs et al. 2006, Gobbi & Francisco 2006, Paxton et al. 2003). The TAS is frequently used to assess activity levels its use within ACR but the use of the TAS across ACR populations has not been evaluated to date.

Exploring the expectations and experiences of patients will provide important information to support the future application and implementation of PROs (Haywood 2006) not only for ACR but potentially across a variety of different healthcare settings. The aim of this programme of research was to evaluate the patient perspective of outcome measurement in articular cartilage repair of the knee.

# **OVERVIEW OF METHODOLOGY AND RESULTS**

The aim of this programme of research was to evaluate the patient perspective of outcome measurement in articular cartilage repair of the knee. The specific objectives were:

i. To establish and evaluate the evidence based for current ACI postoperative practice.

ii. To identify which instrument as between the KOOS and the IKDC subjective knee form measures symptoms and disabilities most important to postoperative ACR patients.

iii. To identify which instrument as between the KOOS and the IKDC subjective knee form captures symptoms and disabilities most important to patients who have undergone initial anterior cruciate ligament reconstruction (ACLR).

iv. To review the use of the TAS for ACR of the knee.

v. To establish a postoperative profile of users of an OHC who have undergone ACR of the knee and to compare this profile with individuals from the same OHC who have undergone initial ACLR.

A range of quantitative and qualitative methodological approaches and statistical analyses were used by the researcher within this body of work to achieve these objectives. A web-based mode of survey delivery was utilised for this programme of research within an OHC specifically for people with knee problems. Study details were submitted to the London Metropolitan University Research Office for ethical approval. The purpose and aims of the programme of research and the role of the participants were clearly communicated as per the then current guidelines for online research (British Psychological Society 2007, Ess 2002). An invitation to participate was posted on the KNEEguru Bulletin Board (Appendix 10a) that included

a URL link to access the opening page of the online survey (Appendix 10b). A participant information sheet provided further details of the study and contact information for the researcher (Appendix 11). Self-registration to the study and self-submission of the survey was taken as further consent for participation (Stevens, van den Akker-Scheek & van Horn, 2005). Data was only saved to a secure server if participants chose to submit the survey and stored data was kept anonymous through the use of unique response identification numbers.

### Pilot work and research question generation

In 2003 the researcher conducted a comparative analysis of rehabilitative guidelines at 11 international ACR centres and identified large variations in clinical practice. Subsequent inductive pilot work evaluated patients' (Hambly 2006a, 2005) and orthopaedic surgeons' (Hambly 2006b) perspectives of the rehabilitation process using a mixed methods approach incorporating grounded theory and content analysis. A mixed methods inductive approach was selected by the researcher to facilitate the development of concepts that could help in the understanding of patient experiences of the ACR rehabilitation process (O'Cathain, Murphy & Nicholl 2007, Pope & Mays 1995). Thematic analysis of the data (Ryan & Bernard 2003) identified issues pertinent to patients' experiences of undergoing ACR. The studies highlighted the importance of a return to activity for ACR patients and the disparity in postoperative care across centres. This work was significant as it highlighted the need to review ACI rehabilitation and resulted in the publication of the first evaluation of the evidence base for postoperative ACI care (Hambly, Bobic et al. 2006). This paper has already been used as the methodological basis for ACI rehabilitation including the Royal National Orthopaedic Hospital (Royal National Orthopaedic

Hospital 2009) as well as an increasing number of published clinical studies where it is receiving important citations as shown in Appendix 7.

Two key research questions emerged from the early exploratory work: what are the symptoms and disabilities most important to ACR patients and are current PRO measures capturing this information? To explore these research questions, two commonly used knee-specific PRO measures (KOOS and IKDC) were evaluated for item importance to ACR patients from an OHC using a clinical impact methodology (Juniper et al. 1997, Guyatt, Bombardier & Tugwell 1986).

### Study design and sampling

A clinical impact method was selected over a psychometric method, as the researcher was interested in the level of importance that patients give items that are a problem rather than solely the frequency with which they experienced a problem (Juniper et al. 1997). An observational cross-sectional study design was used by the researcher as this was a novel research area and the strengths of cross-sectional studies include baseline assessment and hypothesis generation (Levin 2006). A cross-sectional study design can be effectively used in inductive methodologies to identify associations and it has been proposed that results from observational studies in orthopaedics may be closer to those seen in routine clinical practice (Audige, Hanson & Kopjar 2006). However, there are notable limitations associated with the adoption of a cross-sectional study design (Levin 2006, Mann 2003).

It was not possible to obtain a list of all members of this OHC who had undergone either ACR or ACLR procedures and this precludes the opportunity for random sampling within these populations (Andrews, Nonnecke & Preece 2003).

Consequently, the sampling methodology for experimental studies within this series of works was non-probability sampling utilising a self-selected survey in which an invitation was issued to participate. This web-based sampling method has strengths and weaknesses. It is low cost, convenient and provides access to large groups of participants (Couper 2000) but it also potentially incorporates selection bias (Heiervang & Goodman 2011). For example, a higher than expected frequency of TAS level 0 (sick leave or disability pension because of knee problems) was found after ACR (Appendix 5). This could potentially be explained by selection bias as those people with more time, such as when off work due to knee problems, may be more likely to respond to an invitation to participate in a web-based survey than those individuals who have returned to work. In order to evaluate any bias a comparison with non-participants would be needed but in a web-based environment this is not testable. There is an indication that non-response is a particular problem in web-based surveys (Cranford et al. 2008, Manfreda, Batagelj & Vehovar 2002). Those individuals who do respond may be the individuals who have strong views (positive or negative) and, again, this may influence the results (Levin 2006). However, on a positive point it has been proposed that there is less coercion in webbased surveys (Pequegnat et al. 2007). A probability-based sampling approach (Couper 2000) would provide information on the sources of non-response. However, even if these probability-based sampling approaches were adopted in future research the sample would still be restricted to those individuals with internet access (Andrews, Nonnecke & Preece 2003). The sample for these studies was restricted to members of the KNEEguru online health community and consequently, the results can only be generalised to that population. However, this work is significant as it

underpins the justification for a wider application of the methodology and transferability across different health care systems.

The scientific validity of using OHCs in clinical research could be severely hindered by the fact that individuals who participate in online surveys are different to the wider general population (Andrews, Nonnecke & Preece 2003). However, as internet access increases these individuals comprise a growth sector of the general population and therefore warrant attention in their own right. Internet usage currently stands at 82.5% of the UK population and it is predicted that one third of the world's population will be online by the end of 2010 (British Broadcasting Corporation 2010, International Telecommunications Union 2010). Therefore, individuals who do not use the internet are already in a minority in the UK.

# Publication and dissemination of key findings

Taken collectively the two PROs evaluated within this work (IKDC and KOOS) both performed well in capturing items that were both experienced and rated as important by the two patient groups. Overall, functional problems tended to be considered more important to these patient groups than symptoms. The emergent pattern was one of function in sports and recreation activities being important for people who had undergone ACR (Hambly & Griva 2008), more than an ACLR cohort from the same OHC knee population (Hambly & Griva 2010). The findings from these studies added new knowledge to the field as evidenced by the increasing number of citations to the 2008 study as shown in Appendix 8. In response to the original research questions the Hambly and Griva papers (2008, 2010) opened areas for further exploration (Badley 2009). This led to the formulation of an additional

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research question: what is the postoperative physical activity profile of this OHC ACR population?

The TAS is frequently used to assess physical activity level within ACR studies but this use had not previously been evaluated. This raised the issue of selection and use of measurements of physical activity levels for ACR studies. The researcher undertook the first systematic review of the TAS for ACR. The search strategy utilised the principles of systematic review (Glasziou et al. 2001) and was designed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (Moher et al. 2009). The systematic review raised important methodological issues relating to the use and reporting of the TAS in ACR populations (Hambly 2010b). The key findings from this review were utilised to inform the reporting of cross-sectional TAS data for the ACR and ACLR groups from this OHC (Hambly 2010a). The postoperative physical activity profile of this ACR population was one where activity levels increased with postoperative time but remained lower than expected compared with current clinical and normative data. This work sheds new light on how individuals who undergo ACR interact with the postoperative rehabilitation process and raised pertinent issues for the formulation of return to sports and exercise expectations.

The key findings of the programme of research were disseminated back to the OHC participants via the KNEEguru website in a variety of modes. The results were published online by the researcher in a patient-centred report format (Appendix 12a). Participants were kept updated on the progress of the research programme through a BLOG (Appendix 12b) and through news box updates on the KNEEguru Bulletin Board (Appendix 12c). On publication, links to the abstract of the study was provided and the Webmaster of the OHC produced a review of the article (Appendix 12d).

#### DISCUSSION

This research programme explored the patient perspective of outcome through the identification, evaluation and analysis of factors that are important to people who have undergone ACR. This critical appraisal provides an overview of a compilation of five published research papers that collectively make an original and significant contribution to the patients' perspective of outcome measurement after ACR of the knee. The work represents the coherent evolution and development of the author's research in this field over a period of 8 years.

The first decade of the 21<sup>st</sup> century has been one of change in healthcare decision-making and management aimed at reducing global health burden. Health policy changes have included a focus on addressing the global burdens of physical inactivity and osteoarthritis. The endorsement of the WHO ICF framework (World Health Organisation 2001) reinforced the importance of the individual's judgement of limitations and function (Jette 2006). In musculoskeletal medicine, the impact of patient expectations on functional outcome and satisfaction has been recognised (Noble et al. 2006, Mahomed et al. 2002) and the utilisation of PROs in clinical practice has increased (Department of Health 2009b). Concurrently, health policy changes encouraging participation in physical activity (Department of Health 2010. 2009a, Haskell et al. 2007, Department of Health 2006, 2005) have coincided with rapid advances in orthobiologic technologies aimed at restoring functional articular joint surfaces. The cumulative result has been the increasing popularity and demand for ACR in the knee from both providers and customers despite the evidence base remaining at a generally low methodological level (Benthien, Schwaninger & Behrens 2011, Jakobsen, Engebretsen & Slauterbeck 2005). The increased reporting of PROs as a requirement of service delivery in England (Department of
Health 2009b) could be viewed as a move towards a more biopsychosocial and patient-centred approach in line with the WHO ICF framework. However, for individuals to be true partners in their care as proposed within the latest Government white paper 'Healthy Lives, Healthy People' (Department of Health 2010) any PRO that is used would need to represent those issues that the patient perceives to be of the greatest importance. At present PROs are predominantly being used to support the biomedical model especially where there is a single postoperative outcome endpoint. Using PROs in this way continues to emphasise the evaluation of treatment effectiveness whilst precluding the opportunity for patients to fully inform clinicians about their experiences across the full extent of the perioperative period.

The combined works of Hambly have explored what is important to the patient after ACR and have questioned whether the PROs are capturing this information. The researcher's findings have had a significant impact on orthopaedic research and clinical practice as evidenced by the citations for the work to date (Appendices 7 and 8). Issues that are important to patients are now being considered in broader orthopaedic populations and researchers are already drawing on Hambly's work with knee surgery populations and the methodology of rating item importance (Van Assche et al. 2010, Martin, R. et al. 2009).

A key finding from this programme of research was that the IKDC subjective knee form and the KOOS contained a large number of items that were experienced by, and were important to both an ACR and an ACLR population (Appendices 2 and 3). However, the clinical impact profile of individual items varied and differences in individual items were not always evident from either total or subscale ratings. Eleven items demonstrated significant differences in importance rating between males and females in the ACR population (Hambly & Griva 2008). Items related to symptoms

were widely experienced but were not rated overall as being as important to patients as items related to functional activities, especially those related to function in sport and recreation. Pertinently, for the ACR population several items associated with participation in sports and exercise activities demonstrated a higher clinical impact than knee pain (Hambly & Griva 2008). This is the first time that variation in ratings of prevalence and importance of items within these commonly used knee-specific PROs has been evaluated for an ACR population.

The researcher's results are intriguing when considered in terms of the WHO ICF body function, activities and participation domains (Figure 1). Overall, for this ACR cohort items related to the ICF body functions domain were frequently experienced but tended to have the lowest clinical impact (Appendix 2). The exception was 'knee is painful' as this was frequently experienced and rated high in importance. The items extracted from the KOOS and IKDC subjective knee form relating to the ICF activities and participation domains generally had a high clinical impact (Appendix 2). The TAS profile of the ACR population was one where levels increased with postoperative time but remained lower than expected compared with published clinical and normative data (Appendix 5). This is pertinent as the TAS is linked to the activities and participation domains of the functioning and disability part of the ICF (Tengbin & Hartley 2008). Activities and participation were important to this ACR population but this was not reflected in TAS outcomes.

Current recommendations for the reporting of ACR studies recommend a minimum duration of follow-up of twenty-four months (Jakobsen, Engebretsen & Slauterbeck 2005). The guidance on using patient reported outcome measures in the NHS in England advises the use of a preoperative questionnaire and a single followup postoperative guestionnaire (Department of Health 2009b). This practice

assumes that any change between the two time points will be linear and focuses purely on the end result of the intervention rather than the process of getting to the endpoint.

## Patients want to know what to expect

A recent study that looked at changes in patient concerns following TKA found that 'receiving appropriate information regarding, what to expect with rehabilitation following surgery' was rated of high importance by patients and this was maintained across the first 6 postoperative weeks (Rastogi, Chesworth & Davis 2008). This is a concern that is mirrored in the ACR population within this research programme. A typical post on the KNEEguru OHC is "*I guess what I'm asking is what should those of us that are only a few days/weeks out [from knee surgery] have to expect?*" ACR has a lengthy rehabilitation period (Hambly, Van Assche et al. 2006) and an improved understanding of the patient perspective of the recovery process may help in managing patient expectations following ACR surgery.

It is generally acknowledged that patient expectations have the potential to impact on functional outcome and satisfaction (Noble et al. 2006, Mahomed et al. 2002, Mondloch, Cole & Frank 2001). Consequently, how individuals formulate their expectations is extremely pertinent to healthcare decision-making and management. Expectations are multi-dimensional (Venkataramanan et al. 2006, Mancuso et al. 2001); can be influenced by conditioning, verbal persuasion and observational learning factors (Stewart-Williams 2004);, and exhibit complex interactions with selfefficacy (Thomee et al. 2007) and clinical outcomes (Engel, C. et al. 2004). Theories of health expectations are limited but recently Janzen et al. (2006) proposed a model for health expectation development based on a cyclical process that incorporated

prior and subsequent behaviours and attitudes (Janzen et al. 2006). This differed from earlier models of expectations (Olson, J., Roese & Zanna 1996, Thompson & Sunol 1995) in that it focused on the process of expectation development rather than the outcomes of the process (Janzen et al. 2006). This is highly relevant, as OHCs have provided new cognitive learning opportunities with the potential to influence health expectation development.

## Future research

The publication of the author's current concepts paper on ACI postoperative care (Appendix 1) established an evidence baseline that has already been used as the foundation to develop 'accelerated' ACI rehabilitation programmes (Ebert et al. 2010, Wondrasch et al. 2009, Ebert et al. 2008). ACI rehabilitation guidance and practice has progressed since the author conducted the first published comparative analysis in 2003 and it is an appropriate time for an up to date review of current practice. The original review did not grade the evidence to support rehabilitative practice and this should be addressed in any contemporary review. It is proposed that the level of evidence of individual studies be graded using the Oxford Centre for Evidence-Based Medicine's levels of evidence (Phillips et al. 2009). The overall strength of the evidence supporting rehabilitative guidelines generated within the review can be evaluated according to the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) (Guyatt et al. 2008) as well as the Strength Of Recommendation Taxonomy (SORT) to provide a more patient-centred approach (Ebell et al. 2004).

The collective works of Hambly have indicated that ACR patients are willing to express their views and that they are prepared to do so using web-based tools. The

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studies within this research programme were of a cross-sectional design and only covered postoperative time frames. This research was important to identify potential factors that may be associated with expectations of recovery and to evaluate the viability of the methodology. This approach provided a snapshot of the population but it was not able to identify cause-effect relationships or when changes occur. The literature indicates an incomplete understanding of the relationship between expectations and outcomes. This research has indicated that participation in sports and exercise is one of the main reasons why individuals elect to undergo ACR yet a large percentage of these individuals do not return to sports. It was not able to identify when any changes in expectation or goals occurred or why.

This research programme has provided the groundwork necessary to enable the modelling of recovery following ACR from the patient perspective in future research. The methodology for data collection has been shown to be viable and future research should look at establishing whether the prevalence of symptoms and disabilities changes with time and/or whether the importance of symptoms and disabilities experienced by the individual changes with postoperative time. Modelling of early recovery following ACR and the identification of patterns of recovery and predictive variables would enable the production of typical recovery curves. This could be influential in the establishment of expectations for the clinician and the patient as well as the earlier identification of 'at risk' patients with either too high or too low rates. The evaluation of causal relationships between preoperative expectations and return to sports and exercise activities can be used to inform clinical practice specifically in the areas of intervention, education and management of expectations.

A small number of data points has been identified as a limitation of using paper-based PRO data collection in linear modelling in orthopaedic populations (Kennedy, Stratford et al. 2006). Electronic and web-based technologies allow for the assessment of multiple data points that provide the opportunity for more detailed linear modelling across the recovery process. Novel technologies and software packages are now available that meet clinician needs and are increasingly affordable making electronic and web-based diaries viable for clinical and research purposes (Broderick 2008, Piasecki et al. 2007). Excellent agreement has been found in PRO scores between paper, touch and web-based modes of questionnaire delivery for five instruments in an orthopaedic population (Shervin et al. 2011). In addition, in an older orthopaedic population (60.8 years mean age) patient compliance was found to be far superior for electronic reported outcomes using Palm technology when compared to reported compliance for paper reporting (Tippett et al. 2010).

The researcher proposes a prospective observational study using a repeated measures design to examine recovery during the first 24 months following ACR surgery using preoperative status as the baseline. In this way the researcher can evaluate the process and the natural history of recovery after ACR and return to sports and exercise can be appraised using a cohort design and hierarchical linear modelling. Hierarchical linear modelling has the benefit of not requiring an equal number of data points and the timing of observations need not be the same across all participants (Halket et al. 2010, Kennedy, Stratford et al. 2006). The sample size will need to be large enough to be sufficiently powered to assess variables such as age, gender and preoperative baseline function and a multi-centre study design would therefore be advantageous. Electronic data collection systems are already available, such as the SOCRATES<sup>™</sup> orthopaedics outcomes software that is

currently in use in 18 countries (SOCRATES 2010). There is no published research on how patient concerns and expectations change during the early phase of postoperative rehabilitation following ACR. Consequently, an area of focus in subsequent research will be establishing patterns of change for items that were identified in the current research programme to be both experienced and important to ACR patients as demonstrated by a high frequency importance product (FIP) (Hambly & Griva 2008). The evaluation of TAS profiles at varying postoperative times (Appendix 5) indicates that there may be different processes occurring during recovery between these ACR and ACLR populations. Clinicians and researchers continue to support outcomes over process in ACR interventions and the impact of the process on the outcome has not been evaluated. The on-going or more frequent assessment of PROs during the rehabilitation process is likely to provide information that is not available from a traditional pre to postoperative analysis (Csikszentmihalyi & Larson 1987). This additional information could provide insights into the patient\* experience of the recovery process that could aid rehabilitation planning, implementation and evaluation. The timing of delivery of participation information and education within ACR postoperative recovery may be contributing factors implicated in return to sports and exercise activities. In a recent study of a TKA population patient concerns relating to the participation domain of the ICF were the only ones to increase through the first six weeks after surgery (Rastogi, Chesworth & Davis 2008). The authors concluded that patients think about their return to participation early in the recovery process and postulated that the differences they found in importance ratings supported the differentiation of the ICF activity and participation domains (Rastogi, Chesworth & Davis 2008). In this study data was collected from a TKA population so it is not known whether ACR patients will have a similar profile.

However, patients with focal cartilage lesions have been shown to have problems with pain and functional impairment to the same extent as those individuals who are TKA candidates (Heir et al. 2010) so they may exhibit similar profiles. By modelling perioperative change in the patient's perspective of recovery it may be possible for the researcher to establish critical time points for changes that impact upon endpoint outcomes. In particular, modelling an ACR population may identify single or multiple time points where a preoperative intention to return to sport changes and results in an eventual non-return to sport despite having a good clinical outcome. This will enable healthcare professionals to improve the management of patient expectations and provide opportunities for interventions to increase participation in sports and exercise for the health benefits of physical activity. However, it should be recognised that not all people who undergo ACR will either want or be able to return to sports and exercise activities after their surgery. Consideration should be given to establishing ways in which these individuals can integrate sufficient physical activity into their daily lives to help to counteract any potential negative health impact resultant from physical inactivity following ACR.

The works of Hambly have utilised a patient self-reporting methodology. In hip and knee arthroplasty populations a different pattern of recovery and variation in the predictors of change were found between self-report and performance measures (Kennedy, Hanna et al. 2006). Self-reported health status outcomes do not correlate well with performance measures within arthroplasty populations (Kennedy, Hanna et al. 2006, Maly, Costigan & Olney 2006, Walker, D. J. et al. 2002). It is not currently known whether a similar relationship exists within ACR populations and this is an area that requires further research.

## CONCLUSIONS

The combined works of Hambly have explored the patient perspective after ACR using web-based tools to evaluate what is important to the patient. The PRO measures evaluated within this programme captured symptoms and disabilities that were important to ACR patients and identified that function in sports and recreation activities were important for people who have undergone ACR. However, the postoperative physical activity profile of this ACR population was one where activity levels increased with time but remained lower than expected compared with current clinical and normative data. This work has raised pertinent issues for the formulation of return to sport and exercise expectations.

The theoretical contribution of this programme of research is in the advancement of the understanding of the patient perspective of outcome measurement in ACR of the knee. The body of work makes a significant contribution to theory development in two dimensions – utility and originality. From a scientific utility perspective the works have established the viability of capturing the views of patients for research purposes using web-based tools. This programme of research has presented a different way of understanding the phenomenon of return to sport and exercise activity after ACR. The empirical data gained is original in its identification of factors and mediating variables that have the potential to transform the way a patient's involvement in an OHC after ACR is viewed. At the start of this research programme current thinking on the use of PROs in ACR was one where the frequency of experience of items was paramount. This research programme has changed how PROs in ACR can be viewed by recognising and enhancing the significance of the importance attributed to items when they are experienced. This new way of viewing PROs in ACR is highly relevant in relation to patient

expectations and to the greater understanding of the growing global burdens of osteo arthritis and physical inactivity.

The evaluation of the patient perspective of outcome measurement in ACR of the knee within this programme of research has provided important information to support the future application and implementation of PROs across a variety of healthcare settings. The collective works of Hambly have indicated that ACR patients are willing to express their views and that they are prepared to do so using webbased tools. The findings have already had an impact on orthopaedic research and clinical practice. Issues that are important to patients are now being considered in broader orthopaedic populations and researchers are already drawing on Hambly's work with knee surgery populations and the methodology of rating item importance.

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# APPENDICES

# APPENDIX 1: Paper I – Autologous chondrocyte implantation postoperative care and rehabilitation: science and practice

# Autologous Chondrocyte Implantation Postoperative Care and Rehabilitation

## **Science and Practice**

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Autologous chondrocyte implantation is an advanced, cell-based orthobiological technology used for the treatment of chondral defects of the knee. It has been in clinical use since 1987 and has been performed on 12 000 patients internationally; but despite having been in clinical use for more than 15 years, the evidence base for rehabilitation after autologous chondrocyte implantation is notably deficient. The authors review current clinical practice and present an overview of the principles behind autologous chondrocyte implantation rehabilitation practices. They examine the main rehabilitation components and discuss their practical applications within the overall treatment program, with the aim of facilitating the formulation of appropriate, individualized patient rehabilitation protocols for autologous chondrocyte implantation.

Keywords: rehabilitation; cartilage repair; autologous chondrocyte implantation (ACI); knee; patellofemoral; tibiofemoral

Intact articular surfaces are necessary for adequate joint function, as they enable smooth movement and protect the joint against wear by reducing the coefficient of friction and by attenuating peaks of stress. However, damaged articular cartilage has a limited potential for self-repair, and restoration of an adequate articulating surface remains a formidable challenge. Controversy still exists as to whether microfracture, autologous osteochondral grafting, or cultured autologous chondrocyte implantation (ACI) is the best repair technique and to which lesion each should be applied. Numerous attempts to repair damaged articular cartilage have been met with similar problems: inability to produce hyaline cartilage, poor integration with the surrounding cartilage, and gradual deterioration of the repair tissue.<sup>224,187</sup>

Autologous chondrocyte implantation is an advanced, cell-based orthobiological technology used for the treatment of chondral defects of the knee. This first orthopaedic tissue-engineered procedure has been in clinical use since

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The American Journal of Sports Medicine, Vol. 34, No. 6 DOI: 10.1177/0363546505281918 © 2006 American Orthopaedic Society for Sports Medicine 1987 and has been performed on more than 12 000 patients internationally. It has demonstrated significant and durable benefits for patients in terms of diminished pain and improved function.<sup>1,23,113,114</sup> Autologous chondrocyte implantation has always been, and continues to be, very strictly regulated; today it is the most widely researched clinical cartilage repair technique. Despite the fact that ACI has been in clinical use for more than 15 years, the evidence base for ACI rehabilitation is notably deficient. Consequently, to date, guidance for ACI rehabilitation has been predominantly based on a combination of expert opinion, animal studies, basic science, and clinical biomechanics. The objective of this article is to provide an overview of the current understanding, issues, and areas of debate with regard to ACI rehabilitation.

### PROCEDURE AND VARIATIONS OF ACI

The classic autologous chondrocyte transplantation (ACT) was described by Brittberg et al<sup>22</sup> as the first generation of a cell transplantation technique for cartilage repair, based on the implantation of a suspension of cultured autologous chondrocytes beneath a sealed periosteal cover. The technique is characterized by the combination of 2 chondrogenic factors: the implanted suspension of chondrocytes and the cambium cells of the periosteum.<sup>24</sup> The surgical steps include arthrotomy, preparing the defect, periosteal harvest, suturing

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the periosteum over the defect, testing for water-tightness, application of fibrin glue sealant, chondrocyte implantation, wound closure, and rehabilitation.<sup>100</sup> This procedure has certain disadvantages, including the potential leakage of chondrocytes from defects, the dedifferentiation of a cellular phenotype (because the cells are grown in monolayer before implantation), the uneven distribution of cells, and the risk of periosteal complications.<sup>24,87,88</sup> Early problems include periosteal graft detachment and delamination as well as late periosteal hypertrophy.<sup>114</sup>

The second generation of ACI includes the use of a bilayer collagen membrane instead of the periosteal flap. These purpose-designed biomaterials are sutured over the prepared cartilage defect, and the cell suspension is injected underneath. The use of a collagen membrane simplifies the surgical procedure and reduces the number of the incisions to 1, thus reducing the overall surgical morbidity. Furthermore, the complication rates of periosteal hypertrophy may be reduced.<sup>54</sup>

Further technological advances have led to the third generation of ACI, which uses biomaterials seeded with chondrocytes as carriers and scaffolds for cell growth. This composite "all-in-one" tissue-engineered approach combines cultured chondrocytes with 3-dimensional biocompatible scaffolds for the purpose of generating new functional articular tissue. The 3-dimensional scaffolds have been shown to contain the chondrocytes in the defect area and to support the maintenance of a chondrocyte-differentiated phenotype.<sup>52,53,128</sup> After debridement of the defect, the biomaterials with seeded cells are trimmed to exactly match the defect size and are implanted without the use of a periosteal cover or fixing stitches. In most techniques, only fibrin glue is used for the fixation of the graft. Because there is no requirement for periosteal harvest or stitching the cover over the recipient site, a mini-arthrotomy technique can be used. Although the lack of firm fixation is a concern, Marlovits and collaborators<sup>89</sup> reported that the implantation and fixation of a cell-scaffold construct (matrix-induced ACI [MACI]) in a deep cartilage defect of the femoral condyle with fibrin glue and with no further surgical fixation lead to a high attachment rate 34.7 days after the implantation, as determined with high-resolution MRL<sup>84</sup>

When planning to restore the articular defect, the surgeon must diagnose and correct any significant comorbidity: a meniscal deficiency, ligament laxity, or mechanical malalignment of the tibiofemoral or patellofemoral joint. Uncorrected meniscal deficiency and ligament laxity are a contraindication to cartilage restoration procedures. Most lateral patella and trochlear cartilage restoration procedures should be combined with arthroscopic lateral release, preferably at the time of chondral biopsy. The patellar realignment procedure, principally aimed at medialization of the patella to unload the newly restored articular surface, should be performed at the time of open chondrocyte implantation. Medial patellofemoral chondral lesions may be an exception to this principle and may require patellar anteriorization. The role of the hinged patellar brace and incremental increase of knee flexion remains unclear. A high tibial osteotomy is required to correct the varus angulation of the lower limb

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mechanical axis to just beyond neutral when performing a cartilage restoration procedure in the medial compartment of a varus knee. The use of an unloading brace should be considered for postoperative rehabilitation. For valgus angulation of a knee joint, a distal femoral osteotomy is required to restore the mechanical axis to neutral. It is important to carefully plan a sequence of surgical and rehabilitation options and to consider staging procedures if needed.<sup>2</sup>

This article deals with the rehabilitation of cartilage repair with cultured autologous chondrocytes, and from this point onward, we will refer to all the different open chondrocyte implantation techniques (ACI, ACT, MACI, MACT) as ACI.

### PRINCIPLES OF ACI REHABILITATION

Despite the fact that ACI is the most widely researched cartilage repair technique, there are currently only 2 articles that specifically address rehabilitation protocols.<sup>6,14</sup> Rehabilitation after ACI is a long and demanding process that presents challenges to clinicians and patients alike. Autologous chondrocyte implantation rehabilitation differs from other articular cartilage reparative or restorative procedures in 4 pertinent ways: indication, surgical procedure, graft maturation, and evidence base.

### Indication

The ACI procedure is predominantly for larger lesions  $(>2 \text{ cm}^2)$ ,<sup>2</sup> and this indication presents implications for rehabilitative joint loading and the potential for graft disruption, especially when lesions are poorly "shouldered."<sup>85</sup> Autologous chondrocyte implantation is also indicated as a secondary treatment after 1 or more failed alternative cartilage repair procedures, which has rehabilitative implications associated with symptom duration and surgical morbidity.

### Surgical Procedure

In contrast to other cartilage repair procedures, ACI is currently a 2-stage procedure that is often undertaken with concomitant procedures, as previously highlighted. The staging of procedures therefore needs to be considered and planned to avoid competition between postoperative rehabilitation protocols. After the arthroscopic biopsy, sufficient time should be allowed before the cell implantation for the restoration of joint homeostasis. Initial autologous chondrocyte culture time was 6 to 8 weeks, but this has already been halved to 3 to 4 weeks and has potential for further reduction with emerging tissue engineering technologies. However, even without any concomitant procedures, a minimum of 3 weeks is needed after arthroscopy<sup>148</sup> to replace lost synovial fluid, to allow portal wound healing, to allow recovery from analgesia/anesthetic, and to advance into the remodeling/maturation phase of healing. The implantation stage is routinely performed via either open arthrotomy or mini-arthrotomy, resulting in greater surgical trauma and mechanoreceptor disruption, all of which are

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likely to entail a longer rehabilitation process for return to function compared with alternative arthroscopic cartilage repair procedures.

### Graft Maturation

For optimal results, ACI rehabilitation needs to not only follow but also to facilitate the process of graft maturation. Excessive or inappropriate loading of immature neocartilage is therefore not advisable. However, the difficulty arises in the longitudinal assessment of the maturation status of the graft. Graft remodeling and maturation can continue for up to 3 years after ACI implantation, <sup>59</sup> and the length of this process consequently has significant implications for the timing and specifics of the rehabilitation protocol.

A broad timeline for maturation of the ACI graft has been proposed, based on studies in a dog model as well as clinical observations such as second-look arthroscopy, MRI, and patient symptoms.<sup>18,123</sup> However, at this point, there is no established and verified ACI graft maturation timeline.

Canine studies have demonstrated that there are several stages to the healing process.<sup>19</sup> The *proliferative* stage, which seems to last up to 6 weeks, is characterized by a primitive cell response, with tissue fill of the defect. During the transition stage, the tissue is not firm or well integrated, and it feels very soft, almost liquid, when probed with an arthroscopic probe. At this stage, a type II collagen framework is produced along with the proteoglycans that form the cartilage matrix. By 3 to 6 months, the tissue has usually firmed up, it has a gelatin-like consistency, and it is well integrated to underlying bone and adjacent cartilage. Patients will start to experience good symptom relief during this period. At 6 to 9 months, the neocartilage is puttylike. A remodeling and maturation phase occurs over time, lasting as long as 2 years as matrix proteins crosslink and stabilize in large aggregates and the collagen framework reorganizes to integrate into the subchondral bone and to form arcades of Benninghoff. However, the process of tissue maturation that begins during the remodeling stage continues long after this point. Excessive activity during this remodeling stage may cause repair tissue degeneration. Hence, the concept of a timeline of graft healing and remodeling is critically important during ACI rehabilitation.

An increasingly effective, noninvasive method of assessing articular cartilage repair<sup>6,0,0,22,27</sup> and, more specifically, ACI graft maturation<sup>16</sup> is advanced MRI. In particular, MRI can evaluate the degree of defect fill-in, the integration of the neocartilage to the subchondral bone plate, and the status of the subchondral bone plate and bone marrow. The signal intensity of ACI repair tissue is variable and may be heterogeneous. To our knowledge, no longitudinal studies showing the progression of the signal intensities in maturing ACI grafts have been performed. The clinical experience of Alparsian and coauthors<sup>4</sup> has shown that ACI grafts may have a relatively bright signal on fat-suppressed fast spinecho images during the initial weeks after surgery (proliferative phase), and some areas of bright signal may persist for several months after the surgery (transitional phase).<sup>4</sup> The mature, intact ACI repair tissue may appear similar in signal intensity to normal cartilage, mildly brighter or darker

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than normal articular cartilage, or heterogeneous, with a layered or speckled pattern. However, Alparslan and coauthors<sup>4</sup> found that a linear, fluid-like signal, either within the ACI or at its junction with the subchondral bone, usually indicates tear of the periosteal cover or poor integration of the graft, with in situ delamination. A small, cross-sectional qualitative study of the appearance of ACI on MRI found heterogeneous signal intensity to be common within the graft site during the first 3 months, whereas at 1 year the repair cartilage appeared more uniform. After contrast enhancement, grafts during the first 3 months showed heterogeneous uptake of gadolinium-diethylenetriamine pentaacetic acid (Gd-DTPA), whereas grafts between 3 months and 1 year showed very little enhancement. On MRI, the repair tissue within the ACI site should ideally appear as thick as the adjacent native articular cartilage and should have a smooth articular surface that reproduces the original articular contour. When an osteochondral defect is present preoperatively, however, the subsequent thickness of the repair cartilage is usually thicker than that of native cartilage, but the original articular contour is restored. The margins of the graft should be continuous with the adjacent native articular cartilage, with an indiscernible or linear interface. The signal intensity of the junction between the ACI and native cartilage may appear dark, indistinguishable from cartilage, or as bright as fluid. Interestingly, fluidlike signal at these margins may be present with an intact surface and does not necessarily imply that a fissure is present, as long as the fluid-like signal does not extend beneath the remainder of the graft. The clinical significance, if any, of the different signal intensities at the ACI margin is presently unknown.

The subchondral bone plate beneath the ACI may appear either smooth or slightly irregular. If the ACI was performed to repair an osteochondral defect, the level of the subchondral bone plate will be below that of adjacent areas, but the ACI repair tissue should still reproduce the articular contour. Edema-like signal within the bone marrow subjacent to the ACI site is an expected finding in the early postoper ative period. In mature grafts, however, the marrow signal intensity is usually normal or may demonstrate only minimal, linear bright signal on fat-suppressed images. It is still unclear when the subjacent bone marrow signal should return to normal. Subchondral changes and edema of the underlying bone marrow are being reported increasingly frequently,  $^{5}$  and it is suggested that these are normal responses to ACI and reflect graft remodeling and attach-ment to the subchondral bone.<sup>55</sup> If that is the case, then from a rehabilitation perspective, it would be beneficial to know when persistent changes are indicators of abnormal responses to ACI, but this information is as yet unavailable. Our experience has been that the presence of edema-like marrow signal beyond 12 months, or the progressive increase in the quantity of edema-like marrow signal, may herald a poor outcome.

In addition, the influence of factors such as type of chondrocyte cover (periosteum or bilayer collagen membrane), the composition and biomechanics of scaffolds seeded with chondrocytes (MACI<sub>4</sub>Hyalograft C, etc), and the concentration of growth factors, as well as the patient's age, activity

	Patellof	emoral	Tibiofemoral		
	Minimum/Earliest Introduction	Maximum/Latest Introduction	Minimum/Earliest Introduction	Maximum/Latest Introduction	
Time to full weightbearing	6 h postoperatively	12 wk	7 wk	12 wk	
ROM goals for 6 wk postoperatively	<b>30°</b>	120°	90°	130°	
Orthoses	No brace	6 wk locked in full extension	3 wk	8 wk in unloader brace	
CPM	2 h/d while an inpatient (3-5 d)	8-12 h/d for 6 wk	2 h/d while an inpatient (3-5 d)	6-8 h/d for 6 wk	
Patellar mobilizations	Immediately postoperatively	2 wk	Immediately postoperatively	Not included	
Hydrotherapy	2 wk	4 wk	2 wk	4 wk	
Cycling	4 wk	12 wk	2 wk	12 wk	

 TABLE 1

 Comparative Analysis of Ranges in Parameters During Early-Stage ACI Rehabilitation Protocols<sup>a</sup>

"For studies used, see references 8, 15, 29, 99, 120, 124, 138, 149, 154. ACI, autologous chondrocyte implantation; ROM, range of motion; CPM, continuous passive motion.

level, and local nutrition all seem to be important to graft maturation but are still unclear and unsubstantiated.

### **Evidence Base**

At present, the evidence base for ACI rehabilitation is in its infancy. Prior experience of the evolution of procedures such as ACL reconstruction has shown that where the evidence base for rehabilitation is limited, fears of graft failure are paramount. This concern, in conjunction with the relative minority of therapists with experience treating ACI patients, is likely to be reflected in an overcautious approach to ACI rehabilitation at the present time.

To maximize the benefits of ACI surgery, it is essential for patients to be well informed and educated and for them to adhere to a specific rehabilitation program.<sup>1,2,48</sup> Patient education, the management of patient expectations, and clear goal setting are indispensable within ACI rehabilitation. These values are reliant on a collaborative environment, with good communication between the surgeon, therapist, and patient.

The 2 primary goals for an ACI rehabilitation program are (1) local adaptation and remodeling of the repair and (2) return to function. The rehabilitative challenge is to optimize the achievement of these goals within an individualized and progressive, yet safe, framework. The 3 main components of the rehabilitation program are (1) progressive weightbearing, (2) restoration of range of motion (ROM), and (3) enhancement of muscle control and strengthening. The repair site is at its most vulnerable during the first

The repair site is at its most vulnerable during the first 3 months after ACI. At this time, it is important to avoid impact as well as excessive loading and shearing forces. There is a consensus of opinion that weightbearing and ROM should be restricted in early rehabilitation, but there is considerable variation across cartilage repair centers as to the extent and duration of these restrictions, as highlighted in Table 1.

### CLINICAL BIOMECHANICS

An understanding of applied clinical biomechanics and an appreciation of the forces and loads that will be exerted on the graft are essential in the design of an ACI rehabilitation program. The contact area (distribution and magnitude), contact load, and contact pressure during rehabilitation should be considered to minimize the danger of damaging the graft and to support the healing process by stimulating the graft physiologically in harmless positions. An extensive review of clinical biomechanics is outside the scope of this article; for a review of patellofemoral and tibiofemoral biomechanics, we suggest referring to McGinty et al.<sup>96</sup> Grelsamer and Klein, <sup>51</sup> and Martelli and Pinskerova.<sup>90</sup> An overview of the pertinent aspects in relation to ACI rehabilitation will now be presented.

### BIOMECHANICS OF THE PATELLOFEMORAL JOINT

The patellofemoral joint (PFJ) is a sellar joint composed of the patella and the underlying femoral trochlea. Passive stabilization of the PFJ is created by the femoral condyles, the articular surfaces of the PFJ, the peripatellar retinaculum, and the medial and lateral patellofemoral ligaments.<sup>32,96,134</sup> The primary active stabilizer of the PFJ is the quadriceps muscle group; importantly, the sole dynamic restraint to lateral tracking is the vastus medialis obliquus (VMO).<sup>51,84,96</sup> Although normal functioning and stability of the PFJ are highly dependent on the appropriate balancing of these active and passive stabilizers,<sup>76,96</sup> there are additional influencing factors, including tibial and femoral rotations,<sup>51,76</sup> gluteal muscle status, quadriceps anatomy, femoral trochlea anatomy, tibial tuberosity positioning, and foot mechanics.<sup>61</sup>

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Full flexion

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	Summary of Patellar Articulation During Knee Flexion and Extension						
	Articulation	Contact Area					
Full extension	Patella sits above femoral articular surface and rests on supratrochlear fat pad.	No patellofemoral contact with femur.					
10°-20° 30°-60°	Initial contact occurs between inferior patella and trochlea. Middle surface of natella in contact with	Joint contact area increases steadily with flexion. Mean contact area at $10^{\circ} = 126 \text{ mm}^2$ ; mean contact					
00 -00	middle third of trochlea.	area at $60^{\circ} = 560 \text{ mm}^{2}$ . <sup>116</sup>					
60°-90° <sub>t</sub>	Superior patella makes contact with trochlea.	Contact area remains constant.					
90°-135°	Superior patella contact area splits into medial and lateral contact areas that articulate with the opposing femoral condyles.	Controversial—research differs, with contact area either leveling off after 90° or continuing to increase with increasing flexion. <sup>54,81,110,116</sup>					
135°	Odd facet of patella contacts medial femoral condyle.	-					

TABLE 2

The major function of the patella is to increase the mechanical advantage of the quadriceps mechanism and to minimize the concentration of stress by transmitting forces evenly to the underlying bone. In so doing, the patella allows flexion and extension to be undertaken with reduced quadriceps force, resulting in lower stress across the tibiofemoral joint.<sup>51,76,96</sup> Other functions of the patella are to protect the articular cartilage of the trochlea and the femoral condyles by providing a smooth sliding mechanism for the quadriceps muscle with little friction.

Lateral femoral condyle fully covered by patella, and medial femoral condyle nearly completely exposed.

To optimize the distribution of forces and stresses, the patella has a large articulating surface, with the thickest articular cartilage in the human body.<sup>51,76,95</sup> The patellar cartilage shows multiple facets in a pattern that is unique to each individual, and it does not follow the contour of the underlying subchondral bone.<sup>51</sup> The articular surface of the joint is congruent in the axial plane but not in the sagittal plane, and the material properties of the patellar cartilage differ from those in the cartilage of the articulating trochlea.<sup>51,63</sup>

The articulations and contact area at various degrees of knee flexion are pertinent to ACI rehabilitation because of graft location; an overview is shown in Table 2.

The magnitude of the contact area decreases signifi-The magnitude of the contact area decreases signal-cantly in passive compared to active flexion, <sup>104</sup> whereas the contact area significantly increases with weightbearing. The magnitude of the contact area can also be influenced by tibial and femoral rotations.<sup>76</sup> Men have larger absolute contact areas than do women, but there is no significant gender difference when normalized to patellar dimensions.

The patellofemoral joint reaction force (PFJRF) is equal and opposite to the resultant of the quadriceps tendon ten-sion and the patellar tendon tension.<sup>51,96,162</sup> Thus, the compressive force is a measurement of patellar compression against the femur and is influenced by the knee angle and patellar positioning as well as the quadriceps force.  $^{96,152}$  With increasing knee flexion, the PFJRF increases, but as it does

so, the magnitude of the contact area also increases (Table 2). This increased contact area helps to distribute compressive forces over a larger area, thereby reducing contact stress. Hence, the compressive forces imposed on the patellar articular cartilage have to be considered in the context of the con-tact area over which they act.<sup>51,96,152</sup> Therefore, PFJ stress is defined as the PFJRF divided by the area of contact between the articular surfaces of the patella and the femur.<sup>162</sup>

The 2 primary goals of ACI rehabilitation are best achieved by optimizing the PFJ contact area rather than decreasing the force,  $^{63,05,96}$  as this promotes better nutrient exchange of the cartilage  $^{27,03,95}$  and decreases the pressure on the PFJ.

### BIOMECHANICS OF THE TIBIOFEMORAL JOINT

The tibiofemoral joint (TFJ) is a modified hinge joint that has recently been shown to have 6 degrees of freedom: flexion/ extension with translation, axial rotation with translation, and varus/valgus angulation with translation. 96,110 Flexion/ extension of the TFJ is a combination of rolling and gliding of the articular surfaces, with a spin movement that helps to maintain the joint congruency. During closed kinetic chain (CKC) extension, the femur rolls anteriorly and glides posteriorly on the tibia plateau. In the last 30° of extension, there is a medial rotation of the femur, the "screw home" mechanism. In an open kinetic chain (OKC) extension, the kinematics of the joint is vice versa in relation to the moving tibia. The femoral condyles roll posteriorly and glide anteriorly during flexion in a CKC system, with a conjunct lateral rotation of the femur at the beginning of the movement. In OKC flexion, the kinematics of the joint is vice versa in relation to the moving tibia.

The movement of the lateral compartment differs from that of the medial because of the difference in shape of the femoral condyles. In the medial compartment, the magnitude and distribution of the contact area change because

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the amount of rolling and gliding is equal. There is no significant change in the contact area in the lateral compartment, as rolling exceeds gliding in a ratio of 1.7 to  $1.5^{6,64,90,110}$ 

The kinematics of the joint is initiated, guided, and limited mainly by the cruciate ligaments but also by muscles and capsular structures. Injury to one of these structures or loss of function leads to altered arthrokinematics, which may be deleterious to the menisci and cartilage." During normal activities, the joint contact forces (shear and compressive forces) that are produced are attenuated by several structures of the joint. Shear forces are primarily restrained by the cruciate ligaments. Compressive forces are mostly attenuated by the menisci and the carti-lage.<sup>27,83,96</sup> Excessive shear and compressive forces can be deleterious to the menisci and the cartilage. A number of studies have measured these forces<sup>41,110,144,187</sup>; the exact level of musculoskeletal loading is influenced by a number of interindividual factors such as weight, gender, movement coordination, and the activity being undertaken. More pertinently, it is currently unknown at what magnitude compressive and shear forces become injurious to structures such as the menisci and cartilage.

To develop a safe and effective ACI rehabilitation program, shear forces have to be minimized, and the size and location of the defect have to be known because during several activities only parts of the femur/tibia are articulating.<sup>90,110</sup> For example, the posterior aspect of the medial femur condyle contacts the tibia between 90° and 120°<sup>63</sup>; therefore, appropriate loading in positions between 0° and 80° might not be injurious for a graft in this area.

### OPEN KINETIC CHAIN VERSUS CLOSED KINETIC CHAIN EXERCISES

In recent years, the clinical use of CKC exercises has increased, as they are assumed to be more functional than OKC exercises.<sup>96</sup> Additionally, CKC exercises have also been shown to involve multijoint action, muscular cocontraction, and a normal proprioceptive input.<sup>51,189</sup> In contrast, OKC exercises have been described as nonfunctional, lacking in joint proprioception and synergistic muscular cocontractions, and producing a decreased joint compressive force component in conjunction with increased joint shear forces.<sup>51,116,142</sup>

To ensure optimal healing of the ACI graft after surgery, peak compressive forces and shear forces should be avoided. A common opinion is that OKC exercises produce higher patellofemoral compressive forces than do CKC exercises and activities.<sup>5,116,142</sup> However, because of the complicated biomechanics of the PFJ, it is not sufficient to solely differentiate between OKC and CKC modes, as the localization of the graft will influence the rehabilitation program. In CKC exercises, the joint reaction force on the PFJ increases as the knee flexes from 0° to 90° and then decreases from 90° to 120°. The CKC exercises are therefore safest in the range from 0° to 45°, especially if the graft is on the proximal aspect of the patella.<sup>28,61</sup> In full extension, there is no patellofemoral contact (Table 2), so straight-leg raises in all positions are safe and produce no abnormal stress on the

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graft.<sup>28,51</sup> In the OKC exercises, forces are low near full extension  $(25^{\circ}-0^{\circ})$  and at 90° of flexion. Extending from this position, the joint reaction force increases until early flexion  $(25^{\circ})$ .<sup>26,51,95</sup> Therefore, OKC exercises are most safely carried out from 25° to 90° of flexion. But as it has already been mentioned, the rehabilitation should be focused on functional activities, and therefore CKC exercises should be emphasized.

Because of the "roll-and-glide" mechanism, the TFJ demonstrates different kinematics between OKC and CKC exercises compared to the PFJ, and this difference results in altered TFJ shear and compressive forces.<sup>96</sup> Excessive tibiofemoral shear forces and compressive forces may be deleterious for the ACI graft. To reduce the risk of abnormal shear forces, one of the most important requirements for ACI are intact cruciate ligaments. Even with functional cruciate ligaments, OKC exercises produce higher tibiofemoral anterior and posterior shear forces than do CKC exercises<sup>40,96</sup>; CKC exercises produce significantly higher compressive forces and increase muscular cocontraction, which lead to greater joint stability. Tibiofemoral shear forces decrease in CKC systems; hence, the risk of damage to the graft is reduced.<sup>96,144</sup>

The selection and progression of CKC and OKC exercises in ACI rehabilitation are dependent on the surgical technique, lesion location and size, concomitant intra-articular injury, healing stage, and patient compliance. The CKC exercises can be performed in a greater ROM, emphasizing functional activities of daily living, but they alone may not provide an adequate stimulus for optimal quadriceps strengthening. Performing OKC exercises in a small ROM increases quadriceps muscle torque and thus leads to better functional outcome Therefore, rehabilitation after ACI should include both OKC and CKC exercises, with ranges of movement based on the size and location of the ACI graft.

### ACTIVE AND PASSIVE MOVEMENTS

Controlled early resumption of activity can promote restoration of function, whereas prolonged immobilization has been shown to delay recovery and adversely affect normal tissues.<sup>25,16</sup> Therefore, mobility after ACI should be rapidly restored. To protect the graft in the early postoperative stage, a short period of partial immobilization is necessary, often with use of orthoses. The duration and degree of partial immobilization are dependent upon the size and localization of the transplanted area.

In conjunction with partial immobilization, restrictions in weightbearing are also generally advocated, although there is considerable variability in the implementation of partial weightbearing (PWB) across cartilage repair centers (Table 1). A particular issue concerns weightbearing recommendations for patellar repairs. In these cases, it can be argued that if a patient is braced in full extension, there will be no contact with the femoral articular surface, and therefore, there will be no need to restrict weightbearing while mobilizing.<sup>51,65,96</sup> When weightbearing restrictions are advised, it is important to check levels of weightbearing on a regular basis and to educate the patient regarding



Figure 1. Assessment of the degree of partial weightbearing for a patient on crutches using a set of scales.

the correct amount of weight. A practical way for the patient to monitor weightbearing is to use a set of weighing scales, as shown in Figure 1.

To enhance the graft healing process, a controlled increase of ROM through passive and active movements is indicated. Repetitive movement intensifies the synovial fluid flow over the repaired site and enhances local diffusion. Moreover, repetitive movement over a significant range induces intermittent changes of intra-articular pressure.<sup>107,112</sup> Several studies report stimulation of chondrocyte activity induced by intermittent pressures.<sup>62,165</sup> Generally, it is thought that the chondrocyte response to mechanical stimulation contributes to the maintenance of the articular cartilage homeostasis. Besides the biomechanical aspects of movement, hormonal factors such as enzymes, growth factors, and cytokines play a key role in reparative signaling for the involved joint cells and structures.<sup>74,83,146</sup> In addition, ROM exercises promote general circulation, can prevent adhesions, and bring relief of pain.<sup>25</sup>

Muscular activity increases both the joint contact area and the joint reaction forces, resulting in the production of higher joint forces with active movements. It is therefore suggested that active movements, in which the ROM implicates high joint reaction forces, should be increased at a slower rate than passive ROM. For instance, after a PFJ repair, knee extension is first introduced passively during ROM exercises,

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as active knee extension involves quadriceps contraction that results in high compressive forces on the patella.<sup>51,105</sup> To avoid damaging shear forces in the early stages of rehabilitation, active movements of the knee should be performed in a controlled manner. This procedure necessitates a comprehensive program of education and instruction for the patient. First, there is a need for close guidance to ensure correct application of the exercise modality. Second, advice on activities of daily living is essential, as many such activities can provoke excessive shear forces. Good patient understanding and movement control are priorities for optimal care of the healing process in the early stages of rehabilitation.

In summary, active ROM exercises have been shown to be beneficial to increase ROM and to stimulate the healing process.<sup>27,83,160</sup> However, it is imperative that the location and size of the lesion are considered and that the patient progresses through the ROM exercises in a controlled manner.

### CONTINUOUS PASSIVE MOTION

Continuous passive motion (CPM) is commonly used in postoperative rehabilitation of knee disorders to minimize the adverse effects of immobilization and to positively influence the healing process. Immobilization of synovial joints results in compositional alterations of articular cartilage: decreased synthetic activity of chondrocytes, decreased proteoglycan content, and reduced water content. In addition, immobilization results in biomechanical changes, including decreased cartilage stiffness and decreased cartilage thickness.<sup>27,63,131,148,150</sup> Generally, immobilization leads to decreased ROM of the joint, followed by an adaptation process of all the articular structures to the immobilized situation. Thus, early mobilization after surgical procedures in synovial joints is advocated to prevent the consequences of immobilization, such as stiffness and adhesions, through passively moving the joint without jeopardizing the healing process

The biological approach for the use of CPM for cartilage lesions and its positive effects on the healing of full-thickness defects in articular cartilage have been mainly reported by Salter.<sup>129-132</sup> Salter et al<sup>132</sup> described a more rapid metaplasia of the healing tissues within the defect from undifferentiated mesenchymal tissue to hyaline articular cartilage with CPM than with either immobilization or intermittent active motion. Williams et al<sup>153</sup> showed that a period of intermittent active motion followed by CPM may protect and stimulate repair of the articular cartilage matrix. O'Driscoll and Giori<sup>107</sup> proposed the use of CPM as a means to pump blood and edema fluid away from the joint until the swelling no longer develops.

Used postoperatively after periosteal transplantation in patients with full-thickness patellar cartilage defects, CPM shows good results and outcomes, especially compared to the results and outcomes of patients treated only with active motion.<sup>3,82</sup> Postoperative CPM after periosteal transplantation has also shown enhanced cartilage repair tissue that grossly, histologically, and biochemically resembled articular cartilage.<sup>3,108,132</sup> The effect of CPM on ROM is controversial. Investigations comparing CPM with active motion exercise

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after total knee arthroplasty have not shown any significant difference in the improvement of knee mobility.<sup>11,26,70</sup> However, these studies were based on total knee arthroplasty, and it is unlikely that the results are comparable to ACI.

Continuous passive motion is regularly used in rehabilitation after ACI (Table 1); however, to date, there are no published investigations showing the effects of CPM on graft healing or ROM after ACI. Studies advocate the use of CPM for 6 to 8 h/d to optimize cartilage repair.<sup>16,63,100,136</sup> The ROM in which CPM is performed is dependent upon the size and location of the transplanted area, as it is important to avoid high shear forces that could be detrimental to the graft.

### ORTHOSES

Guidelines for ACI rehabilitation frequently mention the use of orthoses (Table 1), which are used to prevent excessive compressive forces over the ACI graft and to facilitate function in the first stages of rehabilitation:

- Postoperative braces can be used to prevent movement ranges. In so doing, they assure that weightbearing is performed in a nonarticulating ROM.
- Functional unloader braces partially unload a specific joint compartment. In addition, some are able to follow the physiological movement of the joint via a specific polyaxial rotation unit.<sup>33</sup>

The recommendation for bracing after a patellar or trochlear repair is generally a postoperative brace (Table 1). In this way, safe ranges of motion can be closely guarded. The maximum length of time that is recommended for bracing patellofemoral repairs is 6 weeks (Table 1).

In terms of bracing for tibiofemoral repairs, there are 2 schools of thought. The first advises initial postoperative bracing for a minimum of 3 weeks, after which an unloading brace can be considered for large uncontained lesions or concomitant osteotomy correction. The second school of thought advises the use of a functional unloading brace right from the outset. Driesang and Hunziker<sup>35</sup> showed high delamination rates of tissue flaps used in articular repair; the functional unloading brace is advocated to prevent early loss of these flaps.<sup>35,67</sup> The maximum length of time that is recommended for bracing tibiofemoral repairs is 8 weeks (Table 1).

### ACI AND PRICES

The combination treatment of protection, rest, icing (cryotherapy), compression, elevation, and stabilizing is commonly known as the PRICES protocol.<sup>68</sup> The PRICES protocol has a key role to play in immediate ACI postoperative care.

Protection of the operated joint is necessary to prevent graft failure. Protection can be accomplished by patient instruction, close guidance the first days postoperatively, and several rehabilitation modalities.<sup>68</sup>

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Relative rest is recommended for the first 48 hours up to 7 days postoperatively.<sup>147</sup> To restore homeostasis, a combination of rest and mobilization is necessary.<sup>66,147</sup> As long as moving around in an upright position induces swelling and pain, bed rest is advised. Mobilizations should be continued.<sup>94,107</sup>

Cryotherapy goals during acute care are to lower tissue temperature, slow metabolism, decrease secondary hypoxic injury, reduce edema formation, facilitate exercise, and speed time to recovery.<sup>71</sup> Cryotherapy facilitates pain reduction by slowing nerve conduction velocity and reducing edema formation.<sup>72</sup> Immediately after knee surgery, there is an increase in intra-articular temperature.<sup>82</sup> However, the temperatures reported postoperatively do not seem to affect chondrocyte viability.<sup>158</sup> Postoperative ice application has been shown to decrease intra-articular temperature.<sup>152</sup> and has also demonstrated significantly decreased pain scores and the number of times analgesia is administered.<sup>109</sup>

The rationale for extended postoperative cryotherapy is more questionable. Cooling increases knee joint stiffness and reduces knee joint position sensitivity.<sup>146</sup> These findings are important in ACI rehabilitation programs that involve exercise immediately after a period of cooling. A combination of excessive ice applications and progressive CPM can increase joint stress and could lead to stress-induced hemarthrosis. Because of decreased pain perception, a further disturbance of homeostasis during "forced" passive mobilization is also possible.<sup>147</sup> In the later phases of ACI rehabilitation, cryotherapy may have a positive effect in speeding up the return to participation in sporting activities<sup>50</sup>, however, the relatively poor quality of studies is an objective concern.

Compression is effective in preventing extra-articular swelling.<sup>71</sup> Compression should be applied continuously and evenly with an elastic wrap.

Elevation should be standard practice in postoperative ACI management. Elevation improves venous drainage and hence facilitates the reduction of edema and swelling.<sup>147</sup> The correct level of elevation is for the limb to be above the heart.

Stabilizing the joint allows the local musculature to relax and prevents further injury while allowing wound healing, return of homeostasis, and scar formation.<sup>147</sup>

# PROPRIOCEPTION AND NEUROMUSCULAR FUNCTION

Neuromuscular re-education and retraining are critical components in the restoration of functional joint stability, yet they are often undervalued within the rehabilitation program. Neuromuscular function broadly involves the detection of afferent input via mechanoreceptors: the processing of a response to the stimulus in the central nervous system and the initiation of an efficient reaction to maintain balance, stability, and mobility.<sup>77</sup> Rehabilitation can assist in the restoration of proprioception, but high-level studies are scarce.<sup>87,76,78</sup>

Proprioceptive deficits in the knee have been observed in conjunction with a number of common injuries and surgical interventions," including osteoarthritis (OA),<sup>12,81,185</sup>

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patellofemoral pain syndrome (PFPS),<sup>9</sup> before and after ACL reconstruction,<sup>10,45,46</sup> and total knee arthroplasty.<sup>7,47</sup> Interestingly, it would seem that proprioceptive loss after injury, surgery, or joint degeneration is not localized to the affected joint. Studies looking at proprioception between operated and nonoperated legs,<sup>47,126</sup> OA and non-OA knees,<sup>135</sup> and ACL-injured and non-ACL injured knees<sup>119</sup> have found reduced proprioception in the contralateral unaffected limb as well as the expected reduction in the affected limb.

Currently, there are no published studies that have researched preoperative and postoperative proprioception and neuromuscular control in patients with local articular cartilage damage of the knee. However, the mere fact that a surgical intervention has taken place will mean that there will be some degree of proprioceptive loss postoperatively.<sup>61,81</sup> It is also likely that open procedures result in a greater degree of proprioceptive loss than do arthroscopic procedures because of an increased level of disruption to joint mechanoreceptors.<sup>46,65</sup> The effects of the size and location of an articular cartilage lesion on proprioception are not known. Moreover, the influence of symptom duration on a patient's preoperative level of proprioception as well as the postoperative time needed and potential for full restoration are in question.

It is important for the ACI rehabilitation program to address proprioceptive and quadriceps activation deficits in a dynamic, functional manner. Quality of neuromuscular control should be a main feature throughout the rehabilitation program. Three windows of opportunity exist for the ACI patient to address proprioceptive losses, and these present in the preoperative stage, between the arthroscopic biopsy and the ACI surgery, and after surgery. Neuromuscular rehabilitation needs to be adequately addressed in each of these stages. Current ACI rehabilitation sufficiently, or they even exclude this important area of rehabilitation altogether.

The focus of neuromuscular-control rehabilitation is the retraining of coordination patterns via feedback and feedforward control systems in a functional, dynamic, and progressive manner. This process involves varying movement speed from slow movements that target the feedback system in the early stages of rehabilitation through progressions to fast movements that focus more on retraining the feed-forward system in the later stages of rehabilitation. The exercises should be performed throughout the full available ROM and should ideally be performed on both the affected and the nonaffected limbs because of the likely decreases in proprioception in the contralateral limb. <sup>47,119,125,136</sup>

Specific exercises for neuromuscular rehabilitation after ACI should be addressed on an individual basis in line with any weightbearing or ROM restrictions that may be in place. Generally, proprioceptive challenges tend to be introduced through balance training and progressed in the following ways:

- 2-legged to 1-legged stance;
- eyes open to shut;



Figure 2. Example of bipodal proprioception exercise using an inflatable disc.

- slow to fast movements;
- introduction of unstable base (eg, mats, unidirectional/multidirectional wobble boards,
- trampet, and gym balls) (Figure 2);
- introduction of resistance and/or center of gravity
- shift (eg, from light to heavy elastic resistance band);
  introduction of distractions (eg, throwing, catching, reaching, turning); and
- introduction of sport- and occupation-specific drills.

In addition, it is essential that more functional, dynamic tests are incorporated into the rehabilitation program. These tests involve working with the patient on the quality of his or her neuromuscular control in activities such as descending stairs, gait, rising from chairs, and in the later stages, running, hopping, and jumping.

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### **HYDROTHERAPY**

Exercises in water allow early active mobilization and early loading and improve neuromuscular performance, especially during the initial phase of a rehabilitation program.<sup>118</sup> The reduction in gravity under water decreases the detrimental effects of weightbearing and the impact forces on joint structures during movement,<sup>117,118</sup> enabling ROM exercises to be performed in a functional position with a reduced risk of high shear forces under compression. Factors such as water depth and flow will also influence the loading demands on the knee joint, so it is important to base the rehabilitation program on the general principles of hydrotherapy.

Exercises under water produe lower EMG activity during isometric and dynamic conditions when compared to similar exercises on dry land,<sup>116</sup> and therefore, joint forces are lower. For this reason, hydrotherapy in ACI rehabilitation, including strengthening, proprioception training, and functional activities, is beneficial. Investigations show that an early and intensive application of hydrotherapy for improving coordination and strength during rehabilitation is advisable.<sup>44</sup> In addition, moving in water endows the patient with a "feeling of freedom," as they can walk without crutches and move around without restriction. This is an important psychological advantage.

### MANUAL THERAPY AFTER ACI

Two conceptual approaches to manual therapy need to be mentioned within ACI rehabilitation: the clinical investigation and the application of manual techniques to re-establish physiological regulation. The ability to define passive movement disorders in a joint, the localization of swelling, the involvement of anatomic structures, temperature, and so on, are not only necessary for good clinical practice but also for a comprehensive tailoring of the rehabilitation.<sup>147</sup> Manual therapy as an independent application of manual techniques for general knee disorders is questionable. However, the combination of manual therapy with exercises and specific manual techniques for the enhancement of ROM prove to be more effective than exercises alone.<sup>4</sup> Manual therapy is often cited as being used to facilitate the restoration of local function, and ACI rehabilitation protocols often mention gentle manual mobilization techniques to prevent parapatellar soft tissue formation (Table 1). Few references are made in the protocols to specific techniques to facilitate accessory movements, as in the use of passive anterior glides to the tibia<sup>8</sup> or lateral rotation of the tibia where there is a limit to TFJ extension, although they prove to be effective in facilitating immediate muscle control.<sup>31,61</sup>

### ELECTROTHERAPEUTIC MODALITIES AND EMG BIOFEEDBACK

The role of electrotherapeutic modalities in postoperative ACI rehabilitation is controversial. In the first few weeks after ACL, rehabilitative exercises are often difficult to perform, not only because of edema and pain but also as a result

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of the joint receptor feedback disruption that is an inevitable consequence of surgical intervention. The proposed therapeutic benefits of electrotherapy include pain reduction, increased ROM, reduced edema, enhanced voluntary muscle recruitment, and the promotion of cartilage healing. However, research remains limited and is often restricted to animal studies, and to date, the effect of electrotherapy on chondrocytes and their maturation in vivo is largely unknown.

### Therapeutic Ultrasound and Laser

Low-intensity pulsed therapeutic ultrasound  $(TUS)^{30,36}$ and low-level laser therapy  $^{66,127,133}$  have been proposed as providing appropriate stimuli for the acceleration of chondrogenesis. However, it has yet to be demonstrated that these therapies can stimulate articular cartilage regeneration in viyo.

### Interferential Therapy

Interferential therapy (IFT) has been shown to have significant effects in reducing postoperative pain, increasing ROM, and reducing edema after knee surgery.<sup>85</sup> However, there are issues regarding functionality, efficiency of therapy time, and clinician dependence.

### Transcutaneous Electrical Nerve Stimulation

The effectiveness of transcutaneous electrical nerve stimulation (TENS) as a pain-relieving modality has been studied in a range of populations with variable outcomes. On one hand, several studies have found TENS to be effective in decreasing pain after knee surgery, <sup>6,66</sup> but other studies have found no significant benefit in pain reduction.<sup>20</sup> A review of the role of TENS concluded that it had no place in the treatment of acute postoperative pain, as it was not an effective analgesic.<sup>97</sup>

Arthrogenic muscle inhibition (AMI), and specifically quadriceps inhibition after knee surgery, has been well documented.<sup>143,166</sup> Recovery of voluntary control of quadriceps function is an important aspect of ACI rehabilitation and should be addressed as early as possible after surgery with isometric quadriceps setting exercises. Transcutaneous electrical nerve stimulation has been proposed as a treatment modality for AMI on the basis that it competes with the type 1 afferent nerve fibers that carry the mechanoreceptor feedback. One study has shown a small increase in voluntary quadriceps activations after TENS in knee surgery patients,<sup>5</sup> but a more recent study found that TENS failed to disinhibit vastus medialis and decrease AMI after knee joint effusion.<sup>59</sup>

### Neuromuscular Electrical Stimulation

An alternative strategy to address AMI utilizes the production of involuntary muscle contractions by neuromuscular electrical stimulation (NMES) (Figure 3). Neuromuscular electrical stimulation has been found to be effective in reducing quadriceps extensor lag<sup>49</sup> and in strengthening 1030 Hambly et al



Figure 3. The use of neuromuscular stimulation to produce isometric involuntary muscle contraction.

the quadriceps after knee arthroplasty<sup>140</sup> and ACL reconstruction.<sup>43</sup> However, it is important to note that voluntary muscle strengthening has been found to be just as effective as NMES.<sup>80,111</sup> We therefore suggest that NMES is a useful adjunct to the primary exercise program in ACI rehabilitation and acknowledge that there may be an increased role for NMES in those patients who are poorly motivated, have long-term muscle weakness, and/or are slow responders.

### EMG Biofeedback

Electromyographic biofeedback has been used as a tool to re-educate patients in voluntary quadriceps contraction through the provision of feedback about the quality of their muscle contraction. Results have shown that EMG biofeedback used with muscle strengthening enhances quadriceps recruitment after arthroscopy,<sup>79</sup> arthroplasty,<sup>141</sup> and ACL reconstruction.<sup>34</sup>

### EXERCISE MODALITIES

There is currently no ACI-specific evidence base to directly support the frequency, intensity, type, and timing of exercise modalities during rehabilitation. Recent studies have advocated the avoidance of certain ranges of knee movement, for example, active knee flexion between  $40^{\circ}$  and  $70^{\circ}$  in the early stages after patellofemoral ACI.<sup>24</sup> However, virtually all exercise modalities, including common activities such as walking, cycling, and rowing, involve a knee flexion/extension pattern within this range.

The incorporation of exercise modalities into ACI rehabilitation programs may be better considered in terms of minimizing joint stress as opposed to the complete avoidance of specific ranges of movement. This result can be achieved through the selection, introduction, and progression of exercise modalities that are appropriate for the graft age, size, and location. An understanding of the variations in the magnitude and direction of loads at the knee and the

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TABLE 3
Overview of the Key Biomechanical Features
of Cycling and Rowing Exercise Modalities

Cycling Ergometer	Rowing Ergometer		
Nonweightbearing/low impact	Nonweightbearing/low impact		
Sagittal plane	Sagittal plane		
Closed kinetic chain exercise	Closed kinetic chain exercise		
Unilateral leg action	Bilateral leg action		
Mean range of knee flexion 30°-110° in 1 pedal revolution	Mean range of knee flexion 0°-130° in 1 rowing stroke		
Minimum 100° of knee flexion required	No minimum degree of knee flexion required		
Maximum knee flexion controlled by saddle height	Maximum knee flexion controlled by length of slide		
High repetitions per minute (60-90 rpm)	Low repetitions per minute (16-30 spm)		

knee flexion angle at which the peak load is exhibited is therefore required for each proposed exercise modality. Exercise modalities should complement but not replace functional movement retraining (eg, stairs).

### Cycling

In comparison with other activities of daily living such as walking or stair climbing, the maximum load-moments on the knee joint in cycling are small.<sup>37</sup> An overview of the pertinent biomechanical features of cycling is presented in Table 3. Increases in the cycling workload result in a signifcant increase in knee load-moments and compressive and shear forces, but increases in the pedaling rate do not appear to affect the maximum knee load-moment.<sup>37</sup> It is therefore possible to introduce stationary cycling at an early stage as long as resistance is minimal and there is sufficient ROM to allow a complete pedal revolution (Table 3).

Along with the correct selection of resistance, another important factor in cycling that needs to be considered is saddle height because of its direct influence on knee flexion angles, as shown in Figure 4.<sup>37</sup> If the saddle height is too low, increased PFJRFs occur,<sup>38</sup> especially if combined with too high a gearing; TFJ load-moments decrease with increasing saddle height.<sup>39</sup> Too high a saddle height, often as a consequence of insufficient available range of knee flexion, results in frontal plane rocking from the pelvis and hip, which is unfavorable for rehabilitation in terms of control and muscle activation patterns. High saddle heights are a predisposing factor for an increased risk of developing iliotibial band friction syndrome (ITBFS), especially if knee ROM is not full.<sup>42</sup> An increase in saddle height for a short postoperative period is unlikely to significantly predispose a patient to ITBFS because the condition is predominantly due to overuse. However, if the saddle height is increased to initially accommodate restrictions in knee ROM, then it is important to normalize the saddle height in parallel with the restoration of knee ROM to reduce the future risk of problems such as ITBFS.

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Figure 4. Stationary cycling showing range of knee flexion from bottom dead center (A) to top dead center (B) at correct saddle-height positioning.

Analysis of the effect that changing the direction of pedaling has on knee joint biomechanics has shown that reverse pedaling requires quadriceps muscle activity in ranges of greater knee flexion compared with forward pedaling<sup>22</sup> and that the vastus medialis is more active in reverse pedaling.<sup>22</sup> Tibiofemoral compressive loads have been shown to be lower in reverse pedaling, especially near peak extension of the knee.<sup>105</sup> However, PFJRFs have been found to be significantly higher in reverse pedaling compared with forward pedaling.<sup>21,105</sup> On the basis of this evidence, reverse pedaling on the knee but should not be advocated for PFJ rehabilitation because of the increases in loading on the knee joint.

### **Recumbent Cycling**

Recumbent cycling is an increasingly common activity in gymnasiums and fitness centers. Overall, general muscle moments are similar between upright and recumbent cycling, but importantly, the magnitudes of the general muscle moments at low workloads are lower during recumbent cycling.<sup>50</sup> This condition is due to the body being in a position in which the hip can apply a greater extensor moment than the knee in the power phase of the pedal revolution at low workloads.<sup>50</sup> Proportionally, the amount of work done by knee flexion is significantly higher in recumbent cycling compared with upright cycling.<sup>122</sup> Reiser et al<sup>121</sup> found no changes in the tension/compression forces at the knee but did find that posterior shear forces were significantly reduced in recumbent cycling. These findings indicate that recumbent cycling is a useful exercise modality in ACI rehabilitation and that there may be advantages in using recumbent cycling as a progression or alternative to upright cycling.

### **Rowing Ergometer**

Similarities exist between cycling and rowing (Table 3) that support the inclusion of rowing as an exercise modality for lower limb rehabilitation. However, there are differences between the 2 exercise modalities that have implications for ACI rehabilitation program design. In cycling, knee flexion has to be  $100^{\circ}$  before a full pedal revolution can be achieved; in contrast, there is no such biomechanical constraint in rowing. Rowing has a number of distinct advantages over

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cycling: active flexion and extension in the ACI limb can be assisted by the non-ACI limb, there is greater proximal stabilization, and loads are applied bilaterally. The relatively slower movement speed of the rowing action facilitates improved neuronuscular control for early-stage rehabilitation, but the higher movement speed of cycling is likely to be more of an advantage in later-stage rehabilitation. Anecdotally, rowing tends to be introduced at a later stage in ACI rehabilitation than is cycling (Table 1), but it is often introduced as a full-range, unrestricted activity.<sup>8,124</sup> With adequate attention to the minimization of joint stress via stroke rate and pace guidance, "no handle" ergometer rowing could be introduced earlier than stationary cycling and could feasibly be utilized as an "active" progression after CPM (Figure 5).

### Other Exercise Modalities

Other low-impact exercise modalities commonly available in fitness centers include elliptical trainers, cross-trainers, ski trainers, and stair climbers. These modalities have the advantage of being CKC activities; however, clinical biomechanical data are limited, and the implications for loading on the knee joint are not fully understood. A major consideration is the potential lack of synchronization between the hip and knee joints that could increase the transfer of forces to the knee and subsequently increase the stress that is placed upon the knee joint.



Figure 5. Ergometer rowing without using a handle at (A) the start of drive, (B) mid-drive, and (C) the end of drive.

Whole-body vibration, in which the patient undergoes a sensory bombardment, has recently become a popular training modality for gaining strength.<sup>126</sup> However, the lack of research concerning cartilage tissue repair, the overload in a sustained exercise position, and the exact effect of different training parameters are all reasons for not implementing whole-body vibration in the early stages of rehabilitation after ACI at this time.

### RETURN TO SPORT AFTER ACI

Rehabilitation after ACI is widely recognized as being lengthy, with maximum improvement in knee symptoms taking as long as 3 years after surgery.<sup>69</sup> This is a pertinent factor to consider because of the level of impact that the duration of the rehabilitation has on the time out of sport. Only 1 multicenter study to date has researched return to sport after ACI.<sup>101,102</sup> Mithöfer et al<sup>101,102</sup> studied the ability of 45 soccer players

Mithöfer et al<sup>101,102</sup> studied the ability of 45 soccer players to return to soccer in a 40-month (±4 months) follow-up period after ACI. They found that despite 72% of players reporting good to excellent knee function, only 33% were able to return to soccer.<sup>101,102</sup> What is unclear is whether the two thirds of players who did not return to soccer were clinically unable to return to play or whether they either chose to switch to a lower-impact activity or opted not to return to sport at all. The definition of "ability to return to sport" and the relevance of current outcome measures to sporting participation require further exploration and clarification. Younger age and shorter preoperative duration of symptoms were also shown to significantly improve the ability to return to soccer could well be due to a greater influence of psychosocial factors and changing life priorities rather than to physiological properties such as healing and chondrocyte maturation. Bowen et al,<sup>16</sup> in their article on return to play after chon-

Bowen et al, " in their article on return to play after chondral injuries to the knee, highlighted the fact that the success of rehabilitation is multifactorial and recognized that psychosocial factors such as patient motivation were important contributors. Drawing heavily on self-determination theory, it is proposed that the type of motivation for returning to sport (internal vs external) is an important factor,

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not only in determining whether the athlete does return but also in the outcome of the return.<sup>115</sup> Recent studies that have considered re-entry into sport after career-threatening injuries have shown that reinjury concerns are significantly implicated in the prevention of an athlete returning to sport<sup>73,115</sup> (N. Walker, unpublished data, 2005). Emotional response to athletic injury should be considered in connection with return-to-sport goals for ACI patients, both preoperatively and postoperatively.

After total knee replacement, advice to patients that highimpact activity may jeopardize their surgery outcomes can result in changes in postoperative activity.<sup>17</sup> Consideration of the impact that advice from the surgeon, therapists, other patients, significant others, and general information sources may have on postoperative activities is an important factor that is underrecognized and poorly evaluated.

With the uncertainties that surround ACI rehabilitation at present, the general consensus of opinion among cartilage repair centers appears to be that ACI surgery should be targeted on the reduction of symptoms and on improving functional daily activities rather than as a method of returning to high-level sports participation for competitive athletes with chondral damage. General recommendations are that lowimpact sports and exercise such as swimming, cycling, and golf can usually be resumed within 6 months.<sup>8,15,120,124,138,149</sup> Recommendations for timescales for a return to higherimpact activities such as racquet sports, team sports, martial arts, and running range from an earliest postoperative return at 12 months up to 18 months. However, there is considerable variation between people, so return to sports after ACI should be based on the key criteria that

- the patient's graft is able to withstand the specific demands of their chosen sport, and
- the patient has been rehabilitated to a point at which they are able to safely return to sports involvement.

Where a return to sport is planned, it is important that sport-specific activities are included as functional progressions within the rehabilitation program.

### ACI REHABILITATION PROGRAMMING

Rehabilitation after ACI is a process and, as such, the staging and progression of individual rehabilitation elements need to be considered with respect to the primary goals of local adaptation and remodeling of the repair and of return to function. A generic ACI postoperative rehabilitation program based on the current understanding of the biology of graft healing and on the corresponding therapy goals, modalities, and criteria for progression has been proposed by us and is shown in Table 4. Time frames have been indicated, but we do not recommend the adoption of a rigid timetable, as the proposed phases are not mutually exclusive, and considerable variation exists between people. Modifications to the rehabilitation program may be necessary based on defect size, location, age, previous activity level, concomitant surgical procedures, and

### TABLE 4

Postoperative Timelines for ACI Rehabilitation Based on Biology of Healing and Corresponding Therapy Goals, Modalities, and Criteria for Progression

PHASE I: RECOVERY AND PROTECTION (WEEKS 0-4) Biology: cell attachment, inflammation, and proliferation

Therapy goals

- Protect healing tissue from load and shear forces and allow
- cell adherence Restore joint homeostasis (for relative rest situation)
  - Prevent adhesions
- Restore full passive knee extension
- Gradually increase pain-free knee flexion Ensure safe transfers at home and for transportation
- Regain quadriceps control

### Modalities

- Education/coaching
- Cryotherapy, elevation, and compression
- Continuous passive motion Active ROM exercises (joint circulation exercises: ankle pumps, heel slides, hip extension and abduction)
- Weightbearing control with crutches for ADL
- Bracing (postoperative or functional unloading) as indicated
- Quadriceps setting
- Patellar mobilization Biofeedback and electrical muscle stimulation as indicated
- Criteria for progression to next phase
  - Minimal pain and swelling, able to perform daily joint circulation exercises
  - Surgical incisions healed
  - Full passive knee extension and voluntary quadriceps activity
  - Active, pain-free knee flexion of 90°
- Earliest time for progression to next phase: 4 weeks postoperatively

### PHASE II: INAUGURATION (WEEKS 4-8)

Biology: cell differentiation and start of maturation phase

- Therapy goals
- Restore joint homeostasis (for daily joint circulation exercises)
- Increase pain-free ROM (local stretching of the joint capsule is acceptable)
- Maintain full extension
- Ensure safe transfers at home and for transportation
- Gradually increase weightbearing for protection of repair
- Gain quadriceps control in safe, multiangle CKC exercises

### Modalities

- Education/coaching
- Active ROM exercises (joint circulation exercises: heel slides, stationary rowing [no resistance], or bicycle (minimal resistance))
- Balance for control of weightbearing for ADL (with brace if indicated)
- Continued bracing (postoperative or functional unloading) as indicated
- Quadriceps isometric multiangle control and coordination Quadriceps setting

(Continued)

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<sup>\*</sup>References 8, 15, 29, 99, 120, 138, 149.

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exercises

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### TABLE 4 (Continued)

- Gluteus maximus, medius, and minimus retraining
- Patellar and soft tissue mobilization
- Biofeedback and electrical muscle stimulation as indicated
   Hydrotherapy for gait coordination and joint circulation
- Criteria for progression to next phase
  - Minimal pain and swelling and voluntary quadriceps activity
  - Full passive knee extension
  - Active, pain-free knee flexion of >110°
  - Ability to perform daily joint circulation exercises
  - for at least 30 minutes within homeostasis
  - Earliest time for progression to next phase: 6 weeks postoperatively

### PHASE III: MATURATION (WEEKS 8-12)

Biology: cell differentiation and maturation

### Therapy goals

- Restore joint homeostasis (for light functional exercises)
  Gain full, active, pain-free ROM (local stretch of the joint capsule is acceptable)
- Ensure safe transfers at home and for transportation
- Gradually increase weightbearing for protection of repair
- Increase quadriceps strength in safe, multiangle
- CKC exercises • Regain quadriceps control in FROM CKC exercises
- Gradually increase ADL
- Regain optimal coordination for walking, stair
  - climbing/descending, and transfers

### Modalities

- Education/coaching
- Active ROM exercises (no resistance over repaired zone and light resistance in safe ranges)
- FWB control in exercise conditions (balance, mat, sport- and occupation-specific)
- Weaning off bracing and/or crutches
- Feed-forward exercises for coordination
- in multidirectional tasks
   Quadriceps settings
- Gluteus maximus, medius, and minimus retraining and strengthening
- Patellar and soft tissue mobilization
- · Biofeedback and electrical muscle stimulation as indicated
- Hydrotherapy for gait coordination and endurance

### Criteria for progression to next phase

- Minimal pain and swelling
- · Full passive knee extension and voluntary quadriceps activity
- Active, pain-free knee flexion of >110°
- Able to walk 1-2 miles or stationary bicycle/rowing
- (light resistance) for 30 minutes within homeostasis
  Earliest time for progression to next phase: 10 weeks postoperatively

### PHASE IV: INTEGRATION (WEEKS 12-26)

Biology: maturation and integration

### Therapy goals

Restore joint homeostasis (for intense low-impact exercises)
Ensure safe static postures

(Continued)

- Increase lower-limb strength through FROM in CKC
- Gradually increase training load and volume
- Maintain joint circulation exercises (3 or more times/wk)
- Modalities
  - Education/coaching
  - Active ROM exercises with light resistance in safe ranges
    Balance exercises in challenging postures (balance,
  - trampoline, flip boards, sport- and occupation-specific) • Feed-forward and feedback exercises for coordination
  - in multidirectional open tasks • Hydrotherapy for gait coordination and endurance
  - Strength training (light resistance over repaired zone and full resistance over other areas)
- Criteria for progression to next phase
  - No pain or swelling after intense low-impact exercises
     Full, pain-free ROM
  - Able to perform daily joint circulation exercises for at least 60 minutes within homeostasis
  - Earliest time for progression to next phase: 12 weeks postoperatively

### PHASE V: FUNCTIONAL ADAPTATION (WEEKS 26-52+)

### **Biology: maturation and integration**

- Therapy goals
  - Restore joint homeostasis (for impact exercises longer than 30 minutes)
  - Ensure safe dynamic postures
  - Aim for unrestricted ADL
  - Gradually increase lower-limb strength in range of repair (OKC and CKC)
  - Maintain training intensity, load, and volume
  - Maintain joint-circulation exercises (daily)
    Prevent future damage/iniury
  - Continually improve comfort and confidence in knee

### Modalities

- Education/coaching
- Active ROM exercises: light resistance, full range
- Balance exercises in challenging, coordinative tasks
- (balance, trampoline, flip boards)
- Hydrotherapy for general endurance
- Sport-specific agility training (unidirectional, noncontact) Strength training (full resistance over repaired zone)
- · Ducing an anning (run resistance over reparred to
- Criteria for progression to next phase
  - No pain or swelling after impact exercises longer than 30 minutes
  - Full, pain-free ROM
  - Graft is able to withstand the specific demands of the activity, as assessed by sport-specific functional testing
  - Patient is motivated to return to sport
  - Earliest time for progression to next phase: 26 weeks postoperatively

### PHASE VI: RETURN TO SPORTS (WEEKS 26-78+)

Biology: maturation and integration

### Therapy goals

- Restore joint homeostasis (for specific sports activities)
  - Maintain safe dynamic postures
- Aim for unrestricted sport (at same or lower level)
- Restore symmetry, including lower-limb strength and flexibility

(Continued)

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### TABLE 4 (Continued)

- Increase training intensity, load, and volume
- Prevent further damage/injury
- Restore confidence in knee
- Restore competition fitness

### Modalities

- Education/coaching
- Active ROM exercises: unrestricted resistance, full range
- Sport-specific agility training (multidirectional, contact)
  Balance exercises in challenging, sport-specific
- coordinative tasks
- Hydrotherapy for cardiovascular fitness
- Pre-sports conditioning (circuits)
- Functional strength training
- Criteria for progression to increased work load
  - No pain or swelling after specific sports activities
  - Full, pain-free ROM
  - Graft is able to withstand the specific demands of the sport
    Earliest time for return to sports: 26 weeks postoperatively
  - for lower-impact activities and 52 weeks postoperatively for higher-impact activities

<sup>4</sup>ACI, autologous chondrocyte implantation; ROM, range of motion; ADL, activities of daily living; CKC, closed kinetic chain; FROM, full range of movement; FWB, full weightbearing; OKC, open kinetic chain.

individual patient demands.<sup>9,63,154</sup> Progression should not be totally dependent on postoperative time; it is more important that goals are reached at the end of each phase. Effective individual patient programming is reliant on good patient education and on regular, informative communication between all members of the rehabilitation team.

### **FUTURE DIRECTIONS**

Although research focused specifically on rehabilitation after ACI is in its infancy, the patient demand for rehabilitation after ACI surgery is a growth sector, with the international expansion of orthopaedic centers offering ACI as a cartilage repair technique. Current ACI rehabilitation is heavily influenced by the fact that the procedure consists of 2 stages, culminating in implantation of cultured autologous chondrocytes via open arthrotomy. The protection of the ACI graft from deleterious forces is further complicated by the lack of definitive research on the stress necessary to disrupt or delaminate the graft.

With the progression of understanding into chondrocyte senescence comes the increasing viability for the utilization of composite ACI techniques for the surgical management of moderate OA.<sup>91</sup> In the near future, this biological alternative could offer significant benefits to the conventional treatment options of tibial osteotomy and partial knee replacement. The evolution of all-arthroscopic techniques will have a significant impact on rehabilitation and should reduce the surgical morbidity associated with open arthrotomy. In addition, developments in novel scaffolds and in vitro chondrocyte maturation before implantation would significantly reduce the inherent fragility of the ACI graft during the early postoperative stage. In the future, is it is likely that it will be possible to ACI Postoperative Care and Rehabilitation 1035

"accelerate" ACI rehabilitation programs to reflect these developments in orthopaedic tissue engineering. However, to optimize ACI rehabilitation for the benefit of future patients, there is an urgent need for further studies to form the foundations of the evidence base for ACI rehabilitation.

Until the time an evidence base is available, clinicians involved in ACI rehabilitation will have to continue depending on knowing precise surgical details (defect location and size and concomitant procedures) and to have an understanding of chondrocyte maturation, clinical biomechanics, and the principles of exercise programming and functional progressions. Such knowledge requires the adoption of a coordinated approach between basic scientists, surgeons, and therapists.

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APPENDIX 2: Paper II – IKDC or KOOS? Which measures symptoms and disabilities most important to postoperative articular cartilage repair patients?

# Including:

Roos, E. M., Davis, A. and Beynnon, B. D. (2009). Letter to the Editor. *The American Journal of* Sports Medicine, 37(5), 1042-1043.

Hambly, K. and Griva, K. (2009). Author's response. *The American Journal of Sports Medicine 37(5),* 1043-1044.

# IKDC or KOOS? Which Measures Symptoms and Disabilities Most Important to Postoperative Articular Cartilage Repair Patients?

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Background: The relevance of knee-specific subjective measures of outcome to patients has not been evaluated for cartilage repair procedures.

Purpose: The aim of this study was to identify which instrument out of the Knee injury Osteoarthritis Outcome Score and the International Knee Documentation Committee Subjective Knee Form measures symptoms and disabilities most important to postoperative articular cartilage repair patients.

Study Design: Cross-sectional study; Level of evidence, 3.

Methods: Data were collected from 58 participants of an Internet knee forum via a self-reported online questionnaire consisting of demographic and surgical data, the Tegner activity scale, and 49 consolidated items from the Knee injury Osteoarthritis Outcome Score and the International Knee Documentation Committee Subjective Knee Form. Item importance, frequency, and frequency-importance product were calculated.

Results: Overall, the International Knee Documentation Committee Subjective Knee Form was the highest scoring instrument in all categories. However, 2 of the Knee injury Osteoarthritis Outcome Score subscales ("function in sport and recreation" and "knee-related quality of life") scored higher on mean importance and frequency-importance product than the overall International Knee Documentation Committee Subjective Knee Form score.

**Conclusion:** The International Knee Documentation Committee Subjective Knee Form provided the best overall measure of symptoms and disabilities that are most important to this population of postoperative articular cartilage repair patients. This brings into question the validity of using the Knee injury Osteoarthritis Outcome Score in shorter-term—less than 10 years—studies. Issues related to sports activity appear to be highly valued and very pertinent to evaluation of outcomes for this patient group.

Keywords: IKDC; KOOS; knee outcome measures; cartilage repair

Thousands of people each year experience symptoms related to chondral defects of the knee that often threaten quality of life (QOL), especially in an active population.<sup>11,45</sup> It is well established that chondral defects have a low intrinsic capacity for repair, but surgical options are now available to many of these patients where previously the only option was arthroplasty.<sup>2.49,65</sup>

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Health-related QOL measures have become vital in the implementation of evidence-based practice.<sup>62</sup> Quality of life in clinical medicine has been defined as "representing the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient."<sup>63(p16)</sup> The concerns and viewpoint of the patient are thus an integral component in the measurement of QOL.

Patient-based measures of outcome have increased exponentially during the last 20 years and are now often used as primary and secondary measures of a treatment's effect.<sup>10,20</sup> The field of articular cartilage repair (ACR) is no exception, and instruments to measure patient-reported outcome are gaining increasing popularity for the evaluation of surgical procedures to repair chondral defects. However, the choice of instrument or instruments is not straightforward or clear

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	Endorsed by at Least			Number of Items With Mean			Number of Items With Mean		
	51% of Patients			Importance Ranking of at Least 3			Importance Ranking of 1 or Less		
Instrument	ACL	Meniscal	OA	ACL	Meniscal	OA	ACL	Meniscal	OA
IKDC (18 items)	13 (72%)	18 (100%)	18 (100%)	2	2	<b>4</b>	6	2	2
KOOS (42 Items)	19 (45%)	36 (86%)	38 (90%)	1	5	14	9	14	3

TABLE 1									
lesults	for	IKDC	and	KOOS	Items	From	Tanner	et	al <sup>68,a</sup>

<sup>a</sup>IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; ACL, anterior cruciate ligament; OA, osteoarthritis.

cut.<sup>19</sup> It was commented in a Journal of Bone and Joint Surgery editorial that "there are almost as many sets of questions asked as there are papers published.<sup>86(p1883)</sup> The author went on to state that it is important to determine whether the questions address an issue of importance to the patient and whether the item has been weighted according to its importance to the patient.<sup>8</sup>

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Any questionnaire used as a primary measure of outcome must reflect areas that are important to patients suffering from the specific disease or condition.<sup>23</sup> This necessitates incorporation of the patient's perspective of outcome in the evaluation of the impact that ACR surgery has on an individual.<sup>20,21</sup> There is currently no agreement regarding a gold standard patient-assessed measure of the effects of cartilage repair surgery. The comparative evaluation of patient-assessed health instruments for the knee has been recommended,<sup>21</sup> and investigators are being urged to consider matching an instrument to the specific purpose of the study.<sup>19</sup>

The diversity in the number of patient-based measures of outcome used in orthopaedics presents a major methodological issue when analyzing outcomes from published studies on ACR.<sup>21,34,70</sup> Patient-based measures of outcome can be categorized as being generic, disease-specific, populationspecific, or site-specific.<sup>19,20</sup> Site-specific instruments are described as containing items that are particularly relevant to patients experiencing treatment for a very specific region of the body.<sup>19</sup> The use of site-specific measures has the proposed advantage that the items in the instrument should be more relevant to a patient group experiencing treatment for the specific region.<sup>19</sup> At present there are no disease-specific instruments for chondral defects, and therefore ACR studies generally use knee-specific instruments. It has been recommended that outcome measures should be validated for use specifically on patients with cartilage injuries.<sup>34</sup>

In 2007, Tanner et al published the first study to compare the ability of knee-specific QOL instruments to detect symptoms and disabilities that are important to patients.<sup>68</sup> The authors consolidated the subjective portion of 11 kneespecific instruments and assessed the frequency and importance of each item. A mixed sample of 153 patients with ACL rupture, isolated meniscal tears, and osteoarthritis were recruited. Both preoperative and postoperative patients were sampled, but the average postoperative times were not detailed, nor were these analyzed as subgroups. The Tanner et al results for Knee injury Osteoarthritis Outcome Score (KOOS) and International Knee Documentation Committee Subjective Knee Form (IKDC) are summarized in Table 1. The authors concluded that out of the general knee instruments studied, the IKDC and the KOOS contained the most items important to patients in their population group.

Clearly research trials should use a validated questionnaire that is specific for the condition being studied.<sup>62</sup> There is a need to establish whether the commonly used knee-specific patient-based measures of outcome are relevant to the actual complaints of patients who undergo cartilage repair procedures. The aim of this study is to identify which instrument out of KOOS and IKDC measures symptoms and disabilities most important to postoperative ACR patients.

It is hypothesized that because chondral defects have been shown to play an integral role in the pathogenesis of osteoarthritis<sup>17,44,48,73</sup> the KOOS will provide a better measure of symptoms and disabilities that are most important to postoperative ACR patients. The scores for both KOOS and IKDC were expected to demonstrate an inverse relationship with postoperative time and a positive relationship with age at time of surgery.

### METHODS

### The Instruments

Two of the most commonly used patient-based measures of outcome in articular cartilage repair are the IKDC<sup>30</sup> and the KOOS.<sup>58</sup> These 2 instruments are both site-specific measures that have been developed to assess health and QOL of patients with a knee problem. The IKDC has been used in clinical studies on autologous chondrocyte implantation (ACI),<sup>§</sup> osteochondral plugs,<sup>12,15,16,39</sup> and microfracture.<sup>13,22,46</sup> The KOOS has been used in clinical studies on ACI,<sup>7,43,49,53,54,74</sup> osteochondral plugs,<sup>30</sup> and microfracture.<sup>13</sup> Several of the studies used both IKDC and KOOS, but no comparative evaluations were made between the 2 instruments.<sup>7,39,49,53</sup>

International Knee Documentation Committee Subjective Knee Form (IKDC). The IKDC is a site-specific instrument designed to measure symptoms, function, and sports activity in patients who have one or more of a variety of knee conditions, including ligament, meniscal, articular cartilage, arthritis, and patellofemoral injuries.<sup>30</sup> The original

<sup>8</sup>References 7, 16, 26, 27, 42, 46-49, 53, 61, 64, 71, 74.

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instrument was developed by an international committee in 1987,  $^{29}$  and the Subjective Knee Form was subsequently added in 2000.<sup>30</sup>

The instrument consists of 18 items related to symptoms, function, and sports activity and is able to differentiate patients with greater knee symptoms and lower levels of function.<sup>4</sup> The IKDC is scored by calculating the difference between the raw score and lowest possible score and then dividing this difference by the range of possible scores multiplied by 100. Higher scores denote greater levels of function and lower knee symptoms. This method of scoring weighs each item according to the number of response options.

Normative data have been established for the US population for age and gender.<sup>4</sup> Women have been found to exhibit lower mean scores than men. It has been recommended that studies with patients less than 18 years or 35 years and older should adjust the Subjective Knee Form scores for age difference for both men and women.<sup>4</sup> The IKDC has been shown to have an internal consistency of 0.92 and a test-retest correlation of 0.94.<sup>21</sup> The overall IKDC score has also been shown to demonstrate acceptable psychometric performance for outcome measures of meniscus injuries of the knee.<sup>14</sup>

Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS is a site-specific instrument that was developed with the purpose of evaluating short-term and long-term symptoms and function in subjects with a variety of knee injuries that could possibly result in osteoarthritis.55 The instrument is based on an extension of the diseasespecific Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index.<sup>5</sup> The KOOS comprises 42 items containing 5 separately scored subscales: pain (9), other symptoms (7), activity in daily living (ADL) (17), function in sport and recreation (Sport/Rec) (5), and knee-related QOL (4).<sup>56</sup> In contrast to the IKDC, in which the items are summed to produce a single index, the KOOS has separate scores for different health dimensions, with higher scores signifying worse functioning in these areas. Importantly, the KOOS is one of the few patient-assessed knee-specific instruments where patients have been involved in the derivation of the items.<sup>21</sup>

The KOOS has been validated for several orthopaedic interventions, including total knee replacement,<sup>59</sup> meniscectomy,<sup>57</sup> and ACL reconstruction.<sup>58</sup> Population-based reference data for age and gender in an adult population has been established.<sup>50</sup> The KOOS has been shown to have an internal consistency between 0.71 and 0.95<sup>57</sup> and a test-retest correlation of 0.75 to 0.93.<sup>56</sup>

The Tegner activity scale. The Tegner activity scale was designed as a score of activity level to complement the functional score of the Lysholm knee score for patients with ligamentous injuries.<sup>69</sup> The instrument scores a person's activity level between 0 and 10 where 0 is "on sick leave/disability" and 10 is "participation in competitive sports such as soccer at a national or international elite level." It is the most widely used activity scoring system for patients with knee disorders.<sup>8</sup> The psychometric properties have been analyzed for patellar dislocation outcomes<sup>52</sup> and meniscal lesions<sup>8</sup> and have demonstrated, in general, acceptable psychometric parameters. However, the Tegner activity scale has not been independently, separately validated<sup>35</sup> or psychometrically assessed specifically for ACR outcomes.

### Demographic Data

The demographic data used to describe the study cohort were self-reported date of birth and gender.

### Surgical Data

Surgical data were composed of self-reported responses for type of cartilage repair surgery, location of areas that were repaired (including multiple), month and year of cartilage repair surgery, and concomitant procedures.

### **Development of the Study Questionnaire**

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The online questionnaire was developed as per the methodology of Tanner et al<sup>68</sup> using the questionnaire activity module (version 2005062701) of Moodle (version 1.5.3). Moodle is an open source software package designed using pedagogical principles to help educators create effective online learning communities (http://moodle.org). The questionnaire activity module is based on Hypertext Preprocessor Easy Survey Package (phpESP) and is a tool to create surveys. The responses from the questionnaire were stored anonymously using numeric reference ID numbers and exported as comma-separated value files for analysis.

A questionnaire of 57 items was developed that included 7 items related to demographic and surgical information; 49 items were consolidated from the IKDC and the KOOS (7 items from IKDC; 31 items from KOOS; and 11 items in both KOOS and IKDC, ie, item overlap) and the Tegner activity scale. To compare results from this study with the Tanner study it was necessary to make some modifications to items from the IKDC and KOOS instruments. In line with the Tanner study, double-barrelled items were separated into 2 items, and questions on the IKDC were changed to the present tense rather than the standard "during the past 4 weeks."

Participants were asked to rate the importance of a described symptom or disability using a 6-point Likert scale as shown in Figure 1. The final questionnaire was pretested in a small sample of noncartilage knee repair patients and orthopaedic colleagues for explanation of purpose, clarity of questions, and ease of completion before it was transferred to an online environment.

### Participant Recruitment

The focus of this study was to assess which instrument best measured symptoms and disabilities important to ACR patients and not the effectiveness of any one surgical procedure. Within this context, the inclusion criteria for participation was an individual who had undergone ACR of the knee rather than a specific surgical repair procedure. The

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Sample Question: Knee is painful.							
Not experienced	Experienced but not important	Experienced and a little important	Experienced and moderately important	Experienced and very important	Experienced and extremely important		
0	1	2	3	4	5		

Figure 1. Sample question and Likert Scale used in the study questionnaire.

study was approved by the London Metropolitan University's ethics committee as part of a larger PhD research study.

Participants were recruited from the KNEEguru Web site (http://www.kneeguru.co.uk). The KNEEguru site is a resource for people with knee problems and has more than 20 000 registered members from across the world. The Web site is based around a dynamic bulletin board to which individuals older than 18 years must register to interact. Potential subjects were invited to participate in the study via postings in relevant topic areas on the KNEEguru bulletin board. The purpose and aims of the study and the role of the participants were included in the invitation as per established guidelines for online research.9,16 Self-registration to the study and self-submission of the questionnaire was taken as consent to participate.<sup>67</sup> Data collection took place during a period of 6 months between July 2007 and January 2008. Access to the questionnaire was via a URL link, and participants were either able to use their existing bulletin board login details or a generic account set up specifically for the survey. Data were only saved to a secure server if participants chose to submit the questionnaire. Stored data for each submitted questionnaire was linked to a unique response identification number.

### **Data Analysis**

All data collected via the online questionnaire were imported into a customized database. Statistical analysis was performed with SPSS for Windows 14.5 software (SPSS Inc, Chicago, Ill). Nonparametric analyses were selected based on the data not being normally distributed and the data categories being predominantly in ordinal format.

The data were summarized using descriptive statistics. Medians and ranges were calculated for ordinal data, but means and standard deviations (SD) were also calculated to make comparisons with previous research<sup>68</sup> as per published recommendation.<sup>40</sup> A series of correlations were carried out using Spearman's  $\rho$  to identify any potential relationships between demographic factors and items ratings. The Mann-Whitney U test and Kruskal-Wallis test were used to compare data between participant subgroups based on age and time elapsed since ACR. Significance levels were set at P < .05.

Two postoperative time categories were established comprising participants who were less than a year after ACR surgery and those who were a year or more. A year was chosen as the break point for the subgroups based on the surgical and rehabilitation recovery timescales.<sup>24,25</sup> The

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participants were also grouped into 2 age categories: <35 years and  $\geq$ 35 years. These age categories were chosen based on the finding that age differences in IKDC scores started to emerge at 35 years of age<sup>4</sup> and that an age greater than 35 years has been shown to be a negative predictor of outcome.<sup>66</sup>

In accordance with Tanner et al<sup>68</sup> and prior recommendations for the development of QOL questionnaires, a clinical impact methodology was adopted.  $^{25,36}$  The item frequency was recorded as the number of patients who listed the item as a problem (maximum 58). The importance ranking was recorded as the value of each item on a Likert scale from 0 to 5 where 0 was "not experienced" and 5 was "experienced and extremely important." The individual patient ranking (IPR) was calculated as the average ranking of items for each patient. The mean importance ranking (MIR) was recorded as the mean ranking of importance for each item. The clinical impact was expressed as the frequency importance product (FIP) where the MIR was multiplied by the proportion of patients experiencing a particular item.<sup>36</sup> It is important to report the MIR alongside the FIP, as they represent different constructs. The MIR indicates the average importance across all patients, including those patients who did not experience a particular item and provides an overall profile of the population. The FIP takes into account that some patients may not have experienced an item, and it therefore provides a more accurate indicator of the clinical impact an item has on a patient who experiences that particular item. A high FIP is an advantage for a healthrelated QOL measure as it is an indication that not only is an item frequently experienced but also that it is an important symptom or disability for patients.

In addition to the overall MIR and FIP for each item in the 2 instruments, the MIR and FIP ratings across the items corresponding to the 5 separate KOOS subscales were also calculated. These summary ratings served as indices of the relevance and importance of the subscales in the populations: how the particular subscale rather than individual items were perceived and evaluated by respondents. This was not performed for IKDC as the measure yields one overall score.<sup>30</sup> In accordance with Tanner et al, <sup>58</sup> calculations were also

In accordance with Tanner et al,<sup>50</sup> calculations were also made for:

- The number of items that at least 51% of the patients rated with a value of at least 1 (experienced but not important) on the Likert scale.
- The number of items that had an MIR of at least 3 (experienced and moderately important) on the Likert scale.
- The number of items that had an MIR of 1 (experienced but not important) or less on the Likert scale.
- The number of items that had an FIP of at least 3.
- The number of items that had an FIP of 1 or less.

### RESULTS

The online survey was completed by 58 participants. Data collection was complete except for 9 participants who incorrectly entered their date of birth. The mean age of

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participants at the time of surgery was 35.5 years (SD, 7.7; range, 23-49 years) and the Tegner activity scale mean score was 2.93 (median, 2.5; range, 0-10). The most common ACR surgical procedure was a marrow-stimulating technique (45%), followed by cell-based repair (31%), and osteo-chondral plugs (19%). More than a quarter of the ACRs were multiple sites (28%), with the most frequent isolated repair areas reported as being medial femoral condyle (12%), patella (19%), and lateral femoral condyle (17%). Overall, 60% of patients underwent a concomitant surgical procedure.

Table 2 displays the MIRs, frequencies, and FIPs for each item, and Table 3 displays the overall MIRs, frequencies, and FIPs for each of the 2 instruments. Average item MIR was 2.81 for the IKDC (SD, 0.72) and 2.31 for the KOOS (SD, 0.84). The IPR for the KOOS and the IKDC were significantly correlated ( $\rho = .944$ ; P < .01). Evaluation of the 2 measures on the 5 set criteria indicates that the IKDC outperformed the KOOS on frequencies, MIR, and FIP ratings.

The study cohort comprised 31 women (mean age at time of surgery, 36.3 years; SD, 7.4; range, 23-49 years) and 27 men (mean age at time of surgery, 34.6 years; SD, 8.2; range, 21-48 years). There was no significant difference in age at time of surgery between men and women (P = .478). A statistically significant difference (P = .042; P < .05) was found in time from surgery between men (13.3 months) and women (27.4 months). However, there were no significant correlations between time from surgery and any of the item ratings for the women. The importance rating for the item "knee is swollen" was significantly negatively correlated to the time from surgery for the men ( $\rho$  = .406; P < .05). Male gender was significantly associated with a higher Tegner activity scale score (P < .05). Table 2 indicates the items where significant differences in importance ratings were found between men and women.

### KOOS

Inspection of ratings for KOOS individual items showed that the item "modified lifestyle to avoid activities that are potentially damaging to knee" exhibited the highest ratings (MIR = 4.00; FIP = 3.86). At the other end of the scale, the KOOS item "can't straighten knee" exhibited the lowest ratings (MIR = 1.10; FIP = 0.38). The 3 KOOS items that were not experienced by at least half of the study group were "can't straighten knee," "lying hurts," and "sitting difficult."

When the KOOS results were split into the 5 subscales as shown in Table 4, it was evident that ADL was neither viewed as being particularly important by this patient cohort (ADL-MIR = 1.86) nor was it frequently experienced (ADL-FIP = 1.32). In contrast, the subscales of function in sports/recreation and knee-related QOL were viewed as being more important than pain, other symptoms, and ADL subscales (Sports/Rec MIR = 3.44; QOL-MIR = 3.72) and were more frequently experienced (Sports/Rec FIP = 3.09; QOL-FIP = 3.57). Many items in the KOOS, despite being experienced, exhibited a low MIR, with 24% (10/42) of the items exhibiting an FIP of 1 or less. These 10 items were in the pain (3), other symptoms (1), and ADL (6) subscales. None of the items in the function in sports/recreation or knee-related QOL subscales had an FIP of 1 or less.

Group comparisons between male (n = 27; mean KOOS item score, 2.01; SD, 1.21) and female (n = 31; mean KOOS item score, 2.58; SD, 1.19) patients indicated that female respondents reported significantly higher KOOS item importance ratings relative to their male counterparts (P =.049; P < .05, respectively). There were no significant differences in MIR and FIP between male and female subjects for the subscales of function in sports/recreation and kneerelated QOL, but the female subjects did score significantly higher MIRs and FIPs for the pain and ADL subscales and MIR for other symptoms (see Table 4).

Inverse correlations were noted between Tegner and KOOS IPR, indicating the lower the Tegner score, the greater the level of experience and importance of the symptoms and disabilities evaluated in the KOOS (P < .01). There were no statistically significant associations between KOOS IPR and postoperative time (P = .942) or age at surgery (P = .487).

### IKDC

Mean importance rankings and FIPs (Table 2) indicated that the majority of the IKDC items were both frequently experienced and perceived to be important. Of the 18 items in the questionnaire, the item "difficult to participate in strenuous activities" received the highest MIR rating (3.71), and the item "running difficult" received the highest FIP rating (3.29). The item that scored lowest for both MIR (1.21) and FIP (0.60) was "sitting difficult." In addition, "sitting difficult" was the only IKDC item that was not experienced by at least half of the study group. The IKDC contained 4 items that were not experienced by at least 76% of the participants. Those items were "sitting difficult" with participant frequencies of experience of 50% (29 of 58); "knee locks, catches, or hangs up when moving" with 69% (40 of 58); "swelling limits strenuous activities" 67% (39 of 58); and "giving way limits strenuous activities" with 69% (40 of 58).

Group comparisons between male (n = 27; mean IKDC item score, 2.57; SD, 1.24) and female (n = 31; mean IKDC item score, 3.02; SD, 1.31) patients indicated that female respondents did not report significantly higher MIR or FIP relative to their male counterparts (see Table 4).

A higher Tegner activity scale score was significantly associated with a lower IPR for IKDC (P < .01). There were no statistically significant associations between IKDC IPR and postoperative time (P = .889) or age at surgery (P = .304).

### DISCUSSION

In the new era of medical research, patients' outcomes other than morbidity and mortality now provide a significant contribution to the discussion and evaluation of most surgical interventions. In ACR research, a 1:1 correspondence between objective indices of procedural success (eg, histology, arthroscopic indentation, or MRI), and patients' symptomatology and functional capacity has not been

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Item Description	Instrument	Mean Importance Ranking (median; range)	Item Frequency of Experience (max 58)	Clinical Impact (FIP)
Knee is painful	IKDC & KOOS	, 3.33 (4.0; 0-5)	55	3.16
Knee is stiff	IKDC	2.50 (2.5; 0-5)	48	2.07
Knee is swollen <sup>6</sup>	IKDC & KOOS	2.02 (2.0; 0-5)	44	1.53
Knee stiff after first waking in morning <sup>b</sup>	KOOS	2.00 (2.0: 0-5)	42	1.45
Knee stiff after sitting, lying, or resting later in the day <sup>b</sup>	KOOS	2.34 (3.0; 0-5)	46	1.86
Knee locks, catches, or hangs up when moving <sup>b</sup>	IKDC & KOOS	2.16 (2.0; 0-5)	40	1.49
Knee grinds, grates, or clicks when knee moves	KOOS	2.59 (3.0; 0-5)	51	2.27
Can't straighten knee fully	KOOS	1.10 (0: 0-5)	20	0.38
Can't bend knee fully	KOOS	1.83 (1.0: 0-5)	35	1.10
Twisting/pivoting on knee is painful	KOOS	2.95 (4.0, 0-5)	46	2.34
Straightening knee fully hurts	KOOS	1.52 (1.0, 0.5)	33	0.86
Rending knee fully hurts	KOOS	1.84 (1.0, 0.5)	38	1 21
Walking on a flat surface burts <sup>b</sup>	KOOS	179 (1.0, 0.5)	36	1 11
Coing up stairs hurts <sup>b</sup>	KOOS	2 79 (3.0-0.5)	48	9.95
Coing down stoirs burts <sup>b</sup>	KOOS	2.12 (3.0, 0.5)	48	2.20
Knog hurts at night when in hed <sup>b</sup>	KOOS	1 95 (9.0.0.5)	40	1 94
Sitting husts	KOOS	1.55(2.0; 0.5)	40 91	0.70
Tring hurts	KOOS	1.90 (1.0, 0.5)	90	0.75
Eying nurus Standina husta	KOOS	1.33 (1.0; 0-3)	29	1.80
Optime down station in difficult <sup>6</sup>	WDC & WOOR	2.02 (2.0; 0-6)	40	1.39
Going down stairs is difficult	INDO & KOOS	2.71 (3.0; 0-5)	40	2.15
Going up stairs is difficult		2.79 (3.0; 0-5)	48	2.31
Rising from sitting is difficult	INDU & NOUS	2.28 (2.0; 0-5)	47	1.84
Standing is difficult	KOUS	1.93 (1.5; 0-5)	40	1.33
Bending to the floor is difficult	KOOS	2.45 (2.0; 0-5)	40	1.69
Walking on a flat surface is difficult	KOOS	1.67 (1.0; 0-5)	35	1.01
Getting in/out of car is difficult	KOOS	1.84 (2.0; 0-5)	42	1.34
Going shopping is difficult"	KOOS	1.83 (2.0; 0-5)	40	1.26
Putting on and taking off socks is difficult	KOOS	1.13 (1.0; 0-5)	29	0.58
Lying in bed and maintaining knee position is difficult	KOOS	1.26 (1.0; 0-4)	32	0.69
Getting in/out of bath is difficult	KOOS	1.41 (1.0; 0-5)	36	0.88
Sitting is difficult	IKDC & KOOS	1.21 (0.5; 0-5)	29	0.60
Getting on/off toilet is difficult	KOOS	1.62 (1.0; 0-5)	36	1.01
Heavy domestic duties are difficult	KOOS	2.79 (3.0; 0-5)	51	2.46
Light domestic duties are difficult	KOOS	1.57 (1.0; 0-5)	34	0.92
Squatting is difficult	IKDC & KOOS	3.19 (4.0; 0-5)	51	2.80
Running is difficult	IKDC & KOOS	3.67 (5.0; 0-5)	52	3.29
Jumping is difficult	IKDC & KOOS	3.47 (5.0; 0-5)	52	3.11
Stopping and starting quickly is difficult	IKDC	3.50 (4.0: 0-5)	52	3.14
Twisting/pivoting on knee is difficult	KOOS	3.62 (4.0: 0-5)	54	3.37
Kneeling is difficult	IKDC & KOOS	3.28 (4.0: 0-5)	51	2.88
Lack of confidence in knee	KOOS	3.71 (4.0: 0-5)	56	3.58
Often aware of knee problem	KOOS	3.79 (4.5.0.5)	56	3.66
Modified lifestyle to avoid activities that are potentially damaging to knee	KOOS	4.00 (5.0; 0-5)	56	3.86
General difficulty with knee	KOOS	3.4 (4.0. 0.5)	54	3,16
Knee limits daily activities	IKDC	3.24 (4 0: 0.5)	50	2.79
Knee nain limits stronuous activities	IKDC	3.62 (4.0.0.5)	51	3.18
Swelling limite strangers activities	IKDC	2.00 (2.0.0.5)	30	1 34
Circing man limits strenuous activities	IKDC	1.09 (1.0-0.#)	40	1 22
Difficult to portioinste in stronger	IKDC	1.00 (1.0; 0-0) 9 71 (5 0, 0 5)	40 51	1.00
activities on a regular basis	*****	0.11 (0.0; 0-0)	01	0.20

TABLE 2 Mean Importance Ranking, Item Frequency of Experience, and Clinical Impact (FIP) for Each Item<sup>a</sup>

"FIP, frequency-importance product; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis big inficant difference in ratings between males and females (P < .05)

'Significant difference in ratings between males and females (P < .01)

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 TABLE 3

 Results of Mean Importance Ranking, Experience Frequency, and Frequency-Importance

 Product for the IKDC and Overall KOOS<sup>a</sup>

· · · · · · · · · · · · · · · · · · ·	IKDC	KOOS
Itens on instrument	18	42
Number of items with an $MIR^a$ of 3 or more $(\%)^b$	9 (50)	10 (24)
Number of items with an MIR <sup>a</sup> of 1 or less $(\%)^b$	0 (0)	0 (0)
Number of items experienced by at least 51% of patients (%)	17 (94)	38 (90)
Number of items experienced by at least 76% of patients (%)	14 (78)	20 (48)
Number of items with FIP of at least 3 (%)	6 (33)	8 (19)
Number of items with FIP of 1 or less (%)	1 (6)	10 (24)

"IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; MIR, mean importance ranking; FIP, frequency-importance product.

<sup>b</sup>Score on a Likert scale of 0 to 5, with 0 being "not experienced" and 5 being "experienced and very important."

 
 TABLE 4

 Mean MIR and Mean FIP for All Items in IKDC, Overall KOOS, and KOOS Subscales for the Total Cohort and Male and Female Subgroups<sup>a</sup>

	Mean MIR				Mean FIP		
Instrument	All	Male	Female	All	Male	Female	
IKDC overall	2.81	2.57	3.02 <sup>b</sup>	2.35	2.11	2.59	
KOOS overall	2.31	2.01	2.58°	1.81	1.52	2.11°	
KOOS Subscales							
Pain	2.16	1.72	2.53	1.58	1.16	2.01°	
Other symptoms	2.00	1.57	2.39°	1.44	1.05	1.86 <sup>b</sup>	
Function in daily living (ADL)	1.86	1.58	2.11°	1.32	1.03	1.62	
Function in sports/recreation	3.44	3.45	3.44	3.09	3.07	3.11	
Knee-related quality of life	3.72	3.54	3.89 <sup>b</sup>	3.57	3.41	3.70 <sup>6</sup>	

<sup>a</sup>MIR, mean importance ranking; FIP, frequency-importance product; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score.

<sup>b</sup>No significant difference between males and females (P < .05).

'Significant difference between males and females (P < .05).

established. The need to consider the patient's perspective has led to the development of numerous measures and instruments to assess and quantify patients' experience and evaluation of knee functioning. Typically these measures focus on a range of symptoms and disabilities, indices of functional capacity, and performance of daily and other valued activities that are thought to be generally applicable to all patients with knee-related pathology and dysfunction. The present study was designed to examine and compare 2 of the most widely used knee-specific patient reported measures in the field, namely the IKDC and KOOS, on the extent to which they assess symptoms and disabilities that are frequently experienced and are ranked as important by patients that have undergone ACR.

Taken collectively, study findings indicate that although both questionnaires comprise items that are experienced by at least half of the respondents, their relative importance ratings vary greatly. It is of note, for instance, that knee pain was experienced by 95% of respondents, yet it was not considered to be as important as, for instance, difficulty running or participating in strenuous activities. Similarly, items associated with pain or difficulty with bending or straightening the knee were scored low, with mean FIPs ranging from 0.38 to 1.21, compared with functional activities such as items associated with going up or down stairs, which scored mean FIPs of 2.15 to 2.31. This suggests that evaluation of symptoms should be secondary to the evaluation of functional problems and performance limitations and activity restrictions, as these appear to be more important to patients.

Despite yielding similar results in terms of the psychometric properties such as internal consistency and construct validity,<sup>4,14,21,29,33,50,56-39</sup> evaluation of the 2 instruments on relevance and importance indices point to the IKDC as the instrument of choice for cartilage repair patients. Across all criteria, IKDC performed consistently better than KOOS. The IKDC contained more items that are both frequently experienced and considered to be important by patients. Half of the

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items (n = 9; 50%) in the IKDC received an MIR of 3 or more (out of a possible 5) suggesting that on the whole, the instrument is tapping into issues that are key in determining how patients make judgments and evaluate their postoperative experience and functioning. This is a particularly intriguing finding because the IKDC was developed by experts without any direct patient input. The convergence of views among health care professionals and recipients of care is encouraging in the context of newly shared models of health care and decision making. On the other hand, this population of patients did not evaluate the KOOS items as favorably. Despite the fact that there were no KOOS items with an MIR of 1 ("experienced but not important") or less (out of a possible 5), a substantial number of items received low FIPs of 1 or less (n = 10): 24%) suggesting that the KOOS demonstrated a higher level of construct irrelevance than the IKDC. There are several plausible explanations for this finding. One reason the KOOS may have exhibited a higher number of irrelevant items is that it includes all WOMAC items and focuses on longer term consequences of osteoarthritis.<sup>59</sup> Additionally, the pilot study that was conducted to identify the subjectively most relevant factors and subsequently derive the items for the KOOS instrument ranged in age from 35 to 76 years (mean, 56 years) and all showed radiological signs of knee osteoarthri-tis.<sup>51,56</sup> The KOOS covers immediate consequences and also the chronic outcome in the older patient, that is, late-disease-specific symptoms of osteoarthritis. However, the natural development of osteoarthritis after knee joint injury can commonly take 10 to 15 years.<sup>41,44,60,72</sup> This brings into question the validity of using the KOOS in short-term studies of less than 10 years postoperative follow-up, especially as current clinical research guidelines for ACR procedures recommend a minimum of only 2 years' follow-up.

It is also important to note the divergence of patients' views regarding the importance of various KOOS domains and subscales. The majority of the items that received low FIP ratings were in the pain, other symptoms, and ADL subscales. Items in the subscales on sports and recreation such as running and jumping were both perceived to be important (MIR = 3.44 and 3.72, respectively) and were frequently experienced (FIP = 3.09 and 3.57, respectively). An opposite pattern of results has been noted in the Tanner et al<sup>58</sup> study, in that disabilities pertaining to participation in moderate to vigorous sports were rated the least important among osteoarthritis patients. Discrepancies in patient characteristics are likely to account for this differential pattern of results. Our study sample consisted of predominantly young adults (mean age at time of surgery, 35.5 years) compared with the osteoarthritis group in Tanner et al (mean age, 59.9 years). These differences were anticipated as children and individuals older than 55 years of age are usually excluded in ACR procedures.<sup>1</sup> This is consistent with the age profile-reported in years-of ACR patients in recently published studies: Horas et al<sup>26</sup> (mean, 33.4; range, 18-44), Knutsen et al<sup>37</sup> (mean, 32.2; range, 18-45), Bentley et al<sup>6</sup> (mean, 31.3; range, 16-49), and Kreuz et al<sup>38</sup> (mean, 35; range, 18-50). Patients eligible for ACR procedures therefore tend to be a younger segment of the patient population compared to the osteoarthritis patient population.

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There were some pertinent differences in the results between the male and female subjects in the study population. The higher Tegner Activity Score for the male subjects was an expected outcome. The statistically significant difference in the overall KOOS ratings between men and women was unexpected. When the KOOS subscales are considered, it appears that women tend to rate several items in the pain, other symptoms, and ADL subscales higher in importance than men. However, there was a statistically significant difference in the time from surgery between male and female subjects, the potential implications of which will be discussed later. For the IKDC, although the women reported higher overall ratings, the lack of a statistically significant difference from the men may be an indication that the IKDC is influenced less by gender than the KOOS. Potential gender differences in ratings of outcome measures have important implications in the comparative analysis of clinical studies, and further research is required in this area.

The findings of the current study should be considered in light of 2 limitations. The first methodological limitation relates to the cross-sectional design of this study, which precludes inferences on the sensitivity or responsiveness of the 2 measures over time. The second methodological issue relates to the sample size and representiveness. The sampling for this study was via online self-selection from a forum for people with knee problems. In the author's experiences of working with online knee forums, it has been found that when an individual's knee problem has either been significantly reduced or eliminated, they frequently leave the forum and do not return unless they encounter a subsequent knee problem. Therefore it is proposed that as postoperative time increases, a continued active presence on a forum such as KNEEguru may be an indication of an individual experiencing higher levels of symptoms and disabilities than those people with the same postoperative time who have left the forum. This may explain why the women in this study demonstrated higher MIRs and FIPs for both instruments as, despite the genders being age-matched, there was a significant difference in the time from surgery, with men completing the survey at an average of 13 months postoperatively and the women at 27 months. If this is the case, the use of online participant recruitment through forums may mean that the results of this study cannot be generalized to the broader ACR patient population. However, these online forums are an important support mechanism for a growing number of orthopaedic patients worldwide and as such warrant evaluation in their own right.

Potential confounding variables that were not evaluated in this study included cultural differences, pain medication, body mass index, symptom duration, or compliance with rehabilitation. Conducting further studies on the broader cartilage repair population not represented in this study would be a fruitful endeavor, and recruiting even larger samples to enable effective multigroup analysis should be pursued in future research. Despite the limitations, the study findings build on previous work by Tanner et al<sup>68</sup> to further the case that we need to look at the relevance of knee-specific patient-reported measures in the context of the specific population under study.

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In conclusion, both the IKDC Subjective Knee Form and the KOOS contained a large number of items that were experienced by, and are important to, this population of ACR patients. The study findings point to the IKDC Subjective Knee Form being the knee-specific instrument of choice for this population of ACR patients due to its overall performance compared with the KOOS.

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# Letter to the Editor

### Dear Editor:

We have with interest read the article by Hambly and Griva titled "IKDC or KOOS? Which Measures Symptoms and Disabilities Most Important to Postoperative Articular Cartilage Repair Patients?" (September 2008, pages 1695-704) and the accompanying editorial by Bruce Reider. As pointed out in the article, there is no agreement regarding a gold-standard patientassessed measure of the effect of cartilage repair surgery, and it is important to compare possible questionnaires. It would indeed improve interpretation of outcome in cartilage repair in particular, and in knee surgery in general, if consensus could be reached on a preferred patient-reported outcomes measure.

Our major concern with the current article is that 1 of the instruments, the Knee Injury and Osteoarthritis Outcome Score (KOOS),<sup>2,4</sup> has been used in a way it was never intended or recommended to be used.<sup>3</sup> In addition, the instructions associated with administration of the KOOS, the questions of the KOOS, and the time frame over which these questions pertain were all modified, without comparative testing with the original version of the KOOS. Consequently, it is unclear if the questions have the same measurement properties. There was also concern with the article with regard to how the KOOS was used because the authors state that "the KOOS has separate scores for different health dimensions, with higher scores signifying worse functioning in these areas. This is not the case; with the KOOS, higher scores signify improved functioning. Thus, readers need to use caution in interpreting the results of the study as a comparison of the KOOS to another questionnaire because the authors have not used the KOOS. Instead, they have created another version of this outcome measure that is verv different.

Hambly and Griva point out that "any questionnaire used as a primary measure of outcome must reflect areas that are important to patients suffering from the specific disease or condition." The problem with knee injury is that structural lesions often are concomitant, and surgical procedures often address more than 1 lesion in the same session. As an example, most patients suffering an ACL tear sustain other simultaneous lesions such as meniscal tears or cartilage lesions. In the article by Hambly and Griva, 60% of the 58 participants with chondral repair had undergone another concomitant surgical procedure. Hence, it is unclear if the outcome measure data reflect the outcome of the chondral repair, the concomitant surgical procedure, or a combination of both. Given this difficulty in the current study and in many other studies of knee injury, it is challenging if not impossible to develop or apply outcome measure for a specific knee injury. Hence, the KOOS was developed to ensure a spectrum of activities relevant for patients with different knee injuries.

The KOOS was developed as a measure for people with knee injury resulting from an ACL tear, meniscal lesion, and/or chondral damage, all injuries known to be associated with an increased longterm risk of osteoarthritis. The idea was that the KOOS could be applied not only in short-term follow-up but also in long-term followup studies of knee injury. The initial literature review and expert

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panels identified items related to pain, other symptoms, kneerelated quality of life, and functional difficulties relating to a higher and a lower activity level for inclusion.<sup>3</sup> Thus, the KOOS includes 2 separate subscales relating to physical function: activities of daily living (ADL) function and sport and recreation function. To be valid for persons with both high and low physical activity levels, and for use in long-term follow-up during which a decrease in activity level may occur, both subscales need to be included in the KOOS.

In the recent article by Hambly and Griva, the conclusion was primarily based on the results for mean importance ranking (MIR) and frequency important product (FIP) of the individual items included in the KOOS and the International Knee Documentation Committee (IKDC) score. When considering the way each measure is intended to be used, as separate subscales for the KOOS<sup>4</sup> or as a total score for the IKDC,<sup>1</sup> these results indicate that the best results were achieved for the KOOS subscales kneerelated quality of life (3.72 and 3.57, respectively) and sport and recreation function (3.44 and 3.09, respectively). The corresponding results for the IKDC were 2.81 and 2.35, respectively. Although the MIR and FIP are interesting, these statistics do not include confidence intervals. The absence of confidence intervals combined with the small sample size of this study limits our ability to draw conclusions and makes it very difficult to interpret the relevance of these differences, at least from a statistical perspective. The MIRs for the other 3 KOOS subscales, pain, symptoms, and ADL function, were 2.16, 2.00, and 1.86, respectively. The corresponding FIPs were 1.58, 1.44, and 1.32, respectively.

Given these results, presented for each questionnaire as they are published, validated, and intended to be used, we suggest that readers interpret with caution the results and conclusion of Hambly and Griva's work. We particularly raise a cautionary note related to the conclusion that "the IKDC provides the best overall measure of symptoms and disabilities that are most important to this population of postoperative articular cartilage repair patients."

In summary, we find that in this study, 1 of the questionnaires was used in a way never intended, recommended, or validated. When the questionnaire was used as developed, in 5 separate subscales, the data provided do not support the conclusion. Further well-designed research is needed to reach consensus on the preferred outcome measures in cartilage repair in particular and in knee surgery in general.

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Authors' Response: We thank the authors of the letter for their interest in our article and for their considered comments to which we appreciate the opportunity to respond.

The major concern of the authors of the "Letter to the Editor" was that the Knee Injury and Osteoarthritis Outcome Score (KOOS)<sup>6</sup> was used in a way that it was never intended or recommended to be used. We believe that the authors of the letter misapprehended the focus of our study, as we did not and never did intend to use the KOOS as an outcome measure, but rather we evaluated the symptoms and disabilities within the KOOS items that were most important to postoperative articular cartilage repair patients.

It has been recommended that "for the purpose of outcomes research, patient-friendly and self-administered questionnaires proven valid to assess the patient's perspective should be used."<sup>4</sup> On the basis of a review of recent outcome studies of articular cartilage repair procedures, we identified the International Knee Documentation Committee (IKDC) subjective form<sup>2</sup> and the KOOS as being frequently used patient-reported outcome measures (page 1696). At the time of our study, neither the KOOS nor the IKDC had been proven valid to assess the patient's perspective for postoperative articular cartilage repair. We extracted symptoms and disabilities from items from the KOOS and IKDC as per a previously published methodology that evaluated the subjective portions of 11 knee-specific instruments for 3 populations—ACL ruptures, isolated meniscal tears, and osteoarthritis.<sup>6</sup>

We hope that we demonstrated in our article that the KOOS is a standardized instrument that is widely used and has been validated in several orthopaedic populations (page 1697). We are aware that the KOOS was not intended to be used as a total score as demonstrated by the fact that we cited this as 1 of the differences between the IKDC and KOOS in our article when we stated that "in contrast to the IKDC, in which the items are summed to produce a single index, the KOOS has separate scores for different health dimensions" (page 1697). However, we wanted to compare the results from our population with those in the Tanner et al<sup>6</sup> article. As the authors of that study analyzed the KOOS items as a total score,<sup>6</sup> we did the same, but, pertinently, we also undertook additional analyses of the symptoms and disabilities included in each of the KOOS subscales.

We did not seek to create another version of an outcome measure. We sought to provide an insight into the importance of the symptoms and disabilities contained within items from 2 existing outcome measures (KOOS and IKDC) for a population of people who had undergone articular cartilage repair of the knee. Although validated in several orthopaedic populations, the KOOS has not, to date, been validated for an articular cartilage repair population. Our study evaluated aspects of the face validity<sup>1</sup> of each of the instruments for the "typical" articular cartilage repair patient. On the basis of the results of our study, we agree with the authors that the profile of a typical articular cartilage repair patient is one that is frequently associated with concomitant injuries and surgical procedures. The authors stated that "it is unclear if the outcome measure data reflect the outcome of the chondral repair, the concomitant surgical procedure, or a combination of

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both." The data presented in our article reflect the symptoms and disabilities that people who have undergone articular cartilage repair procedures find important to them at their respective individual postoperative times. At no point were we looking to evaluate the outcome of a chondral repair procedure, and this point was made very clearly in our article in the first sentence under "Participant Recruitment" (page 1697). We valued Bruce Reider's insightful editorial comments<sup>3</sup> and concur that although the worth of considering the patients' perspectives by evaluating what is important to them in the present is acknowledged, there is an onus on clinicians to evaluate longer term health outcomes after knee surgery.

The authors state that "the absence of confidence intervals combined with the small sample size of this study limits our ability to draw conclusions and makes it very difficult to interpret the relevance of these differences, at least from a statistical perspective." We agree that not including confidence intervals was an omission on our behalf and thank the authors for highlighting this point. We have addressed this issue in providing the confidence intervals for the mean importance rankings and mean frequency important products in Table 1. The fact that none of the lower limits of the ranges were less than 1 and that the ranges are narrow (especially for the KOOS function in sports/recreation and knee-related quality of life subscales) provides statistical confidence to support the conclusions that we have drawn.

Finally, we did not suggest that the KOOS was inappropriate for our population, but we did highlight that some subscales were viewed by our participants as being more pertinent than were others. Our article clearly indicated in the "Results" section of the abstract (page 1695) that 2 of the KOOS subscales scored higher on mean importance ranking and frequency important product than did the overall IKDC score. However, overall the percentage of items that were experienced by patients were consistently higher for the IKDC compared to the KOOS (Table 3, page 1701), and symptoms and disabilities from 3 of the 5 KOOS subscales were not viewed as being as important to our population (Table 4, page 1701).

We recognize that there was an error in our article where we stated that higher KOOS scores signified worse functioning, as this should have read that lower KOOS scores signified worse functioning. The authors stated that the presence of this error means that readers need to use caution in interpreting the results of our study. This is not the case as we only referred to the KOOS scoring system in the overview of the instrument, and we never used the KOOS scoring system in our methodology. This error, although regrettable, has no bearing on the interpretation of the results of our study.

In summary, from a clinical utility perspective, the IKDC did provide the best overall measure of symptoms and disabilities that were the most important to this population of postoperative articular cartilage repair patients. Our interpretation of our results was based on the fact that the IKDC contained the highest number of items with symptoms and disabilities that not only were experienced but also were seen as being important by this group of patients. We are in agreement with the authors that further research is needed on patient-reported outcome measures in cartilage repair.

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······································		Mean MIR			Mean FIP	
Instrument	Mean	SD	95% CI	Mean	SD	95% CI
IKDC items overall	2.81	0.74	2.62-3.00	2.35	0.83	2.14-2.56
KOOS items overall	2.31	0.85	2.09-2.53	1.81	0.99	1.55-2.07
KOOS subscales						
Pain ,	2.16	0.66	1.99-2.33	1.58	0.80	1.37-1.79
Other symptoms	2.00	0.47	1.88-2.12	1.44	0.59	1.29-1.59
Function in daily living	1.86	0.61	1.7-2.02	1.32	0.60	1.17-1.47
Function in sports/recreation	3.44	0.21	3.39-3.49	3.09	0.25	3.03-3.15
Knee-related quality of life	3.72 .	0.25	3.66-3.78	3.57	0.29	3.50-3.64

 
 TABLE 1

 Mean MIR and Mean FIP for All Items in IKDC, Overall KOOS, and KOOS Subscales for the Total Cohort With 95% Confidence Intervals<sup>a</sup>

<sup>°</sup>CI, confidence interval; FIP, frequency importance ranking; IKDC, International Knee Documentation Committee; KOOS, Knee Injury and Osteoarthritis Outcome Score; MIR, mean importance ranking.

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APPENDIX 3: Paper III – IKDC or KOOS: Which one captures symptoms and disabilities most important to patients who have undergone initial anterior cruciate ligament reconstruction?

# **IKDC** or **KOOS**

# Which One Captures Symptoms and Disabilities Most Important to Patients Who Have Undergone Initial Anterior Cruciate Ligament Reconstruction?

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Background: Knee-specific patient-reported outcome measures are frequently used after anterior cruciate ligament reconstruction but little is known about whether they measure outcomes important to patients.

Purpose: The aim of this study was to identify which instrument, the Knee injury and Osteoarthritis Outcome Score (KOOS) or the International Knee Documentation Committee Subjective Knee Form (IKDC), captures symptoms and disabilities most important to patients who have undergone initial anterior cruciate ligament reconstruction.

Study Design: Cross-sectional study; Level of evidence, 3.

Methods: Data were collected from 126 participants of an Internet knee forum. A self-reported online questionnaire was developed consisting of demographic and surgical data, the Tegner Activity Scale, and 49 consolidated items from the KOOS and the IKDC. Item importance, frequency, and frequency-importance product were calculated.

**Results:** Seventy-eight percent of the items from the IKDC were experienced by more than half of the patients, compared with 57% from the KOOS. Items extracted from the Function in Sports/Recreation and Quality of Life KOOS subscales were highly important to this group of patients. For patients 12 months or more after anterior cruciate ligament reconstruction, 94% of the IKDC items had a frequency-importance product of 1 or less compared with 86% of the KOOS items.

**Conclusion:** Overall, the IKDC items outperformed the KOOS items on all of the 5 criteria with the exception of the frequencyimportance product for patients who were 12 months after anterior cruciate ligament reconstruction. The KOOS Function in Sports/Recreation and Knee-Related Quality of Life subscales outperformed the IKDC for the total cohort as well as for male and female subgroups. However, differences in individual items were not always evident from either total scale or subscale ratings. Studies should use patient-reported outcomes that reflect patients' most important concerns and further prospective longitudinal research is required in this area.

Keywords: Knee injury and Osteoarthritis Outcome Score (KOOS); International Knee Documentation Committee Subjective Knee Form (IKDC); outcome measures; anterior cruciate ligament (ACL) reconstruction; knee ligament; patient-reported outcome

Anterior cruciate ligament (ACL) reconstruction is one of the most common knee surgical procedures performed in sports medicine. Consistently good patient outcomes are now reported as a result of the extensive research that has taken place on the surgery and rehabilitation for ACL reconstruction over the past 20 years.<sup>44</sup> However, clinician-based

The American Journal of Sports Medicine, Vol. 38, No. 7 DOI: 10.1177/0363546509359678 © 2010 The Author(s) outcomes such as instrumented laxity testing and arthrometric measurements have not been shown to correlate well with patient-reported outcomes (PROs) such as patient satisfaction or subjective function.<sup>20,24,33</sup> One study by Kocher et al<sup>24</sup> analyzed determinants of outcome after ACL reconstruction and found that, although some specific surgical and objective variables were important, it was actually the subjective variables of symptoms and function that had the most robust associations with patient satisfaction. Consequently, clinical measures such as laxity are invaluable in the assessment of outcome after ACL reconstruction yet they do not provide all of the answers explaining patients' recovery, rehabilitation, and postoperative functioning.

A review of 197 articles reporting on clinical outcome of the ACL-deficient knee identified over 54 different

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outcome measures in use,<sup>22</sup> highlighting the need for further research in the area of ACL outcome measures. The recent recognition of the patient as the major stakeholder in modern health care has given rise to an increased trend in the use of PRO measures. It has been stated that for an outcome measure to be truly valid, it needs to reflect patients' perceptions by describing the effect of a condition on the aspects of patients' lives that they consider to be of greatest importance.<sup>45</sup> Consequently, a valid PRO for ACL reconstruction should have a high percentage of items that are perceived to be of relevance to this patient group as determined by their individual needs, priorities, and preferences.<sup>8,19,29</sup>

Seven major categories of PRO measures have been identified, including site-specific and disease/conditionspecific PRO measures.<sup>11</sup> Disease/condition-specific PRO measurement categories for knee ligament injury include the Cincinnati Knee Ligament Rating Scale and the Lysholm Knee Scoring Scale.<sup>54</sup> Current literature proposes that disease/condition-specific PRO measures may be too focused to allow for comparisons between studies.<sup>57</sup> For this reason, funding and regulatory agencies are increasingly requesting the inclusion of general and site-specific PRO measures alongside disease/condition-specific PRO measures to allow comparisons across different populations or conditions.<sup>11</sup> Two commonly used site-specific PRO instruments for the knee are the International Knee Documentation Committee Subjective Knee Form (IKDC)<sup>21</sup> and the Knee injury and Osteoarthritis Outcome Score (KOOS).42

The IKDC has been used to assess outcome in recent clinical studies on ACL reconstruction<sup>2,24,31,33,35,46,52</sup> and is one of the most frequently used PRO measures for patients with ACL deficiency.<sup>22</sup> The KOOS is a newer PRO measure that was developed in Sweden and is increasingly being used in clinical studies on ACL reconstruction, especially in Europe.  $^{26,27,32,33,52,56}$  Only a few studies to date have used both the IKDC and the KOOS for assessing ACL deficiency. One recent study used the IKDC and the KOOS for patients with nonreconstructed ACL injuries,<sup>25</sup> while an earlier study used the IKDC and the KOOS for ACL-injured patients reconstructed with artificial ligaments.33 Pertinently, neither of the studies either presented a rationale for why both the IKDC and the KOOS were used nor did they subsequently directly analyze or explore the relationship between the results of the IKDC and the KOOS. With the emergence of new national and international directives and regulations on clinical trials<sup>28</sup> and the call for standardization of outcome measurement in orthopaedics,<sup>38</sup> there is a growing need for further evaluation of presently utilized PRO measures.

The aim of the current study was to identify which instrument, KOOS or IKDC, captures symptoms and disabilities most important to patients who have undergone initial ACL reconstruction. Postoperative recovery and rehabilitation after ACL reconstruction is an active process and as such the focus of this investigation was on evaluating process variables across the spectrum of postoperative time scales rather than final clinical end points.

# METHODS

# The Instruments

International Knee Documentation Committee Subjective Knee Form (IKDC). The IKDC is a site-specific instrument that was designed to measure symptoms, function, and sports activity in patients who have 1 or more of a variety of knee conditions including ligament, meniscal, articular cartilage, arthritis, and patellofemoral pathologies.<sup>21</sup> The original instrument was developed by an international committee in 1987 and the Subjective Knee Form was subsequently added in 2000.<sup>21</sup>

The instrument consists of 18 items related to symptoms, function, and sports activity and is able to differentiate patients with higher levels of knee symptoms and lower levels of function.<sup>3</sup> The IKDC is scored by calculating the difference between the raw score and lowest possible score and then dividing this difference by the range of possible scores multiplied by  $100.^{21}$  Items are summed to produce a single index, with higher scores denoting greater levels of function and lower knee symptoms. This method of scoring weights each item according to the number of response options.

Normative data for the IKDC have been established for the United States population for age and gender.<sup>3</sup> Women have been found to exhibit lower mean scores than men. It has been recommended that studies with patients younger than 18 years or  $\geq$ 35 years of age should adjust the Subjective Knee Form scores for age difference for both men and women.<sup>3</sup> The IKDC has been shown to have an internal consistency of 0.92 and a test-retest correlation of 0.94<sup>12</sup> and has been validated for an ACL reconstruction population.<sup>40</sup>

Knee injury and Osteoarthritis Outcome Score (KOOS). The KOOS is a site-specific instrument that was developed with the purpose of evaluating short-term and long-term symptoms and function in patients with a variety of knee injuries that could possibly result in osteoarthritis.42 The instrument is based on an extension of the disease-specific Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>5</sup> The KOOS comprises 42 items within 5 separately scored subscales: Pain (9), other Symptoms (7), Function in Daily Living (ADL) (17), Function in Sport and Recreation (Sport/Rec) (5), and Knee-related Quality of Life (QoL) (4). In contrast to the IKDC in which the items are summed to produce a single index, the KOOS has separate scores for different health dimensions, with lower scores signifying worse functioning in these areas. Importantly, the KOOS is one of the few patient-assessed knee-specific instruments where patients have been involved in the derivation of the items.

The KOOS has been validated for ACL reconstruction,<sup>42</sup> and population-based reference data for age and gender in an adult population have also been established.<sup>37</sup> The KOOS has been" shown to have an internal consistency between 0.71 and 0.95 and a test-retest correlation of 0.75 to 0.93.<sup>42</sup>

The Tegner Activity Scale. The Tegner Activity Scale (TAS) was included as it is the most widely used activity

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	S	ample Question:	Knee is painful		
Not experienced	Experienced but not important	Experienced and a little important	Experienced and moderately important	Experienced and very important	Experienced and extremely important
0	1	2	3	4	5

Figure 1. Sample question and Likert scale used in the study questionnaire.

scoring system of activity level for patients with knee disorders<sup>6</sup> and has been tested for validity in an ACL injury population.<sup>55</sup> The instrument scores a person's activity level between 0 and 10, where 0 is "on sick leave/ disability" and 10 is "participation in competitive sports such as soccer at a national or international elite level."

# **Demographic Data**

The demographic data that were used to describe the study cohort were self-reported date of birth and gender.

# Surgical Data

Surgical data comprised self-reported responses for type of ACL reconstruction surgery, month and year of ACL reconstruction surgery, and concomitant procedures.

# Development of the Study Questionnaire

The online questionnaire was developed per the methodology of Hambly and Griva<sup>16</sup> using the questionnaire activity module (version 2005062701) of Moodle (version 1.5.3). Moodle is an open-source software package designed using pedagogical principles to help educators create effective online learning communities (http://moodle.org). The questionnaire activity module is based on phpESP (an opensource online survey support application) and is a tool to create surveys. The responses from the questionnaire were stored anonymously using numeric reference identification numbers and exported as comma-separated value files for analysis.

A questionnaire of 57 items was developed that included 7 items related to demographic and surgical information; 49 items were consolidated from the IKDC and the KOOS (7 items from IKDC, 31 items from KOOS, and 11 items in both KOOS and IKDC [ie, item overlap]) and the TAS. In line with the study by Tanner et al,<sup>54</sup> double-barreled items were separated into 2 items and questions on the IKDC were changed to the present tense rather than the standard "during the past 4 weeks."

Participants were asked to rate the importance of a described symptom or disability using a 6-point Likert scale<sup>30</sup> as shown in Figure 1. The final questionnaire was pretested in a small sample of non-ACL reconstruction knee patients and orthopaedic colleagues for explanation of purpose, clarity of questions, and ease of completion before it was transferred to an online environment. The transfer of PRO instruments from a paper to electronic administration environment has been shown to be acceptable practice.<sup>15</sup>

# Participant Recruitment

The focus of this study was to assess which instrument best measured symptoms and disabilities important to ACL reconstruction patients and not the effectiveness of any 1 surgical procedure. Within this context, the inclusion criteria for participation was an individual who had undergone initial ACL reconstruction of the knee rather than a specific type of graft procedure.<sup>1</sup> No specific inclusion requirements were set related to time elapsed since ACL reconstruction to ensure that the recruited sample captured the course/spectrum of postoperative experience. This approach was adopted because the focus of the investigation was on evaluating process variables rather than final clinical end points. All ACL reconstruction revisions and multiple ligament repairs were excluded. The study received ethics committee approval as part of a larger doctoral research study.

Participants were recruited from the KNEEguru Web site (http://www.kneeguru.co.uk). The KNEEguru Web site is a resource for people with knee problems with over 22000 registered members from across the world. The Web site is based around a dynamic online forum for which individuals have to register to allow interactivity. Potential participants were invited to participate in the study via postings in the ACL reconstruction section of the KNEEguru online forum. The purpose and aims of the study and the role of the participants were included in the invitation as per established guidelines for online research.<sup>7</sup> Self-registration to the study and selfsubmission of the questionnaire was taken as consent to participate. Data collection took place between July and December 2008. Access to the questionnaire was via a Uniform Resource Locator (URL) link and participants used a generic account set up specifically for the survey. Data were only saved to a secure server if participants chose to submit the questionnaire. Stored data for each submitted questionnaire were linked to a unique response identification number.

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	TABLE 1           Postoperative Patient Infor	mation	
	Total	Males	Females
Number	126	61	65
Mean age at time of surgery, years (range) <sup>a</sup>	32.58 ± 9.70 (14-59)	31.60 ± 8.77 (16-59)	33.49 ± 10.48 (14-53)
Mean time from surgery, months (range) <sup>a</sup>	10.96 ± 14.54 (0-114)	$12.22 \pm 17.94 (0-114)$	$9.78 \pm 10.42 (0.48)$
Median Tegner Activity Scale score (range) <sup>b</sup>	4.0 (0-10)	5.0 (0-10)	4.0 (0-9)

<sup>a</sup>No significant difference between males and females ( $P \ge .05$ ).

<sup>b</sup>Significant difference between males and females (P < .05).

# Data Analysis

All data collected via the online questionnaire were imported into a customized database. The statistical analysis was performed with SPSS for Windows 14.5 software package (SPSS Inc, Chicago, Illinois). Nonparametric analyses were selected based on the data not being normally distributed and the data categories being predominantly ordinal format.

The data were summarized using descriptive statistics. Medians and ranges were calculated for ordinal data but means and standard deviations were also calculated to make comparisons with previous research.<sup>64</sup> A series of correlations were carried out using the Spearman rho to identify any potential relationships between demographic factors and items ratings. The Mann-Whitney *U* test was used to compare data between participant subgroups based on age, graft type, concomitant surgery, and time elapsed since ACL reconstruction. Significance levels were set at P < .05.

In accordance with Tanner et al<sup>54</sup> and prior recommendations for the development of quality of life questionnaires, a clinical impact methodology was adopted.14,23 The item frequency was recorded as the number of patients who listed the item as a problem (maximum 126). The importance ranking was recorded as the value of each item on a Likert scale from 0 to 5, where 0 was not experienced and 5 was experienced and extremely important (Figure 1). The individual patient ranking (IPR) was calculated as the mean ranking of items for each patient. The IPR indicates the mean importance of items extracted from each of the PROs and provides a profile of the individual patient. The mean importance ranking (MIR) was recorded as the mean ranking of importance for each item. The clinical impact was expressed as the frequencyimportance product (FIP), where the MIR was multiplied by the proportion of patients experiencing a particular item.<sup>23</sup> It is important to report the MIR alongside the FIP as they represent different constructs. The MIR indicates the average importance across all patients including those patients who did not experience a particular item and provides an overall profile of the population. The FIP takes into account that some patients may not have experienced an item and it therefore provides a more accurate indicator of the clinical impact an item has on a patient who does experience that particular item. A high FIP is an advantage for a health-related quality of life measure as it is an indication that not only is an item frequently experienced but also that it is an important symptom or disability for patients.

In addition to the overall MIR and FIP for each item in the 2 instruments, the MIR and FIP ratings across the items corresponding to the 5 separate KOOS subscales were also calculated. These summary ratings served as indices of the relevance and importance of the subscales in the population—how the particular subscale rather than individual items was perceived and evaluated by respondents. This was not performed for the IKDC as the measure yields 1 overall score.<sup>21</sup>

In accordance with Tanner et al<sup>54</sup> and Hambly and Griva,<sup>16</sup> calculations were also made for the following: (1) the number of items that at least 51% of the patients rated with a value of at least 1 (experienced but not important) on the Likert scale, (2) the number of items that had an MIR of at least 3 (experienced and moderately important) on the Likert scale, (3) the number of items that had an MIR of 1 (experienced but not important) or less on the Likert scale, (4) the number of items that had an FIP of at least 3, and (5) the number of items that had an FIP of 1 or less.

# RESULTS

The online survey was completed by 141 participants, but the responses of 15 participants were excluded as they had either undergone an ACL graft revision procedure or had multiple ligament repairs. The demographics for the remaining 126 participants are shown in Table 1. Data collection was complete aside from 4 participants who incorrectly entered their time of surgery.

The most common reconstruction technique was a semitendinosus-gracilis 4-stranded hamstring autograft (40%), followed by bone-patellar tendon-bone (PT) ipsilateral autograft (32%) and bone-patellar tendon-bone allograft (13%). In total, 58 patients (46%) underwent a concomitant surgical procedure, with the majority of these procedures (69%) comprising meniscal trim/repair.

Two graft subgroups were established, with the first group comprising the hamstring autografts (n = 51) and the second group comprising the PT and quadriceps tendon (QT) ipsilateral autografts (n = 48) (allografts and contralateral autografts were excluded). There was no significant difference between the 2 graft subgroups in age at time of surgery (P = .363), time from surgery (P = .458), TAS scores (P = .067), or age over 35 years at time of surgery

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	TABLE 2		
Results of Mean Importance Ranking,	Experience Frequency, and	Frequency-Importance	Product for the IKDC
	and Overall KOOS <sup>a</sup>		

		IKDC (18 item	s)		KOOS (42 item	s)
	Total	<12 Months Postop	12 Months+ Postop		<12 Months Postop	12 Months+ Postop
No. of items with an MIR of 3 or $more^{b}$	0	3 (17%)	0	0	5 (12%)	0
No. of items with an MIR of 1 or less <sup>b</sup>	3 (17%)	1 (6%)	9 (50%)	17 (40%)	8 (19%)	29 (69%)
No. of items experienced by at least 51% of patients	14 (78%)	15 (83%)	7 (39%)	24 (57%)	33 (76%)	13 (31%)
No. of items experienced by at least 76% of patients	6 (33%)	10 (56%)	0	9 (21%)	14 (33%)	2 (5%)
No. of items with an FIP of at least 3	0	0	0	0	+ 0	0
No. of items with an FIP of 1 or less	8 (44%)	4 (22%)	17 (94%)	26 (62%)	23 (55%)	36 (86%)

<sup>a</sup>IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee injury and Osteoarthritis Outcome Score; MIR, mean importance ranking; FIP, frequency-importance product.

<sup>b</sup>Score on a Likert scale of 0 to 5, with 0 being not experienced and 5 being experienced and very important.

(P = .369). However, there were significant differences in individual item ratings that will be presented later.

When the patients who underwent concomitant meniscal trim/repair (n = 40) were compared with those who did not undergo any concomitant surgery (n = 68), there was a significant difference in age between the groups (Mann-Whitney U = 965.50; P = .016), with the meniscal trim/repair group being younger (mean, 29.2 years; standard deviation [SD], 9.52 years) than those who had no concomitant surgery (mean, 33.8 years; SD, 9.37).

The study cohort comprised 65 females and 61 males, with the patient demographics as shown in Table 1. There was no significant difference between male and female respondents in age at time of surgery (P = .193) or time from surgery (P = .650). Male participants reported a significantly higher mean TAS score compared with female participants (P = .037). Mean TAS scores were also found to be significantly different between patients under 35 years of age (n = 73) and those patients  $\ge 35$  years of age (n = 52) (Mann-Whitney U = 1468.0; P = .030), with the younger patient group exhibiting higher TAS scores.

The Appendix (see online Appendix for this article at http://ajs.sagepub.com/supplemental/) displays the MIRs, frequencies, and FIPs for each item and Table 2 displays the overall MIRs, frequencies, and FIPs for the 2 instruments for the total cohort and 2 postoperative time subgroups. Evaluation of the 2 measures on the 5 set criteria indicates that the IKDC outperformed the KOOS on frequencies, MIR, and FIP ratings.

There were 9 items where significant differences in importance ratings were found between males and females as indicated in the Appendix. The average item MIR was 1.76 for the IKDC (SD = 0.66) and 1.43 for the KOOS (SD = 0.71). The IPR for the KOOS and the IKDC were significantly correlated (rho = .966; P < .001).

# Knee Injury and Osteoarthritis Outcome Score

Inspection of ratings for KOOS individual items showed that the item "often aware of knee problem" exhibited the highest ratings (MIR = 2.88; FIP = 2.49). At the other end of the scale, the KOOS item "lying hurts" exhibited the lowest ratings (MIR = 0.49; FIP = 0.14). The KOOS IPR was significantly correlated with postoperative time (rho = -.537; P < .001).

When the KOOS results were split into the 5 subscales as shown in Table 3, it was evident that the items in the Function in Daily Living (ADL) subscale were neither viewed as being particularly important by this patient cohort (ADL MIR = 0.98) nor were they frequently experienced (ADL FIP = 0.47). In contrast, the subscales of Function in Sports/Recreation and Knee-related QoL were viewed as being more important than Pain, other Symptoms, and Function in Daily Living subscales (Sports/Rec MIR = 2.47; QoL MIR = 2.57) and were more frequently experienced (Sports/Rec FIP = 1.93; QoL FIP = 2.15). Many items in the KOOS, despite being experienced, exhibited a low MIR, with 62% (26 of 42) of the items exhibiting an FIP of 1 or less. However, none of the items in the Function in Sports/Recreation or Knee-related QoL KOOS subscales had an FIP of 1 or less.

The PT/QT ipsilateral autograft group (n = 48) demonstrated a higher overall KOOS IPR than the hamstring autograft group (n = 51) (Mann-Whitney U = 880.5; P = .016), as well as producing higher individual item ratings for 11 of the KOOS items compared with the hamstring autograft group. There were 3 items that were significant at the P < .01 level; these were "kneeling difficult" (Mann-Whitney U = 812.0; P = .003), "often aware of knee problem" (Mann-Whitney U = 750.5; P = .001), and "general difficulty with knee" (Mann-Whitney U = 823.5; P = .004).

Group comparisons between male (n = 61; mean KOOS IPR = 1.22; SD = 0.94) and female (n = 65; mean KOOS IPR = 1.61; SD<sub>\*</sub> = 1.08) patients indicated that female respondents reported higher KOOS item importance ratings relative to their male counterparts (Mann-Whitney U = 1564.5; P = .041). A higher TAS score was significantly associated with a lower IPR for KOOS for both males (rho= -746; P < .001) and females (rho= -.720;

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TABLE 3	
Mean MIR and Mean FIP for All Items in IKDC, Overall KOOS, and KOOS Subscales for the T	otal
Cohort and Male and Female Subgroups <sup>a</sup>	

	Mean MI	R (95% Confidence	e Interval)	Mean FIP (95% Confidence Interval)		
Instrument	All	Male	Female	All	Male	Female
IKDC overall	1.76 (1.64-1.88)	1.51 (1.35-1.67)	1.99 (1.82-2.16)	1.19 (1.08-1.30)	0.99 (0.84-1.14)	1.41 (1.24-1.58)
KOOS overall	1.43 (1.31-1.55)	1.22 (1.05-1.39)	1.62 (1.43-1.82)	0.91 (0.79-1.03)	0.75 (0.59-0.91)	1.09 (0.91-1.27)
KOOS subscales						
Pain	1.07 (0.98-1.16)	0.90 (0.79-1.01)	1.24 (1.11-1.37)	0.58 (0.50-0.66)	0.44 (0.35-0.53)	0.74 (0.63-0.85)
Other symptoms	1.55 (1.47-1.63)	1.36 (1.25-1.47)	1.72 (1.61-1.83)	0.96 (0.88-1.04)	0.82 (0.72-0.92)	1.11 (0.99-1.23)
Function in daily living (ADL)	0.98 (0.92-1.04)	0.79 (0.72-0.88)	1.15 (1.04-1.26)	0.47 (0.42-0.53)	0.33 (0.28-0.38)	0.63 (0.51-0.75)
Function in sports/recreation	2.47 (2.43-2.51)	2.15 (2.08-2.22)	2.76 (2.72-2.80)	1.93 (1.89-1.97)	1.65 (1.58-1.72)	2.19 (2.16-2.22)
Knee-related quality of life	2.57 (2.50-2.64)	2.36 (2.25-2.47)	2.77 (2.67-2.87)	2.15 (2.07-2.23)	1.96 (1.83-2.09)	2.34 (2.22-2.46)

<sup>a</sup>IKDC, International Knee Documentation Committee Subjective Knee Form; KOOS, Knee injury and Osteoarthritis Outcome Score; MIR, mean importance ranking; FIP, frequency-importance product.

P < .001). The KOOS IPR was significantly inversely correlated with postoperative time for both males (rho= -.484; P < .001) and females (rho= -.563; P < .001). There was not a significant correlation for the KOOS IPR and age at the time of surgery for males (rho = .154; P = .242) or females (rho = .045; P = .725).

# International Knee Documentation Committee Subjective Knee Form

The MIRs and FIPs (see online Appendix for this article at http://ajs.sagepub.com/supplemental/) indicated that the majority of the IKDC items were both frequently experienced and perceived to be important. Of the 18 items in the questionnaire, the item "kneeling is difficult" received the highest MIR rating (2.74) and the highest FIP rating (2.24). The item that scored lowest for both MIR (0.55) and FIP (0.17) was "sitting difficult." The IKDC IPR was significantly negatively correlated with postoperative time (rho = -.554; P < .001).

The PT/QT ipsilateral autograft group (n = 48) demonstrated a higher overall IKDC IPR than the hamstring autograft group (n = 51) (Mann-Whitney U = 867.0; P =.012). In addition, the PT/QT ipsilateral autograft group produced significantly higher individual item ratings for 7 of the IKDC items compared with the hamstring autograft group. These items were "knee stiff" (Mann-Whitney U = 1075.0; P = .021), "kneeling difficult" (MWU = 812.0; P = .003), "knee limits daily activities" (Mann-Whitney U = 887.0; P = .014), "knee pain limits strenuous activities" (Mann-Whitney U = 914.5; P = .026), "swelling limits strenuous activities" (Mann-Whitney U = 913.0; P = .019), "giving way limits strenuous activities" (Mann-Whitney U = 898.0; P = .009), and "difficult to participate in strenuous activities on a regular basis" (Mann-Whitney U =758.0: P = .001). There was no significant difference in ratings for the remaining IKDC items between the 2 graft subgroups.

Group comparisons between male (n = 61; mean IKDC IPR = 1.51; SD = 1.11) and female (n = 65; mean IKDC IPR = 1.99; SD = 1.32) indicated that female respondents

reported significantly higher IKDC item importance ratings than their male counterparts (Mann-Whitney U = 1578.5.0; P = .049). A higher TAS score was significantly associated with a lower IPR for IKDC for both males (rho= -.749; P < .001) and females (rho= -.716; P < .001). The IKDC IPR was significantly inversely correlated with postoperative time for both males (rho = -.469; P < .001) and females (rho = -.590; P < .001). There was not a significant correlation for the IKDC IPR and age at the time of surgery for males (rho = .078; P = .557) or females (rho = .039; P = .760).

# DISCUSSION

Modern health care acknowledges that the patient is a key stakeholder, and individual assessment of their outcome has increasing clinical and economic implications. In response to this paradigm shift, there has been an enhanced expectation for clinicians to focus assessment of outcome after surgical intervention on patient-derived subjective assessment of symptoms and function. The present study was designed to examine the extent to which items extracted from 2 commonly used knee-specific PRO instruments assess symptoms and disabilities that are experienced and seen as being important by patients who have undergone initial ACL reconstruction.

Tanner et al<sup>54</sup> published the first study to compare the ability of knee-specific health quality of life instruments to detect symptoms and disabilities that are important to patients with ACL tears. They found that 72% of the items in the IKDC were endorsed by at least 51% of patients compared with only 45% for the KOOS.<sup>54</sup> In addition, they found that 6 items in the IKDC had an MIR of 1 or less compared with 9 items from the KOOS<sup>54</sup> in comparison with this study, where there were only 3 items in the IKDC with an MIR of 1 compared with 17 items from the KOOS (Table 2). These differences may be a reflection of the smaller sample size (58 patients) in the study by Tanner et al and the fact that the sample was a combination of preoperative (16) and postoperative (42) patients with no

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mean postoperative times reported. In comparison with an articular cartilage repair population, individuals who have undergone ACL reconstruction tend to experience fewer symptoms and disabilities and when they do, the level of their importance is perceived as being lower.<sup>16</sup>

Overall, for the 5 criteria the IKDC items outperformed the KOOS items for the whole cohort (Table 2) and gender (Table 3) subgroups. However, when comparisons were performed for each of the different KOOS subscales in line with the instrument's scoring instructions, a different picture emerged, with those items extracted from the KOOS subscales of Function in Sports/Recreation and Knee-related QoL outperforming the IKDC for the total cohort and male and female subgroups, suggesting that these 2 subscales are particularly pertinent to ACL patients' postoperative experience and possibly their agenda for seeking reconstructive surgery. It is also interesting to note that those items extracted from the "other Symptoms" KOOS subscale outperformed both the Pain and the Functions in Daily Living subscales. This is in contrast to the articular cartilage repair population, where items extracted from the KOOS Pain subscale were seen to be more important as well as more frequently experienced than the items extracted from the KOOS subscale for other Symptoms.<sup>16</sup> It is likely that differences in the surgery and rehabilitation between articular cartilage repair and ACL reconstruction may at least partially explain this observation. This reinforces the need for careful consideration in the selection of a PRO measure based on the patient population under investigation.

Literature reviews have suggested that successful outcome after ACL reconstruction is not primarily determined by graft type.<sup>18,49,51</sup> A recent study comparing 2-year outcomes between patellar tendon and hamstring tendon ACL reconstruction grafts found no significant group differences in any of the KOOS subscales.<sup>17</sup> The composite results from this study support this view as there was no significant correlation between either IKDC or KOOS IPR and graft type. However, when individual items were considered, it was found that there were significant differences between PT/ QT ipsilateral autografts and hamstring ipsilateral autograft groups for a number of items. Given the surgical technique, it is not surprising that individuals who have either an ipsilateral PT or QT autograft ACL reconstruction experience problems kneeling and that the item "kneeling is difficult" was rated significantly higher by the PT/QT ipsilateral autograft group compared with the hamstring ipsilateral autograft group. Although this analysis was not the main focus of the study, the results do highlight the fact that differences in surgical procedure may not significantly influence overall PRO measures but may influence individual items within a PRO, resulting in variations in the clinical impact on the patient.

The mean age for the cohort in this study was a few years higher than in other studies but the age range and ratio of male to females was comparable.<sup>9,13,24</sup> Previous research has indicated that age does not influence outcome when evaluated with the KOOS<sup>53</sup> and that age is not a factor in outcome<sup>34</sup> and consequently should not be considered in isolation when advising patients on ACL reconstruction outcome.<sup>50</sup> This was supported by the results of this study, as age at time of surgery was not significantly correlated with the overall composite score for the IKDC, the KOOS subscale scores, or any of the individual items.

There is more diversity in the literature regarding the influence of gender on outcome after ACL reconstruction. One study found no difference in functional outcome between males and females as measured by overall Lysholm knee score,47 while another found no differences between males and females on the ACL QoL scale at an average of 5 years after ACL reconstruction.<sup>36</sup> In contrast, Swirtun and Renstrom<sup>53</sup> found that female patients experienced more problems than males as measured by the KOOS. This study concurs with the results of Swirtun and Renstrom in finding that female participants in the study reported higher MIR and FIP ratings than their male counterparts for both KOOS and IKDC (Table 3). However, there were also gender differences in individual item ratings (see online Appendix for this article at http://ajs.sagepub.com/supplemental/) and it would appear that using composite scales might mask gender differences in individual item ratings. Future research is warranted to explore gender-related differences in functional outcomes using a triangulation of different methods and instruments.

The validity of the KOOS for an ACL reconstruction population was recently evaluated using Rasch analysis where it was found that only the Knee-related QoL and Function in Sports/Recreation subscales exhibited unidimensionality.<sup>9</sup> The authors found that the Pain and other Symptoms subscales measured 1 common overall construct rather than separate distinctive constructs and concluded that the KOOS was not a valid instrument for functional assessment of individuals with a recent ACL reconstruction (20 weeks postoperatively).9 The findings of the current study complement these results in that items extracted from the KOOS Pain subscale and KOOS ADL subscale are neither widely experienced nor perceived as being important by ACL reconstruction patients. The results of the KOOS other Symptoms subscale indicates that these items are more frequently experienced than the Pain and ADL subscale items but are still not rated particularly highly in importance. The finding that some symptoms may be prevalent in this population yet not be perceived as significant by the patients reinforces previous findings on the importance of  $PRO.^{23,29}$  This clearly suggests that in evaluating the postoperative symptomatic experience, one needs to consider not just the prevalence or frequency of symptoms in terms of objective symptom count but also perceived severity or disruption or burden associated with those symptoms at various postoperative time points.

Clinical expectations after ACL reconstruction are for a return to full activity at 5 to 6 months,<sup>10</sup> with a typical return to risk activities by 12 months postoperatively,<sup>27</sup> although it should be noted that there is interindividual variation across\_patients. Study findings indicated that this might be an important parameter in patients' judgments of the items.<sup>27</sup> Overall, it has been found that items extracted from the IKDC and KOOS were more relevant to patients' experience when they were less than 12 months after surgery. More than half of those patients who were

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less than 12 months from surgery experienced over threefourths of the items extracted from the IKDC (83%) and the KOOS (76%). This is in comparison with those patients who were 12 months or more postoperative, where more than half of the patients only experienced 39% (IKDC) and 31% (KOOS) of the items. The FIPs of the items from the instruments were both low in the group of patients who were 12 months or more postoperative, with 94% of items from the IKDC rated as either not experienced or experienced but not important compared with 86% of items from the KOOS. This pattern of results in frequency ratings was expected, as symptom experience and burden diminish with postoperative time.<sup>24,48</sup>

Initial comparisons of patients' ratings across the 2 instruments demonstrated a trend for the KOOS items to perform better as postoperative time increased compared with the IKDC, albeit performance on the 5 set criteria were not radically different. Combined with the knowledge that radiographic signs of osteoarthritis develop in 50% of patients with ACL injury regardless of treatment, <sup>4</sup> there is the suggestion that the KOOS may be more appropriate for the assessment of patients in the longer run as, unlike the IKDC, it incorporates the WOMAC. <sup>5,43</sup> More studies are necessary to explore the association of time interval (short-, medium-, or long-term) since surgery and patients' ratings and their perception of the symptoms and functions most pertinent and important in the long-term postoperative period.

A number of potential confounding variables were not evaluated in this study including symptom duration, preinjury/presurgery activity levels, rehabilitation compliance, postoperative knee laxity, cultural differences, and body mass index. The findings of this study should be considered in the light of several potential limitations. First, the sampling for this study was via self-reporting from an Internet knee forum. However, the profile of items from the KOOS subscales of the sample and demographics were found to be comparable with other ACL reconstruction studies.<sup>41,42</sup> Second, the study design was cross-sectional and as such it has not been possible to evaluate the sensitivity or responsiveness of the items from either of the PRO measures over time. This is an important clinical issue as, while the worth of considering the patient's perspective by evaluating what is important to them in the present has been acknowledged, there is an onus on clinicians to evaluate longer term health outcomes after knee surgery.

Future prospective, longitudinal studies are warranted to evaluate how subjective ratings of frequency and importance of symptoms change across short- and long-term postoperative periods in patients after ACL reconstruction. It is also necessary to determine to what degree patientimportant outcomes clinically affect longer term functional status and satisfaction after surgical interventions such as ACL reconstruction. This information has important implications for patient management.

# CONCLUSION

The IKDC and the KOOS are both PRO measures that are increasingly being used for ACL reconstruction, but do

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their items measure outcomes important to patients? The present study was designed to examine the extent to which items extracted from the KOOS and the IKDC capture symptoms and disabilities that are not only experienced by, but are also seen as being important to, patients who have undergone initial ACL reconstruction.

Overall, the IKDC items outperformed the KOOS items on all of the 5 established criteria with the exception of patients who were 12 months after ACL reconstruction, where the KOOS had a lower proportion of items with an FIP of 1 compared with the IKDC. When the items extracted from the KOOS subscales were evaluated, the subscales of Function in Sports/Recreation and Kneerelated QoL outperformed the IKDC for the total cohort as well as for male and female subgroups. However, differences in individual items were not always evident from either total scale or subscale ratings.

There is not a direct answer as to which of the PRO measures captures symptoms and disabilities that are most important to patients who have undergone initial ACL reconstruction. The selection of a PRO measure needs to be based on the target population and the appropriateness to the study aims. Studies should use PROs that reflect patients' most important concerns; however, when time completion requirements and respondent burden are an issue, the brevity of the PRO measure is an important consideration. For those clinicians and researchers considering using only the IKDC as their patient PRO measure for ACL reconstruction, we suggest including as a minimum the KOOS Knee-related QoL subscale as, based on our findings from this study, the 4 items within this subscale are the ones that are most important to patients who have undergone ACL reconstruction and these items are not fully represented in the IKDC.

Further prospective longitudinal research is required to assess the clinical effect of the postoperative process and to evaluate these findings with respect to clinical and functional outcome prediction and long-term health prognostics.

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Appendix: Mean Importance Ranking, Item Frequency of Experience and Clinical Impact (FIP) for Each Item \*

Item Description	Instrument	Mean Importance Ranking (median; range)	Item Frequency of Experience (max 126)	Clinical Impact (FIP)
Knee is painful	IKDC & KOOS	1.72 (1:0-5)	98	1.34
Knee is stiff	IKDC	2.10 (2:0-5)	101	1.69
Knee is swollen	IKDC & KOOS	1.56 (1:0-5)	80	0.99
Knee stiff after first waking in morning	KOOS	1 75 (1:0-5)	84	1 17
Knee stiff after sitting, lying or resting later in the	KOOS	2.06 (1:0-5)	98	1 60
day		2.00 (1,0-0)		1.00
Knee locks, catchs or hangs up when moving	IKDC & KOOS	0.84 (0;0-5)	51	0.34
Knee grinds, grates or clicks when your knee moves	KOOS	1.49 (1;0-5)	86	1.02
Can't straighten knee fully	KOOS	1,18 (0:0-5)	51	0.48
Can't bend knee fully	KOOS	1.93 (1:0-5)	74	1.13
Twisting/pivoting on knee is painful	KOOS	1.60 (1:0-5)	81	1.03
Straightening knee fully hurts	KOOS	1.08 (0:0-5)	60	0.51
Bending knee fully hurts	KOOS	1.89 (1:0-5)	81	1.21
Walking on a flat surface hurts *	KOOS	0.54 (0:0-5)	39	0.17
Going up stairs hurts **	KOOS	1.01 (0:0-5)	61	0.49
Going down stairs hurts **	KOOS	1.21 (1:0-5)	68	0.65
Knee hurts at night when in bed	KOOS	0.67 (0:0-5)	41	0.22
Sitting hurts	KOOS	0.69 (0:0-5)	45	0.25
Lving hurts	KOOS	0.49 (0:0-5)	36	0.14
Standing hurts	KOOS	0.89 (0:0-5)	58	0.41
Going down stairs is difficult **	IKDC & KOOS	1.44 (1:0-5)	71	0.81
Going up stairs is difficult **	IKDC & KOOS	1.14 (1:0-5)	65	0.59
Rising from sitting is difficult **	IKDC & KOOS	1:00 (1:0-5)	65	0.52
Standing is difficult	KOOS	0.73 (0:0-5)	51	0 30
Bending to the floor is difficult	KOOS	1.49 (1:0-5)	78	0.92
Walking on a flat surface is difficult	KOOS	0.57 (0:0-5)	41	0.19
Getting in/out of car is difficult	KOOS	1 00 (1:0-5)	64	0.51
Going shopping is difficult	KOOS	0.96 (0:0-5)	47	0.36
Putting on and taking off socks is difficult	KOOS	0.94 (0:0-1)	58	0.43
Lying in bed and maintaining knee position is difficult	KOOS	0.84 (0;0-5)	52	0.35
Getting in/out of bath is difficult	KOOS	0.89 (0:0-5)	52	0.37
Sitting is difficult	IKDC & KOOS	0.55 (0.0-5)	39	0.17
Getting on/off toilet is difficult	KOOS	0.62 (0:0-5)	42	0.21
Heavy domestic duties are difficult *	KOOS	1.63 (1:0-5)	76	0.99
Light domestic duties are difficult	KOOS	0.85 (0:0-5)	45	0.30
Squatting is difficult *	IKDC & KOOS	2 19 (2:0-5)	100	1.74
Running is difficult *	IKDC & KOOS	2.44 (2:0-5)	92	1.78
Jumping is difficult	IKDC & KOOS	2.59 (3:0-5)	96	2.01
Stopping and starting quickly is difficult	IKDC	2.30 (2:0-5)	98	1.75
Twisting/pivoting on knee is difficult	KOOS	2.39 (2:0-5)	49	1.86
Kneeling is difficult	IKDC & KOOS	2.74 (3:0-5)	103	2.24
Lack of confidence in knee	KOOS	2.75 (3:0-5)	111	2.42
Often aware of knee problem	KOOS	2.88 (3:0-5)	109	2.49
Modified lifestyle to avoid activities that are	KOOS	2 70 (3:0-5)	105	2.25
potentially damaging to knee				
General difficulty with knee	KOOS	1.96 (2:0-5)	93	1.45
Knee limits daily activities	IKDC	2.00 (1:0-5)	76	1.21
Knee pain limits strenuous activities	IKDC	2.13 (2:0-5)	86	1.45
Swelling limits strenuous activities	IKDC	1.48 (0.5:0-5)	63	0.74
Giving way limits strenuous activities	IKDC	1.04 (0:0-5)	50	0.41
Difficult to participate in strenuous activities on a	IKDC	2.39 (2:0-5)	89	1.69
regular basis				

<sup>a</sup> FIP, frequency-importance product; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score.

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\* Significant difference in ratings between males and females (p<.05) \*\* Significant difference in ratings between males and females (p<.01

# APPENDIX 4: Paper IV – The use of the Tegner activity scale for articular cartilage repair of the knee: A systematic review

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# KNEE

# The use of the Tegner Activity Scale for articular cartilage repair of the knee: a systematic review

Karen Hambly

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# Abstract

*Purpose* The Tegner Activity Scale (TAS) was developed in 1984 and has been widely used in studies on knee populations. The primary objective of this study was to undertake a systematic review on the use of the TAS for articular cartilage repair (ACR) of the knee.

*Methods* A systematic review was conducted using electronic databases (MEDLINE, CINAHL, SPORTDiscus<sup>TM</sup>, NHS Evidence, ISI Web of Knowledge, AMED, BNI, PEDro and The Cochrane Collaboration of Systematic Reviews) and reference lists from extracted articles. Studies were selected that were published between 1984 and 2009 in which the TAS was reported for patients who had undergone ACR of the knee.

**Results** The search strategy identified 442 citations of which 34 articles met the inclusion criteria. There was a large degree of study heterogeneity especially regarding data reporting a wide variation in the number of participants (range 5–137), participant age (range 12–76 years), follow-up time (range 3–120 months) and male-to-female participant ratio. Where pre- to postoperative TAS change was analysed, 88% of studies demonstrated a significant improvement in postoperative TAS scores.

*Conclusions* In general, TAS data were inconsistently reported and methodological detail was often lacking. Caution is advised in the interpretation of TAS scores following ACR of the knee where there are large ranges in

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K. Hambly Faculty of Life Sciences, London Metropolitan University, London, UK postoperative follow-up times, mixed gender cohorts and wide ranges in participant ages. TAS data should be presented and analysed fully and ideally in a standardised fashion to facilitate the comparison of outcomes between studies.

**Keywords** Physical activity · Knee · Articular cartilage · Outcome assessment · Cartilage repair

# Introduction

Activity levels have the potential to provide a valuable dimension to outcome measurement. It has been recommended that due to the measurement of different constructs, any studies on knee populations should use a general health questionnaire, a knee-specific instrument and an activity level scale [5, 50]. Activity level scales complement existing outcome instruments by providing a measure of 'what patients are doing'. In the last decade, seven different activity level scales have been identified as being potentially applicable to outcome studies in sports medicine [39, 40, 66]. One of the more frequently used activity level scales is the Tegner Activity Scale (TAS) (Fig. 1) [61].

The TAS was designed as a score for activity level to complement the functional Lysholm knee score for patients with ligament injuries [61]. The instrument scores a person's activity level between 0 and 10 where 0 is 'on sick leave/disability' and 10 is 'participation in competitive sports such as soccer at a national or international elite level'. Pertinently, activity levels 6–10 can only be achieved if a person takes part in recreational or competitive sports. The TAS has been, and continues to be, a popular rating scale for postoperative knee patients, predominantly due to its ease and speed of use. The high Please indicate below the HIGHEST level of activity that you are able to participate in CURRENTLY.

Level 9 Competitive sports-soccer, football, rugby (lower divisions), ice hock wrestling, gymnastics, basketball     Level 8 Competitive sports-racuetball, squash or badminton, track and field	key,
Level 8 Competitive sports-racquetball, squash or badminton, track and field	
athletics (jumping, etc.), downhill skiing	
Level 7 Competitive sports-tennis, running, motorcars speedway, handball	
Recreational sports-soccer, football, rugby, ice-hockey, basketball, squash, racquetball, running	
Level 6 Recreational sports-tennis and badminton, handball, racquetball,	
downhill skiing, jogging at least 5 x per week	
Level 5 Work-heavy labor (construction, etc.)	
Competitive sports-cycling, cross-country skiing	
Recreational sports-jogging on uneven ground at least twice weekly	
Level 4 Work-moderately heavy labor (e.g. truck driving, etc.)	
Recreational sports-cycling, cross-country skiing, jogging on even ground at least twice weekly	
Level 3 Work-light labor (nursing, etc.)	
Competitive and recreational sports-swimming, walking in forest possible	
Level 2 Walking on uneven ground possible, but impossible to back pack or	hike
Level   Work-sedentary (secretarial, etc.)	
Level 0 Sick leave or disability pension because of knee problems	

Fig. 1 The Tegner Activity Scale (TAS) [61]

clinical utility of the TAS [59] has contributed to its widespread use in orthopaedics and sports medicine. It has been cited as being the most widely used activity scoring system for patients with knee disorders [5, 21]. Although the TAS is frequently used as a subjective patient-reported scale, it is important to note that it was initially established as a clinician-administered tool [15].

The TAS has demonstrated acceptable psychometric parameters for a range of knee disorders including testretest reliability and ceiling and floor effects [5, 6, 18, 50, 53]. The TAS has been shown to exhibit a moderate correlation with the Physical Activity Scale [63] and to correlate with the Marx Activity Rating Scale [40]. Reported correlations range from 0.24 [50] to 0.346 [31] for the Lysholm scale and range from 0.22 [6] to 0.54 [50] for the International Knee Documentation Committee (IKDC). In terms of criterion validity, significant correlations have been found between the TAS and the physical component of the SF-12 scale for knee disorders [5, 6] but not for the mental component of the SF-12 [6].

Two studies have evaluated TAS responsiveness in knee populations. In the first study, a moderate effect size was found for isolated meniscal lesions (0.61) and a large effect size for combined meniscal lesions (0.836) [5]. In the second study, a large effect size (1.0-1.1) was found in ACL injuries for all postoperative times aside from 6 months where there was a moderate effect size (0.74) [6]. This indicates that the TAS has the ability to measure moderate to large changes in activity level in these populations but may not be sensitive enough to measure small changes in activity level.

The study by Briggs et al. [7] is the only research to date to have established normative knee data for the TAS. They found that the average TAS was 5.7 (range 1-10) for a population of 488 people who considered their knee function normal. The TAS was inversely correlated with age, and the average TAS for men (6.0) was higher than for women (5.4) [7].

Articular cartilage repair (ACR) is an umbrella grouping for surgical interventions developed to address the problem of chondral defects in the knee. Although ACR is rapidly evolving, the literature regarding postoperative activity levels is currently limited. The first published article on human results for autologous chondrocyte implantation (ACI) appeared in 1994 [8]. Interestingly, a point that was raised soon after publication was that this study did not include sufficient detail on activity levels [51]. This is an issue as rehabilitation following ACR is lengthy and time to return to sport guidance varies between 6 and 18 months dependent on the nature of the activity and the type of ACR surgery [43]. Mithoefer et al. [43] reported that the average postoperative TAS score following ACR for studies including mixed gender and ages was 6.1.

Returning to sports and exercise activity is one of the main reasons given for individuals to elect to undergo cartilage repair surgery [22], and function in sports is viewed as an issue of high importance by postoperative cartilage repair patients [23]. A small unpublished retrospective study found that despite 35% of individuals citing returning to sport and exercise activity as their main reason for electing to undergo ACI surgery at a mean follow-up time of 29 months (range 13-48), only 18% of individuals had made a full return to their sports/exercise activity. The majority (82%) either returned to their original sports/exercise activity with limitations (29%), returned to a different lower level sport/exercise activity (35%) or did not return to sports/exercise at all (35%). In a recent study, 83% of competitive players returned to soccer after ACI surgery but of the 26 recreational players in the study 14 players had excellent or good clinical outcomes yet none returned to soccer at any level [45]. One study that used the TAS in an ACR population concluded that returning to preinjury performance levels is by no means assured in the first 24 months after ACI [33]. Mithoefer et al. [43] reported that younger age resulted in better rates of return to sport participation across a variety of ACR surgical techniques.

The objective of this systematic review was to evaluate the use of the Tegner Activity Scale for articular cartilage repair of the knee.

# Methods

## Search strategy

The search strategy utilised the principles of systematic review [17] and was designed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [47]. A computerised literature search was undertaken in January 2010 and repeated in

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March 2010 for validation. The researcher searched MEDLINE, Cumulative Index for Nursing and Allied Health Literature (CINAHL), SPORTDiscus<sup>TM</sup>, NHS Evidence, ISI Web of Knowledge, Allied and Complimentary Medicine Database (AMED), British Nursing Index (BNI), Physiotherapy Evidence Database (PEDro) and The Cochrane Collaboration of Systematic Reviews for studies published between 1984 and 2009. The search was conducted using Boolean logic [AND] for the three key phrases 'Tegner', 'knee' and 'cartilage or chondral'. Additional information sources utilised included reference lists from articles in search results and published orthopaedic and sports medicine conference abstracts. All searches were carried out with the following inclusion and exclusion criteria.

Inclusion criteria:

- Clinical studies that reported a minimum of postoperative TAS results.
- Studies where the primary treatment was an articular cartilage repair surgical procedure.
- English language studies.
- Studies reported between 1984 and 2009.

Exclusion criteria:

- Review, in vitro and non-clinical studies.
- Non-English language studies.
- Studies where the primary treatment was not an articular cartilage surgical repair procedure.
- Studies with osteoarthritic populations.
- Studies that did not report a minimum of postoperative TAS scores.
- Studies that used a modified TAS such as the Wallgren-Tegner Scale [65]

# Study selection

A process of study selection was implemented across all studies resultant from the search strategy. First, all duplicates, review studies and papers not in the English language were excluded. The abstracts of the remaining citations were then reviewed for potential eligibility against the inclusion and exclusion criteria. The full-text articles were retrieved for all the studies that looked to meet the inclusion criteria based on review of the abstracts. Following review of the full-text articles, those studies that met the inclusion criteria were included within the systematic review.

Data extraction and analysis

Data were extracted using a standardised tabular form. If reported, the following data were extracted from each

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paper with method of presentation: type of articular cartilage repair surgery, follow-up time(s), patient demographics (including age and gender) and Tegner Activity Scale data (preinjury, preoperative and postoperative) for each eligible study. The data extracted from the selected studies were compiled in table format and on completion the data were verified for each study by crosschecking the table back against the full article.

# Results

Search results

The flow diagram in Fig. 2 summarises the results of the process of selection of studies for inclusion in this



Fig. 2 Flow diagram summarising the process of selection of studies for inclusion

systematic review. The initial search across all the databases resulted in a total of 442 citations. After duplications, review studies and papers not in English were removed 84 studies remained. The abstracts of these remaining 84 citations were reviewed and 36 studies were identified where the primary treatment was an articular cartilage repair procedure. The full-text articles for these 36 studies were accessed and following additional review, 4 studies were excluded as 2 studies only reported pre- to postoperative change in TAS and 2 studies only reported TAS in graphical format with no data values. Review of the references in the remaining 32 retrieved full-text articles resulted in two further articles for possible inclusion. The systematic review identified 34 studies [1-4, 10, 12, 14, 16, 19, 20, 24, 28-30, 32, 33, 36-38, 41, 42, 44-46, 49, 52, 54-57, 62, 64, 67, 68] that were found to meet the inclusion criteria, and a summary of the data extracted from these studies is presented in Table 1. Due to the large degree of heterogeneity between the studies, particularly in terms of data reporting, it was not possible to conduct a metaanalysis.

# Overview of study results

There was wide variation in the patient demographics across the 34 studies. The number of participants in each study ranged from 5 to 137 patients; participant age ranged from 12 to 76 years; and follow-up time ranged from 3 to 135 months. Thirty-one of the studies (91%) were a mixed gender sample with variable male-to-female ratios.

The mode of collection of TAS data was poorly reported throughout the studies. The format of data collection (e.g. verbal, written or electronic) and the administration of the scale (e.g. independent patient reporting, clinician supervised patient reporting or clinician reporting) were not clearly delineated. In terms of presentation of the TAS scores, 30 studies (88%) reported TAS data using parametric methods of means and standard deviations whilst 4 studies (12%) used non-parametric methods [16, 29, 32, 62]. Where a parametric presentation approach was adopted, a very few studies reported assessment of the data distribution.

The majority of the studies (85%) reported TAS scores for a single postoperative time point with only 5 studies reporting longitudinal postoperative TAS scores [19, 24, 32, 37, 68]. In 3 (9%) studies, preoperative TAS scores were not reported at all and in an additional 3 (9%) studies preoperative TAS scores were only reported graphically. Only 9 (26%) studies reported preinjury TAS scores. Twenty-four (71%) of the studies analysed preoperative to postoperative differences in TAS scores. Of those studies that carried out a pre- to postoperative analysis, the majority (88%) found a significant (minimum level of significance of 0.05) improvement in TAS scores after ACR surgery.

# Discussion

The most important finding of this present study was that TAS data for ACR of the knee is generally inconsistently reported and methodological detail is often lacking. Of the reviewed studies that analysed pre- to postoperative change in TAS scores, 88% demonstrated significant increases in TAS scores. Two of the studies that demonstrated a nonsignificant improvement in TAS scores were likely to be type II errors due to small sample sizes [11, 68]. Overall, this is an indication that the TAS has the ability to measure change in activity level in an ACR population but further research is required to evaluate responsiveness and effect sizes.

The low methodological quality of articular cartilage repair studies has previously been reported [25]. Three of the recommendations from Jakobsen et al. were that the timing of the outcome assessment should be clearly stated; that results from various time-points after surgery should not be reported as one outcome; and that the minimum duration of follow-up should be more than twenty-four months [25]. Only five of the studies reviewed (15%) reported longitudinal TAS scores [19, 24, 32, 37, 68]. Interestingly, Tegner states that "the main advantage of the activity scale is not to compare different patients but to note changes in activity level in the same person at different times" [60]. However, the majority of the studies in this review (85%) reported TAS scores for a single postoperative follow-up time point. One study presented crosssectional TAS scores for varying postoperative follow-up times [4]. The time points for reporting the TAS across the included studies varied between 3 months and 11.3 years postoperatively, making comparisons of TAS levels between studies difficult. In addition, there were often large ranges in postoperative follow-up times, some of which were in excess of 5 years. These large ranges in postoperative follow-up time compromise the validity and usefulness of the reported TAS scores. This is particularly pertinent when the minimum postoperative follow-up times are less than 24 months due to the rehabilitation timescales following articular cartilage repair [22].

An important finding from this review was the lack of consistency in the statistical reporting of TAS. In his original thesis, Tegner states that non-parametric methods should be used for the TAS as data on the activity score behaves like data on an ordinal scale [60]. Although ordered, the intervals between points on the TAS cannot be presumed equal and as such, TAS scores should be classified as ordinal data and presented using medians,

Table 1 Publish Tibial Osteotomy	led articular cartilage rep y, MACT Matrix-Associa	pair studies from 1st Ja ted Chondrocyte Tran	anuary 1984 to 31st Dec splantation, IQR Inter Q	ember 2009 reporting Tegne uartile Range, OAT Ostochoi	r Activity Scale ndral Autograft	e (ACI Autologous Chone Transplantation)	drocyte Implantation, HTO High	608
Study	Surgery	Preinjury TAS (a) Mean ± SD (b) Median (range)	Preoperative TAS (a) Mean ± SD (b) Median (range)	Postoperative TAS (a) Mean 土 SD (b) Median (range)	TAS-pre- to postoperative	Follow-up Mean or Median (range)	Patient Demographics Mean or Median (range)	
Zeifang et al. [68]	ACI (periosteal) MACI	Data not reported Data not reported	(a) 3.7 ± 1.9 (a) 4.1 ± 2.8	(a) 4.6 ± 2.0 (a) 5.3 ± 1.9 (a) 4.2 ± 2.0 (a) 4.7 ± 2.9	NS NS NC	12 months 24 months	10 patients (10 men) mean age $29.1 \pm 7.5$ years 11 natients (6 men & 5 women)	
Tetta et al. [62]	OAT	(b) 7 IRQ 6-9	(b) 3 IRQ 1-4	(p) 6 IRQ 5-7	SP = 0.001	24 months 24 months Median 113 months (IQR	mean age 29.5 ± 11.0 years 24 patients (70.8% men) mean age 29.9 ± 8.7 years	
Wondrasch et al [67]	. MACI accelerated weight bearing group MACI delayed weight bearing group	Data only reported graphically Data only reported t graphically	Data only reported graphically Data only reported graphically	(a) 3.87 (a) 3.87	1 1	106–122 months) 104 weeks 104 weeks	16 patients (12 men & 4 women) mean age 28.3 years (18-53) 15 patients (11 men & 4 women) mean age 38 years	
Pascual-Garrido et al. [49]	ACI	Data not reported	(a) 4 ± 3	(a) 6 土 5	S P < 0.5	4 years (2-7)	(18-55) 52 patients (26 men & 26 women) mean age	
Salzmann et al. [52]	MACT OAT	Data not reported Data not reported	Data not reported Data not reported	(a) 5.4 ± 1.9 (a) 5.0 ± 2.1	1 1	42.0 months (25–77) 41.3 months (23–75)	<ul> <li>31.8 ± 8.6 years</li> <li>9 patients (8 men &amp; 1 woman) mean age 32.7 ± 7.2 years</li> <li>9 patients (8 men &amp; 1 woman)</li> </ul>	
McNickle et al. [41]	ACI	82% of patients TAS of $\ge 6$	32% of patients TAS of $\geq 6$	65% of patients TAS of ≥ 6	S <i>P</i> < 0.001	4.3 ± 1.8 years (2.0−9.7)	mean age 33.9 $\pm$ 7.5 years 137 patients (79 men & 58 women) mean age 30.3 $\pm$ 0.1 years (13.0 A0.00)	Knee Sur
Gobbi et al. [19]	ACI second generation (patellofemoral)	(a) 6.8 土 1.8	(a) 2.56 ± 1.5	(a) 4.94 (a) 4.68	S P < 0.0005	2 years 5 years	34 patients (23 men & 11 5 women) mean age 31.2 years [15-55]	z Sports Tr
Gigante et al. [16]	MACI (patella)	Data not reported	(b) 1 (25th to 75th percentiles 1–1)	(b) 4 (3-7) (25th to 75th percentiles 4-5)	S P < 0.05	36 months	12 patients (6 men & 6 women) median age 31 years (25th to 75th percentiles 25-35 years)	aumatol
Kim et al. [29]	ACI (using Fibrin)	Data not reported	(b) 2 (1-4)	(b) 7 (5–8)	S P < 0.05	24 months	30 patients (24 men & 6 women) median age 35 years (15-55)	Arthrosc
Kon et al. [32]	Microfracture ACI	(b) 7 (6–8) (b) 7 (6–7)	(b) 3 (3-4) (b) 1 (1-3)	(b) 6 (6-7) (b) 5 (4-6) (b) 6 (3-7) (b) 6	S <i>P</i> < 0.001	2 years 5 years 2 years 5 years	40 patients (27 men & 13 women) mean age 30.6 years 40 patients (33 men & 7 women) mean age 29.0 years	(2011) 19:604-
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Table 1 continue	q						
Study	Surgery	Preinjury TAS (a) Mean ± SD (b) Median (range)	Preoperative TAS (a) Mean ± SD (b) Median (range)	Postoperative TAS (a) Mean 土 SD (b) Median (range)	TAS—pre- to postoperative	Follow-up Mean or Median (range)	Patient Demographics Mean or Median (range)
Kumar et al. [33]	ACI	(a) 8.8	(b) 3.7	(a) 6.4	1	23.4 months (18-32)	18 patients (14 men & 4 women) mean age 31 years
Franceschi et al. [14]	ACI + HTO	Data not reported	(a) 3.7 (b) (3-5)	(a) 7 (b) (5–8)	S <i>P</i> < 0.05	28 months	8 patients (4 men & 4 women) mean age 50 years
Spahn et al. [54]	Bipolar radiofrequency chondroplasty Mechanical shaver chondroplasty	Data not reported Data not reported	<ul> <li>(a) 5.1 ± 1.2</li> <li>(b) (4-8)</li> <li>(a) 5.3 ± 1.1</li> <li>(b) (3-8)</li> </ul>	(a) 2.8 ± 0.8	S <i>P</i> < 0.001 S <i>P</i> < 0.001	l year 1 year	30 patients (13 men & 17 women) mean age 42.9 years ± 10.4 (20-57) 30 patients (15 men & 15 women) mean age 437 verse + 9.0 (71-58)
Asik et al. [1]	Microfracture	Data not reported	(a) 2.6 ± 1.5 (b) (2−5)	(a) 5.2 ± 1.3 (b) (4−9)	S P < 0.0001	Mean 68 months (24–108)	90 patients (43 men & 47 women) mean age 34.5 years (20–58)
Davidson et al. [11]	Osteoarticular allografts (distal femoral)	Data not reported	(a) 4.3 ± 2.8 (b) (1−9)	(a) 5.3 ± 1.1 (b) (4−7)	NS P = 0.160	40 months (23-60)	8 patients (4 men & 4 women) mean age 32.6 years (21-48)
Knutsen et al. [30]	ACI Microfracture	Data not reported Data not reported	(a) 3.28 (a) 3.16	(a) 4.05 (a) 4.36	S P = 0.007 S P = 0.002	5 years 5 years	40 patients mean age 33.3 years 40 patients mean age 31.1 years
Marcacci et al. [37]	Osteochondral graft	(a) 7.1 ± 2.1	(a) 2.9 ± 1.3	(a) 6.2 ± 2.8 (a) 5.6 ± 2.8	S P < 0.0005	24 months 84 months	30 (22 men & 8 women) patients mean age 29.3 years
Barber and Chow [2]	Osseous autograft transplantation	Data not reported	Data not reported	(a) 5	I	48 months (24-89)	36 patients (20 men & 16 women) mean age 43 years
Mithoefer et al. [46]	Microfracture	Data only reported graphically	Data only reported graphically	S	S P = 0.001	Mean 41 months (24-54)	32 athletes. Mean age 38 years
Behrens et al. [4]	MACT	Data not reported	(a) 3.2 ± 2.0 (b) (0−8)	(a) 3.6 ± 1.8 (b) (1-8)	NS $P = 0.41$	Mean 34.5 months (6-60)	38 patients (19 men & 19 women) mean age 35 years (18-58) 25 patients > 24 months
Barber and Iwasko [3]	Shaving Shaving + monopolar radiofrequency probe	Data not reported Data not reported	(a) 3.0 (a) 2.3	(a) 3.3 (a) 3.8	S P < 0.05	19 months (12–27)	postop (10 met & 1 wonten) In total 60 patients (28 men & 32 women) mean age 49 years (22–76)

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Study	Surgery	Preinjury TAS (a) Mean ± SD (b) Median (range)	Preoperative TAS (a) Mean ± SD (b) Median (range)	Postoperative TAS (a) Mean ± SD (b) Median (range)	TASpre- to postoperative	Follow-up Mean or Median (range)	Patient Demographics Mean or Median (range)	
Spahn and Kirschbaum [55]	Abrasion arthroplasty Periosteal arthroplasty	Data not reported Data not reported	(a) 5.5 ± 2.1 (a) 5.5 ± 2.1	(a) 2.7 ± 0.6 (a) 4.9 ± 1.2	S <i>P</i> < 0.05 NS	Mean 3.2 years ± 1.1 Mean 3.1 years ± 1.1	25 patients (10 men & 15 women) mean age 26.7 years ± 6.6	
							17 patients (10 men & 7 women) mean age 25.7 years ± 6.5	
Mithoefer, Minas et al. [44]	ACT	Data not reported	Data only reported graphically	(a) 6.1 ± 0.5	S <i>P</i> < 0.001	41 土 4 months	45 patients (soccer players) (32 men & 13 women) mean age 26 vears ± 1 (14-43)	the second s
Marder et al. [38]	Microfracture	Data not reported	(a) 3 ± 1	(a) 6 ± 2 (b) (2-9)	<i>S P</i> < 0.01	4.2 years (2-9)	43 patients (24 men & 19 women) mean age 39.7 years (16-66)	and the second se
Karataglis et al. [28]	MEGA-OATS	Data not reported	(a) 2 (b) (1-3)	(a) 4 ± 1.9 (b) (2−7)	I	32.8 months (30–36)	5 patients (3 men & 2 women) mean age 29.8 years (22-41)	
Gobbi et al. [20]	Microfracture	(a) 7	(a) 3.2	(a) 6 (a) 5	ł	2 years 72 months (36–120)	53 athletes (33 men & 20 women) mean age 38 years (19-55)	
Mithoefer, Peterson et al. [45]	ACT	(a) 8.2 ± 0.2	(a) 3.8 ± 0.3	(a) 7.8 ± 0.3	S <i>P</i> < 0.001	47 months (23–91)	20 patients (soccer players) (15 men & 5 women) mean age 15.9 vears ± 0.3 (12-18)	
Ma et al. [36]	OAT *	Data not reported	(a) 2.22 (b) (1-4)	(a) 6.11 (b) (4-8)	I	42 months (24-64)	18 patients (12 men & 6 women) mean age 29 years (16-51)	
Miller et. al. [42]	Microfracture	Data not reported	(a) 2.9 (b) (1-6)	(a) 4.5 (b) (2–7)	S <i>P</i> < 0.05	2.6 years (2-5)	81 patients (49 men & 32 women) mean age 49.4 years (40-70)	
Sterett et al. [57]	Abrasion & microfracture	Data not reported	Data not reported	(a) 5.0 (b) (1-10)	ł	45 months (24–80)	38 patients (28 men & 10 women) mean age 51.3 years (34-72)	
Visna et al. [64]	ACI Abrasive techniques	(a) 7.85 ± 1.0 (a) 7.10 ± 1.1	(a) 3.23 ± 0.8 (a) 2.30 ± 1.1	(a) 5.92 ± 0.8 (a) 4.20 ± 1.1	S <i>P</i> < 0.01 S <i>P</i> < 0.01	12 months	25 patients (18 men & 7 women) mean age 29.48 years (18–50)	
-							25 patients (16 men & 9 women) mean age 32.20 years (21-50)	
(56)	Microfracture	Data not reported	(a) 3.1 ± 1.7 (b) (1−6)	(a) 5.8 ± 1.5 (b) (2-9)	S P < 0.05	11.3 years (7–17)	72 patients (45 men & 23 women) mean age 30.4 years (13-45)	

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Study	Surgery	Preinjury TAS (a) Mean ± SD (b) Median (range)	Preoperative TAS (a) Mean ± SD (b) Median (range)	Postoperative TAS (a) Mean ± SD (b) Median (range)	TAS-pre- to postoperative	Follow-up Mean or Median (range)	Patient Demographics Mean or Median (range)
Cherubino et al. [10]	MACI	Data not reported	(a) 2.6 (b) (1-4)	(a) 6.5 (b) (5-7)	I	6.5 months (2-15)	13 patients (9 men & 4 women) mean age 35 years (18-49)
Horas et al. [24]	ACI		(a) 1.60	(a) 1.55	ł	3 months	20 patients (8 men & 12
	Osteochondral		(a) 1.60	(a) 2.95		6 months	women) mean age 31.4 years
	cylinder			(a) 4.25		12 months	(18-42)
				(a) 5.10		24 months	20 patients (15 men & 5
				(a) 1.55		3 months	(21-44)
				(a) 3.55		6 months	
				(a) 5.00		12 months	
				(a) 5.20		24 months	

percentiles and interquartile range [13, 27, 58]. Lavalley and Felson reviewed statistical presentation of ordered categorical outcome data in rheumatology journals and found that the most common error was the presentation of summary measures of ordinal data with only 39.4% of articles adopting an appropriate methodology [34]. Similarly, Jakobsson reviewed the statistical presentation of ordinal data in nursing research and found that only 49% of articles had appropriate data presentation [26]. The majority of studies (88%) in this review reported TAS by mean (with or without standard deviation) as shown in Table 1. Only four studies within this review presented TAS scores using the non-parametric descriptors of median and range [16, 29, 32, 62]. Where parametric methods were used, it was generally unclear from the statistical reporting within the articles whether the data had been assessed for normality. This is highly relevant as the one study that has evaluated TAS in normal knees found that TAS data demonstrated significant departure from a normal distribution [7]. The fact that TAS data are not normalised is especially pertinent in considering study cohorts with wide ranges of ages and time from surgery as is typical for ACR studies within this review. However, more recent commentaries have challenged the view that parametric statistics should not be used for ordinal data and have justified that it is appropriate to use parametric statistics due to their robustness [9, 48]. Whilst there is no consensus in the literature on the appropriate way to present and analyse TAS data, comparative analyses between studies using TAS will be restricted and the usefulness of the results will be jeopardised.

Despite gender having been implicated as a potential factor in TAS reporting [15], there is currently limited data on gender differences in TAS scores following ACR. The majority of studies (91%) within this review had mixed gender cohorts yet only one of the studies [4] analysed TAS scores for gender sub-groups. Behrens et al. found no significant difference in TAS score between men and women (P = 0.07); however, the group sizes were small with only 15 women and 10 men [4]. In a normal population, significant differences have been reported in the average TAS between men (6.0) and women (5.4) [7]. Consequently, the ability to compare TAS results from the review studies with this normative data is severely compromised as the majority of studies within the review had mixed gender cohorts. In addition, where the review studies had mixed gender cohorts, the ratio of male to female participants were found to be extremely variable which further restricts the potential for comparative analysis.

The sport exercise life course is one where participation in sport and exercise decreases with age [35]. A recent study looking at knee function and self-reported activity

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levels in soccer players found a decrease in the TAS scores of 0.8 (95% CI 0.4, 1.1) for each 10-year period of older age [15]. This trend has also been established in TAS profiles in a normal knee population with TAS exhibiting an inverse correlation with age [7] but has not been established in ACR. This is pertinent as participant age ranged from 12 to 76 years in the review studies and where standard deviations of age were reported they tended to be between 7 and 11 years. The reduction in the level of activities with age needs to be taken into account in the interpretation of TAS scores, possibly through the implementation of a correction factor as suggested by Briggs et al. [7].

The TAS has previously been shown to demonstrate acceptable psychometric properties; however, if the instrument is used in a non-standardised or inappropriate fashion, its value as a clinical outcome measure may well be compromised irrespective of the quality of its psychometric profile. Generally, the results from the studies in this review show a significant improvement in TAS preoperative scores after ACR surgery. This is highly relevant in an era where patients are requesting realistic expectations regarding return to activity and sports following orthopaedic surgical procedures. However, based on the heterogenic collection and reporting of the TAS data, it is not currently possible to stratify TAS expectations in relation to domains such as patient age or gender. Further research is needed to assess the clinical validity of the TAS for ACR populations and to develop functional activity profiles of individuals who have undergone ACR.

Several limitations of this systematic review need to be highlighted. First, the analysis was based on published literature and therefore may be subject to publication bias. In addition, restricting the review to only studies published in the English language may have introduced bias. The heterogeneous nature of the TAS data collection and inconsistent reporting made comparisons between studies difficult and not amenable to meta-analysis.

# Conclusions

This was the first systematic review of the methodological use of the TAS for articular cartilage repair of the knee. In general, TAS data were inconsistently reported and methodological detail was often lacking. Caution is advised in the interpretation of TAS scores following ACR of the knee where there are large ranges in postoperative follow-up times, mixed gender cohorts and wide ranges in participant ages. If the TAS is used as an outcome measure within clinical studies on ACR of the knee, it should be presented and analysed fully and ideally in a standardised fashion to facilitate the comparison of outcomes between studies.

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# APPENDIX 5: Paper V – Activity profile of members of an online health community after articular cartilage repair of the knee

Including:

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# [ Orthopaedic Surgery ]

# Activity Profile of Members of an Online Health Community After Articular Cartilage Repair of the Knee

Karen Hambly, MCSP PGDip

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Background: Articular cartilage repair (ACR) procedures aim to alleviate pain and restore function for individuals with chondral defects. Rehabilitation is lengthy, and there are limited data on return to sports and exercise activities after ACR in non-elite-athlete populations. The Internet is a growing source of health-related information for patients, and it has resulted in the emergence of online health communities.

Purpose: To establish a postoperative activity profile of users of an online health community who have undergone ACR of the knee and to compare this profile with those from the same community who have undergone initial anterior cruciate ligament reconstruction (ACLR).

Study Design: Cross-sectional.

Methods: Tegner Activity Scale ratings were collected via a self-reported online questionnaire from 201 participants of an online health community who had undergone tibiofemoral and/or patellofemoral ACR (n = 75) or ACLR (n = 126).

Results: A higher Tegner activity level was significantly correlated to time from surgery for ACR (P < 0.005) and ACLR (P < 0.01). At a minimum of 24 months' follow-up, the ACR group had a median postoperative Tegner score of 3, compared with 6 for the ACLR group. Tegner score was significantly negatively correlated with age at time of surgery for ACLR (P < 0.05) but not for ACR. Men demonstrated significantly higher Tegner activity levels than did women for both ACLR and ACR (P < 0.05).

Conclusions: Activity levels after ACR in this population increased with postoperative time but remained lower than expected when compared with current published clinical and normative data.

Clinical Relevance: Engagement with an online health community may influence expectations regarding return to sports and exercise activities. Reporting of activity-level data within clinical studies should be differentiated on the basis of sex. Further research is needed to elucidate factors that determine return to sports and exercise activities after ACR.

Keywords: articular cartilage repair; knee; Tegner Activity Scale; outcome measures; sport

rticular cartilage repair (ACR) procedures aim to alleviate pain and restore function for people with chondral defects. Activity-level assessment after tibiofemoral and patellofemoral ACR is important, given that rehabilitation is lengthy<sup>47</sup> and clinicians are being increasingly confronted with patients who have the desire to continue with sports activity after knee surgery.<sup>18,60,71</sup> Even though returning to sport and exercise activities is one of the main reasons people elect to undergo ACR,<sup>28</sup> there are limited data on return to sports and exercise activities in non-elite-athlete populations.<sup>26,27,57</sup>

Activity-level scales provide a measure of "what patients are doing." Because of the measurement of different constructs, knee population studies should use a validated patientreported outcome measure, a general health questionnaire, and a validated activity scale for knee pain and mobility impairments.<sup>0,0,6,63</sup> The Tegner Activity Scale (TAS) was published in 1985<sup>80</sup> and is cited as the most widely used activity scoring system for patients with knee disorders.<sup>10,23</sup> The first systematic review of TAS usage for ACR of the knee was published in 2010.<sup>26</sup>

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Although the medical profession remains the most trusted source of health information for orthopaedic patients,<sup>14</sup> the Internet is a growing source of supplemental information on health-related issues. 13,22,37,66.72 People are often keen on being in contact with others with similar health conditions,38 and this has played an important role in the development of online health communities (OHCs).2,15,19 Return to sport is one of the most frequent question themes posted on Internet message boards relating to knee problems9 and is a common topic of discussion on knee OHCs.9.25 The upsurge of OHCs provides opportunities for online health consumers to influence their own and their peers' health care decisions, expectations, perspectives, and, ultimately, outcomes. However, the limited research in orthopaedic and musculoskeletal fields has focused on how online consumers search for health information on the Internet rather than how participation in an OHC may affect expectations and outcomes. 22,64,72,74

The aim of this study was to establish a postoperative activity profile of users of an OHC who had undergone ACR of the knee and to compare this profile with users from the same OHC who had undergone initial anterior cruciate ligament reconstruction (ACLR).

# METHODS

# Setting and Participants

The focus of this study was on participants from the KNEEguru OHC (http://www.kneeguru.co.uk). The KNEEguru website is a resource for people with knee problems, with more than 22 000 registered members at the time of this study, principally from the United Kingdom and the United States. A published analysis of patient information about knee arthroscopy on the web identified KNEEguru as 1 of only 16 sites that provide patient information of sufficient quality such that it can be recommended to patients.70 The KNEEguru OHC is based on a dynamic bulletin board to which participants older than 18 years must register to interact. The bulletin board is an active community, and for the duration of the survey, there was an average of 407 new topics and 7125 new posts per month. Research has indicated that function in sports and return to sports activity are viewed as issues of high importance by participants on this OHC who have undergone either ACR or initial ACLR of the knee.28,29

An online questionnaire was developed through Moodle 1.5.3 (http://moodle.org) using the questionnaire activity module (version 2005062701). Responses were stored anonymously with numeric reference identification numbers and exported as comma-separated value files for analysis. The demographic data used to describe the study cohort were self-reported date of birth and sex. Surgical data comprised self-reported responses for type, location, month, and year of knee surgery (Table 1). The ACR group included participants who had undergone either marrow stimulation, osteochondral grafting, or cell-based ACR procedures (Table 1). The ACLR group included those who had undergone initial ACLR; those who had undergone either revision ACLR procedures or Table 1. Self-reported surgical characteristics of articular cartilage repair group.

Articular Cartilage Repair	Patients, n (%)		
Туре			
Plugs <sup>a</sup>	14 (19)		
Cell based <sup>b</sup>	22 (29)		
Microfracture	35 (47)		
Other	4 (5)		
Location	1.010		
Medial femoral condyle	26 (35)		
Lateral femoral condyle	9 (12)		
Patella	16 (21)		
Trochlea	3 (4)		
Tibia	1 (1)		
Multiple	17 (23)		
Don't know 3 (4)			

\*Osteochondral autograft transfer, mosaicplasty; OsteoBiologics, Inc. \*Autologous chondrocyte implantation; autologous chondrocyte transplantation; matrix-induced autologous chondrocyte implantation.

multiple-ligament repairs were excluded. The recruited sample captured the course/spectrum of postoperative experience of each procedure. Information and support needs change over time.<sup>5,69</sup> Therefore, no specific inclusion requirements were set that related to time elapsed since surgery. Potential OHC users were invited to participate in the study via postings in relevant topic areas on the KNEEguru online bulletin board.

The purpose and aims of the study and the role of the participants and their rights were included in the invitation to participate, per established guidelines for online research.<sup>7,18</sup> Institutional ethical approval was obtained as part of a larger study. Self-registration to the study and self-submission of the questionnaire were taken as further consent to participate.<sup>75</sup> Data collection took place between July 2007 and December 2008. Participants who were younger than 18 years at the time of their surgery were excluded. Data were saved to a secure server only if participants chose to submit the questionnaire. Stored data for each submitted questionnaire were linked to a unique response identification number.

# Outcome Measure

The TAS was used as the self-report measure of physical activity level.<sup>79,80</sup> A gold standard self-report physical activity scale has not yet been identified for use with ACR populations. The TAS was selected because it is one of the most widely used activity scoring systems for patients with knee disorders,<sup>10,23</sup> because there are published TAS normative data,<sup>12</sup> and because it is frequently used as a patient-reported

	Articular Cartilage Repair		Anterior Cruciate Ligament Reconstruction	
Participants, n	7	5	126	
Age at time of surgery				
Mean years (range)	34.8 (	20-52)	32.6 (1	4-59)
Standard deviation	8	.1	9.	7
Average time from surgery			an and the state	
Months (range)	15.6 (0-51)**		11.0 (0-	-114)**
Standard deviation	13.8		14	.5
Tegner Activity Scale	-			
Mean $\pm$ standard deviation	2.9 ± 1.9**		4.2 ± 2.7**	
Median (range)	3 (0-10)		4 (0-10)	
	Men	Women	Men	Women
Participants, n	. 32	43	61	65
Age at time of surgery				1
Mean years (range)	34.5 (20-47)	35.1 (22-52)	31.6 (16-59)	33.5 (14-53)
Standard deviation	7.9	8.5	8.8	10.5
Average time from surgery			(Section)	
Months (range)	13.9 (1-50)	16.8 (0-51)	12.2 (0-114)	9.8 (0-48)
Standard deviation	12.6	14.7	17.9	10.4
Tegner Activity Scale	to a source party of	AN DOLLAR	n or hereiter a beiter	
Mean $\pm$ standard deviation	3.5 ± 1.9*	2.2 ± 1.4*	4.8 ± 2.7*	3.7 ± 2.7*
Median (range)	3.5 (0-10)	2.0 (0-6)	5.0 (0-10)	4.0 (0-9)

\*P < 0.05 (between men and women).

\*\*P < 0.001 (between articular cartilage repair and anterior cruciate ligament reconstruction groups).

activity scale in ACR and ACLR clinical studies.26 The TAS scores a person's activity level between 0 and 10, where 0 is on sick leave/disability and 10 is participation in competitive sports such as soccer at a national or international elite level. In this study, respondents were instructed to indicate the highest level of activity in which they were able to participate at the time of completing the survey, by clicking on 1 of 11 available options.

# Data Analysis

Statistical analysis was performed with SPSS 15.0, and data were summarized with descriptive statistics. Medians and ranges were calculated for ordinal data,76 but means and standard deviations were also calculated to make comparisons with previous research, per published recommendation.40 Nonparametric analysis was performed with the Mann-Whitney U test for comparison of data among participant subgroups. Spearman ρ was used for assessing associations between variables.

Participants were grouped on the basis of time from surgery at survey completion: 0-3 months, 4-6 months, 7-12 months, 13-24 months, and 25 months and longer. Participants were also subgrouped on the basis of sex and age at time of surgery. Prior studies on ACLR have selected a cutoff point of 40 years of age to delineate between young and middle age, and on this basis, 2 groups were established for this study comprising those participants younger than 40 years and those 40 years or older at the time of surgery.<sup>3,8,52</sup> Reported P values are 2-tailed with an  $\alpha$ level of 0.05 indicating significance.

# RESULTS

The online survey was completed by a total of 201 participants (75 ACR and 126 ACLR). Data collection was complete, aside from 12 participants who failed to enter a valid date of birth. (Table 2).



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Figure 1. Box plot of self-reported Tegner Activity Scale for articular cartilage repair at different postoperative times. The bold line represents the median value; the box area represents 25th and 75th quartiles; and the whiskers represent the 10th and 90th percentiles. Outliers are shown.

The ACR group tended to be slightly older at time of surgery, with an average age of 34.8 years, compared with 32.6 years for the ACLR group, but this difference was not significant (P = 0.124). However, there was a significant difference in average time from surgery between the ACR group (mean, 15.6 months) and ACLR group (mean, 11.0) (Mann-Whitney U = 3329.0, P = 0.001) and in TAS between the ACR group (median, 3.0) and ACLR group (median, 4.0) (Mann-Whitney U = 3243.0, P = < 0.000).

TAS was negatively correlated with age at time of surgery for ACLR ( $\rho = -0.213$ , P < 0.05); for ACR, there was no significant correlation. TAS was positively correlated to time from surgery for ACLR ( $\rho = 0.713$ , P < 0.01) and for ACR ( $\rho = 0.322$ , P < 0.005) (Figures 1 and 2).

There were no significant differences in age at time of surgery or average time from surgery between men and women for each surgical procedure (Table 2). There was, however, a significant difference in TAS between men and women for both the ACR group (P = 0.005) and the ACLR group (P = 0.037), with men exhibiting a significantly higher TAS than women. There was no significant difference in TAS between participants who were 40 years and older at the time of surgery and those who were younger for either the ACR group (P = 0.294) or the ACLR group (P = 0.214).

Eleven percent of participants from the ACR group reported a TAS of 0, with a mean postoperative time of  $6.38 \pm 6.16$ months and a maximum reported postoperative time of 17 months. Nine percent of participants from the ACLR group



Figure 2. Box plot of self-reported Tegner Activity Scale for anterior cruciate ligament reconstruction at different postoperative times. The bold line represents the median value; the box area represents 25th and 75th quartiles; and the whiskers represent the 10th and 90th percentiles. Outliers are shown.

reported a TAS of 0, with a mean postoperative time of  $0.82 \pm 0.75$  months and a maximum postoperative time of 2 months.

# DISCUSSION

The most important finding of the study was that activity levels after ACR in this OHC population increased with postoperative time but remained lower than expected when compared with clinical<sup>34,35,51,56,57,62</sup> and normative data.<sup>12</sup> Current published literature indicates that a postoperative TAS score of 6 is a common outcome after both ACR<sup>34,35,51,56,57,62</sup> and ACLR\* This compares well with a reported average activity level of 5.7 for a population with normal knee function.<sup>12</sup> On this basis, someone undergoing either of these knee surgeries can expect to return to an activity level close to that of a person of similar age and sex with normal knee function. This is at a level that includes participation in a recreational sport such as tennis or jogging at least 5 times a week (TAS, 6).

The activity levels of participants from the 2 groups were significantly correlated with time from surgery; so, in overall terms, people who undergo these interventions can expect their activity levels to improve with postoperative time (Figures 1 and 2). TAS scores for the ACR group were expected to be lower than the ACLR group for the first 18 postoperative months because of differences in rehabilitation

\*References 1, 21, 36, 39, 41, 42, 57, 73, 77, 78, 85.

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and return-to-sport guidance.<sup>2731.5565.82</sup> However, despite initial improvements after surgery, the ACR group reached a maximum median TAS level of only 3 (Figure 1), an unexpected result based on current published literature.<sup>46,57</sup> Importantly, at no postoperative time point did the 75th quartile reach a TAS level of 6 for this group. These results are intriguing, especially given the reason participants from this OHC frequently give for undergoing ACR—namely, to take part in sports and exercise.<sup>24,28</sup> In contrast, the ACLR group demonstrated a median TAS score of 6 from 13 months postoperatively onward (Figure 2), which compares well with the expected TAS score based on clinical studies<sup>4</sup> and with a noninjured population.<sup>12</sup>

The majority of participants who had undergone ACR returned to basic activities of daily living, including walking, light work, and low-impact exercise; however, few went on to return to participation in sports activities. Physical inactivity has been cited as the biggest public health problem of the 21st century,4 and the promotion of physical activity is now a major worldwide public health initiative.<sup>16,30</sup> The relatively low median postoperative activity level found in this ACR group may have wider long-term health implications, especially for those who are younger at the time of ACR surgery. The reporting of a TAS level does not distinguish between a restriction in participation due to an impairment in body function and structure (eg, reduced knee range of movement) or one due to the influence of environmental or personal contextual factors (eg, OHC culture, fear of future impairments, expectations, empowerment, self-efficacy).81

Another pertinent finding from this study was the difference in profile between the ACLR and ACR groups for those who were on sick leave or disability pension because of knee problems (TAS, 0). Patients undergoing ACR are expected to take longer to return to work than those undergoing ACLR based on the longer rehabilitation timescales for ACR procedures.<sup>27</sup> However, the mean time that individuals were on sick leave or disability pension was 6.4 months for ACR, compared to only 0.8 months for ACLR. This tends to indicate that the ACR group was experiencing higher levels of limitation of activity and/or restriction of participation than that expected based on published outcomes.<sup>26</sup>

Significant differences have been reported in TAS ratings for men and women in a noninjured population.<sup>12</sup> Although sex has been implicated as a potential factor in TAS reporting,<sup>20</sup> this is the first study to have analyzed TAS scores by sex following ACR.<sup>26</sup> Although the results showed a good range of TAS for men (0-10) for ACR and ACLR, the range for women was slightly lower for ACLR (0-9) and considerably lower for ACR (0-6). Overall TAS scores for women were found to be significantly lower than for men for both ACLR and ACR groups (Table 2), which is in accordance with normative data for ACLR<sup>10</sup> and which was expected per the established research on women's participation in sport.<sup>47</sup>

<sup>†</sup>References 1, 21, 39, 41, 42, 73, 77, 78, 85.

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The sport exercise life course is one where participation in sport and exercise decreases with age.<sup>97</sup> This trend has been established in TAS profiles in a normal knee population.<sup>12</sup> A decrease in TAS score over time was therefore expected as a reflection of the normal adaptation to older age and changed phases of life.<sup>36,77</sup> In this study, the TAS score was significantly negatively correlated to age at time of surgery for ACLR but not for ACR. This may indicate that other factors have a greater influence on return to sports activity than does age at time of surgery in an ACR population.

Any explanation for the difference in activity levels between ACR and ACLR groups will likely be multifactorial. There are 3 areas that are worthy of further consideration. First, ACLR surgical techniques are more established and have a higher prevalence than do ACR techniques. At the current time, the evidence base for ACLR is larger and more complete than that of ACR, especially in the area of postoperative return to physical activity. Where techniques are novel or literature is sparse, clinicians are likely to adopt a more cautious and conservative approach to advice for their patients regarding such aspects as returning to sport and exercise participation. Second, ACR requires a significantly longer rehabilitation process than that of ACLR, which has a psychological<sup>84</sup> and social support impact. This may result in differences in coping styles and drives between the 2 groups that are subject to change with postoperative time.5 It may also result in differences in perception of each condition that are exhibited in subsequent differences in illness behavior. Third, the ACR group in this study is not representative of the general ACR population. The use of a nonprobabilitybased sampling technique may have resulted in selection bias. The evaluation of selection bias poses a particular problem for web-based surveys, given that it is difficult to determine nonresponse rates and that selective participation may result in responders' having stronger views (positive or negative) than nonresponders.<sup>6,44</sup> The higher-than-expected TAS level of 0 (sick leave or disability pension because of knee problems) is potentially explained by selection bias because those people with more time may be more likely to respond than those who have returned to work.

The absolute activity levels reported in this study for the ACR group were significantly lower than expected, which raises the issue of representativeness of the general ACR population. Lee and Hawkins<sup>43</sup> proposed that the higher an unmet need for information or support, the more likely a person is to spend time in social support groups such as OHCs.<sup>43</sup> Therefore, those who are using the KNEEguru OHC following their surgery may arguably have unmet needs for information or support. Conversely, when these needs are met, a person is less likely to spend time on an OHC. Anecdotal evidence from OHC participants supports this view in relation to returning to physical activity: "If they healed fine and returned to sport, they are not generally hanging out on this board" and "I don't know if this is the best place to look for positive encouragement in general about returning to sports following

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a surgery." This potentially explains why the ACR group's TAS levels were lower than expected, but if this is the case, then why did a large proportion of the ACLR group members not only return to sport activities but remain on the OHC once they had returned?

Research has indicated that participation in OHCs empowers patients, especially in the areas of "being better informed" and "enhanced social well-being."83 However, clinicians need to be cognizant of the potential negative influences that an OHC can have on functioning and disability. The Internet provides an opportunity for nonrepresentative groups to exert a potentially more rapid and larger effect than that of individuals on their own, according to social capital theory.59,66 Strong subgroups within an OHC influence a community and its membership.48,86 There is rationale for proposing that a lack of successful former patients on an OHC, who have returned to higher levels of activity, may contribute to more negative expectations of the group overall, by virtue of their absence. The rise of OHCs has many positive benefits; however, the presence of nonrepresentative subgroups increases the potential for dissemination of false, inaccurate, or misleading information to patients.45

A counterargument is that the ACR group may actually represent the general ACR population and that it is the results of published studies that are not representative. A recent review of the quality of ACR studies concluded that "caution is required when interpreting results after surgical cartilage repair."32 Publication bias is a widely accepted phenomenon in clinical literature that affects patient care.33.61 It is generally accepted that specialist centers are more likely to publish, that some studies introduce participant bias by using inclusion criteria that select only those patients who have the best chances to do well, and that clinicians often expect and/or rate function and activity levels higher than do patients.50.58.67,68 A recently published study from a major European cartilage center found that if all the published randomized controlled trial inclusion criteria were utilized, 95.6% of their patients with symptomatic focal cartilage defects in the knee would be ineligible for participation.17 This study concluded that results from published randomized controlled trials might not be representative of the gross cartilage population. The issue of representativeness requires further research, given the considerable implications for the generation of expectations from clinician and patient perspectives and the subsequent management of these expectations.

Several limitations to this study focused on the outcome measure used and the study design implemented. The clinical utility of the TAS has contributed to its widespread use in orthopaedics and sports medicine, but it has received criticism. The TAS is based on specific sports deemed arbitrarily categorized<sup>53</sup> and not necessarily representative of sports across all cultures. If an individual does return to his or her original sport, it may be with limitations in level, frequency, and/or duration of training and competition. This is not something that the TAS picks up.<sup>54</sup> Therefore, it may be preferable to

measure components of sports function rather than specific sports.<sup>53</sup> This approach has not been widely adopted in ACR studies to date, possibly because of the lack of a suitable outcome measure.

In terms of study design, the study had 4 limitations. First, the participants were self-registered, and they self-reported their activity levels, surgical procedure, and location of lesion. Second, details were not known, including duration of symptoms, alignment, number of lesions, lesion size, and rehabilitation programs. Third, although more than 200 participants responded, the subgroups were often of fairly small sample sizes. Fourth, the study was a cross-sectional design and looked at postoperative TAS scores only.

# CONCLUSIONS

Overall, both groups demonstrated postoperative trends in activity levels related to time, age, and sex that were consistent with the literature, but the activity levels of the ACR group were much lower than expected from the current evidence base. The results highlight the potential impact that engagement with an OHC can have on expectations regarding return to sports and exercise activities. Reporting of activitylevel data within clinical studies should be differentiated on the basis of sex.

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# [ Editorial ] Internet Medicine

t's hard to believe how much the medical world has changed in the last 25 years: from inpatient hospital-based practices to outpatient centers, health management organizations, and health saving accounts. As the venues have transitioned and the amount of information available on the Internet has grown, many health care consumers have chosen the Internet as their preferred source of medical information. Some have chosen . the Internet due to the spiraling cost of traditional medicine, while others distrust physician sources. A study conducted in 12 countries by Bupa Health Plus' found that nearly one-half of the people seeking Internet medical information do so to make a self-diagnosis; 75% of these do nothing to check the accuracy of online medical advice. With the current cost of medical care and the number of uninsured, it is not surprising that people search for sources of medical information outside their doctors' offices. What is concerning is the self-diagnosis based on the Internet information. After all, anyone, even a 7-yearold, can set up a Web site.<sup>10</sup> There is no guarantee that medical information online is accurate, let alone helpful. In medicine and in other matters, wrong information can hurt someone.

Part of the problem with Web medicine is that there is often no separation between the marketing and the medical science. A number of studies have addressed the issue, including Pandolfini et al,9 by giving readers guidelines on how to surf the Web for good sites and studies. Since I am an online "immigrant"-that is, I did not grow up on the Web-I spent some time recently researching some hot topics and scams. Vaccinations and their relationship to autism have recently been discussed extensively due to a research scandal in Britain.8 A very interesting report by Wolfe et al12 examined 22 antivaccination Web sites. All 22 sites claimed that vaccinations caused idiopathic illness without scientific evidence. Asthma, seizures, brain damage, attention-deficit disorder, diabetes, autism, and sudden infant death syndrome were all attributed to vaccines. Seven of the sites claimed that the vaccines were manufactured with aborted fetal tissue. Twenty-one of 22 sites claimed that vaccines even erode immunity. The sad truth is that much of the medically unsophisticated public cannot differentiate these claims from scientific fact gleaned from welldesigned clinical studies. The medical profession should be concerned about this. It would be a mistake for the medical profession not to recognize the power of Web communications. Recent political developments in the Middle East emphasize how powerful this communication tool can be. Right or wrong, good or bad, the Internet empowers many.

With these factors in mind, the medical profession should try to educate the public on how to use the Web safely to

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search for medical information. The American Academy of Orthopaedic Surgery Web site<sup>1</sup> recommends comparing information on the Web with other sources, checking the credentials of the author or organization presenting the material, being cautious of Web sites that advertise and sell products, and, of course, talking with your physician about information on the Web.

With all of the reservations listed above, it was interesting for me to discover online health communities (OHCs) after reviewing the article by Hambly et al titled "Activity Profile of Members of an Online Health Community After Articular Cartilage Repair of the Knee." The focus of the study was participants from the KneeGuru OHC,5 which had 22 000 registered participants in 2007-2008. Two hundred and one individuals that had undergone either an articular cartilage repair (ACR) procedure or an anterior cruciate ligament reconstruction (ACLR) completed an online questionnaire based on the Tegner<sup>11</sup> Activity Scale. At a minimum of 24 months postoperatively, the ACR group had a median Tegner score of 3, compared to a 6 for the ACLR group. A Tegner score of 3 indicates a return to basic activities of daily living, including walking, light work, and low-impact exercise, but no return to competitive sports. This was of great interest to me, having undergone microfractures 18 and 4 years ago with what I thought were pretty good results.

These results are quite telling because most participants in this OHC underwent the procedure to return to sports and exercise. Furthermore, current reports suggest a much higher level of function after ACR<sup>57</sup> So, where is the truth? Are the clinical reports more indicative of the results because the OHC is populated with patients that are not doing well and are searching for answers? Or, is the OHC information more accurate and the published clinical results tainted by publication bias: specialty centers selecting study inclusion criteria that favors selection of patients for study participation who have the best prognosis?

I am not sure where the truth lies, but I can see the value of Web-based patient-desired information and the probable flaws in the medical scientific literature. It's probably best to keep an eye on both while realizing their inherent weaknesses and limitations. Besides, the Web does feature some approaches that are worth reading, such as this one: "Top 10 Reasons to Fire Your Doctor."<sup>3</sup>

> Edward M. Wojtys, MD Editor-in-Chief

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# **APPENDIX 9: Contributing Author Declarations**

On all papers where Hambly has been the first, and lead author, Hambly initiated the concept of each study and all the methodology and analysis were Hambly's work. For those items that were not sole authorship the contributing author declarations, where available, are included within this Appendix.

J.

# a) Paper I: Mr Vladimir Bobić

# **Contributing Author Declaration**

This contributing author declaration relates to the following publication:

Hambly, K., et al. (2006). Autologous chondrocyte implantation postoperative care and rehabilitation: science and practice. *Am J Sports Med*, 34(6), 1020-1038.

Karen Hambly and Vladimir Bobic initially developed the concept of the paper. Karen Hambly presented the outline of the paper to the American Journal of Sports Medicine Current Concepts Editor in Boston, USA in 2004 and once commissioned Dieter Van Assche, Barbara Wondrasch and Stefan Marlovits were invited to be co-authors.

Karen Hambly was the lead and communicating author of this paper and project managed the writing plan, integration of co-author submissions, revisions of drafts, responses to reviewers, references and final submission. All authors reviewed and contributed to all sections. The sections for which authors were responsible for producing the initial draft are listed below:

**Overall manuscript - Hambly** Abstract - Hambly Introduction - Hambly/Bobic Procedure and variations of ACI - Marlovits Graft maturation - Bobic Evidence base - Hambly Comparative analysis (including Table 1) - Hambly Clinical biomechanics - Wondrasch/Marlovits Table 2 - Hambly OKC versus CKC - Wondrasch/Marlovits Active and passive movements and CPM (including Figure 1) -Wondrasch/Marlovits Orthoses - Van Assche ACI and PRICES - Van Assche Proprioception and neuromuscular function (including Figure 2) - Hambly Hydrotherapy - Wondrasch/Marlovits Manual therapy after ACI - Van Assche Electrotherapeutic modalities and EMG feedback (including Figure 3) -Hambly Exercise modalities (including Figures 4 & 5 and Table 3) Hambly Return to sport after ACI - Hambly ACI rehabilitation programming (including Table 4) - Van Assche/Hambly/Wondrasch Future directions - Hambly/Bobic Reference coordination and formatting - Hambly

I confirm that this is an accurate summary of the author contributions for this paper.

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VUDIMIR BOBIC

SIGM

DATE:

# b) Paper I: Dr Dieter Van Assche

# **Contributing Author Declaration**

This contributing author declaration relates to the following publication:

Hambly, K., et al. (2006). Autologous chondrocyte implantation postoperative care and rehabilitation; science and practice. Am J Sports Med. 34(6), 1020-1038.

Karen Hambly and Vladimir Bobic initially developed the concept of the paper. Karen Hambly presented the outline of the paper to the American Journal of Sports Medicine Current Concepts Editor in Boston, USA in 2004 and once commissioned Dieter Van Assche, Barbara Wondrasch and Stefan Marlovits were invited to be co-authors.

Karen Hambly was the lead and communicating author of this paper and project managed the writing plan, integration of co-author submissions, revisions of drafts, responses to reviewers, references and final submission. All authors reviewed and contributed to all sections. The sections for which authors were responsible for producing the initial draft are listed below:

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SIGNED: DATE: 12/1/20

# c) Paper I: Ms Barbara Wondrasch

# **Contributing Author Declaration**

This contributing author declaration relates to the following publication:

Hambly, K., et al. (2006). Autologous chondrocyte implantation postoperative care and rehabilitation: science and practice. *Am J Sports Med*, 34(6), 1020-1038.

Karen Hambly and Vladimir Bobic initially developed the concept of the paper. Karen Hambly presented the outline of the paper to the American Journal of Sports Medicine Current Concepts Editor in Boston, USA in 2004 and once commissioned Dieter Van Assche, Barbara Wondrasch and Stefan Marlovits were invited to be co-authors.

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I confirm that this is an accurate summary of the author contributions for this paper.

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# d) Paper I: Professor Dr Stefan Marlovits

# **Contributing Author Declaration**

This contributing author declaration relates to the following publication:

Hambly, K., et al. (2006). Autologous chondrocyte implantation postoperative care and rehabilitation: science and practice. *Am J Sports Med*, 34(6), 1020-1038.

Karen Hambly and Vladimir Bobic initially developed the concept of the paper. Karen Hambly presented the outline of the paper to the American Journal of Sports Medicine Current Concepts Editor in Boston, USA in 2004 and once commissioned Dieter Van Assche, Barbara Wondrasch and Stefan Marlovits were invited to be co-authors.

Karen Hambly was the lead and communicating author of this paper and project managed the writing plan, integration of co-author submissions, revisions of drafts, responses to reviewers, references and final submission. All authors reviewed and contributed to all sections. The sections for which authors were responsible for producing the initial draft are listed below:

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I confirm that this is an accurate summary of the author contributions for this paper.

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SIGNED:

DATE:

25/01/2011

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# e) Papers II and III: Dr Konstadina Griva

Dr K. Griva supplied the following statement as evidence of the extent of her contribution to the papers she has second authored as received on email to Professor Eileen O'Keefe on 14<sup>th</sup> September 2008.

To whom it may concern,

Ms Karen Hambly has produced an exceptional research output related to her PhD work. She has been the first author on the following papers:

Hambly, K. & Griva, K. (2008) IKDC or KOOS? Which one measures

symptoms and disabilities most important to postoperative articular cartilage repair patients? *Am J Sports Med.* 36(9):1695-1704

Hambly, K. & Griva, K. (2010) IKDC or KOOS: which one captures
 symptoms and disabilities most important to patients who have
 undergone initial anterior cruciate ligament reconstruction? *Am J Sports Med.* 2010; 38: 1395-404.

She has been responsible for designing the study, collecting and analysing the data and writing the papers. My personal contribution as a second author on the above work has been minimal and involved general advice and recommendations on statistical approach to be adopted and reviewing/commenting on the final drafts of the manuscripts prior submission.

Yours sincerely

Dr Konstadina Griva

Department of Psychology, National University of Singapore

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# APPENDIX 10: Participant recruitment

# a) Screen shot: Invitation placed on the KNEEguru Bulletin Board

E Author	opic: Have you had cartilage repair? (Read 584 times)		
The KNEEguru Moderator SuperKNEEgook Offline Posts: 2085 KNEES The KNEEguru	Have you had cartilage repair? * on: July 13, 2007, 02:57:28 PM *		
	Hi everyone If you are interested in helping with an academic survey, please give this your attention. The questionnaire only takes 5 minutes. Your bulletin board login should access the questionnaire too. Thanks. KNEEguru		
	Have you had articular cartilage repair surgery?		
	If so in sparing a few minutes of your time you could help improve treatment for people with articular cartilage damage to the knee. To find out how please read on.		
	Articular cartilage repair surgery is a fast moving area of orthopaedic surgery and doctors are keen to find out which techniques are the most successful. The main types of articular cartilage repair surgery are autologous chondrocyte implantation (ACI or ACT), OATS, Mosaicplasty or microfracture. If you have had one of these surgical procedures you may well have been asked to fill out some questionnaires about how your knee is doing.		
	There are quite a few different questionnaire assess how well articular cartilage repair pati doing. One commonly used group of questior quality of life and they have been evaluated problems such as meniscal damage, ACL tea no one has looked at these questionnaires for	s that are currently used to lents and their knee(s) are nnaires measures knee-specific for patients with other knee rs or osteoarthritis but, to date, rr articular cartilage repair.	
	This online survey has been designed to com used knee-specific quality-of-life questionnai disabilities that are important to you, the ca is crucial as it is only by knowing this inform community can select a questionnaire that er perspective is considered in the outcome of o	apare the ability of two commonly res to detect symptoms and rtilage repair patient. This ation that the medical asures that the patient's cartilage repair procedures.	
	If you have had an articular cartilage repair procedure (e.g. ACI, OATS, Mosaicplasty or microfracture) we would like to invite you to help find out which questionnaire is better at detecting symptoms and disabilities that are important to cartilage repair patients by completing an online survey. While there may be no immediate benefit to you as a result of your participation in this survey, it is hoped that valuable information can be gained that can improve treatment for people with articular cartilage damage to the knee.		
	A summary of the overall results of the surv KNEEguru website once the data has been an	ey will be published on the nalysed and reviewed.	



KNEEguru

b) Screen shot: Online survey opening statement





# Symptoms and Disabilities Most Important to Patients

## Cartilage Repair of the Knee

This survey has been designed to compare the ability of two commonly used Knee-Specific Quality-of-Life Instruments to detect symptoms and disabilities that are important to you, the patient. Similar surveys have been carried out for patients with other knee problems such as meniscal damage, ACL tears or osteoarthritis but to date no one has looked at how well these instruments detect the symptoms and disabilities that are important to cartilage repair patients. This is important as it is only by knowing this information that the medical community can select an instrument that ensures that the patient's perspective is considered in the outcome of cartilage repair procedures. Your completion and submission of the survey represents your consent to serve as a subject in this study. The information that you give us in the survey will be recorded in anonymous form. We will not release information that could identify you. All completed surveys will be kept securely and will not be available to anyone not directly involved in this study. While there may be no immediate benefit to you as a result of your participation in this study, it is hoped that we may gain valuable information that can improve the treatment of people with articular cartilage damage to the knee.

# **APPENDIX 11: Participant information sheet**

You are being asked to take part in a research study. Before you decide whether you are willing to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

# Why is this study being done?

The purpose of this study is to find out what symptoms and disabilities are important to people who have undergone articular cartilage repair of the knee and what activities people return to after articular cartilage repair. The purpose of this study is NOT to find out whether one articular cartilage repair procedure is more effective than another.

# Why have I been chosen?

We are asking you to take part in this study because you have undergone articular cartilage repair surgery. About 75 people will take part in this study.

# What will happen in this study?

If you decide to take part in this study you will be asked to complete an online questionnaire. It takes about 5 minutes to fill out the questionnaire. The questionnaire can only be accessed via the internet. While we hope that you will answer all the questions, you can skip any questions you don't want to answer.

# Do I have to take part in the study?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will still be free to withdraw at any time and without giving a reason.

# Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. None of the information held by the researcher will identify you by name. The procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998.

The information that you provide in the questionnaire will be stored on a computer. It will contain information that identifies you to your study ID number and not your name.

The researcher will not be able to access your email address.

# If I take part in this study, how will you protect my privacy?

If you agree to be part of this study you will be giving the researchers your permission to obtain, use and share information about you for this study. The results of this study could be published in an article, but would not include any information that would let others know who you are.

# What are the risks and possible discomforts from being in this study?

There is no treatment or intervention involved in this study so the foreseeable risks and discomforts for participation in this study are minimal. However, there are questions related to pain and other symptoms and the ability to participate in daily activities including sports.

- Embarrassment when answering questions of a personal nature. If any questions make you feel uncomfortable, you may skip those questions and not give an answer.
- Psychological distress may occur rarely.
- There may be other side effects that are not known at this time.

To minimise these risks the data collection system will allow you to stop and save your data and rest as needed. Additionally you will be free to withdraw from the study at any time.

# What are the possible benefits from being in this study?

You may not benefit from taking part in this study. We cannot promise the study will help you but the information we get might help improve the treatment of people with articular cartilage damage to the knee. You will not get paid to take part in this study.

# What happens when the research study stops?

The results of this study will be written up and submitted as part of a PhD programme for the researcher and will be submitted to appropriate journals for publication.

# Who is organising and funding the research?

This research study is being organised by the Department of Health and Human Sciences at London Metropolitan University and is being funded by the researcher.

# If I have questions or concerns about this study, who can I contact?

Please contact the principal researcher listed below.

Karen Hambly BSc(Hons) MCSP

+44 207133 2274

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Department of Health and Human Sciences

London Metropolitan University

166-220 Holloway Road

London N7 8DB

UK

APPENDIX 12: Dissemination of findings to the online health community

# a) Screen shot: Return to activity after ACI - survey results

Return to activity after ACI - survey results | KNEEguru notebook



# Advertisement Ask a Knee Doctor Online 18 Doctors Are Online. Current Wait er.com/knee

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### Return to activity after ACI - survey results

Submitted by admin on February 29, 2008 - 12.05pm. ACT articular cartilage repair hambly survey reports

Understanding the cartilage repair experience from the patients' perspective. by Karen Hambly BSc MCSP (Sports Scientist/Physiotherapist)

In December 2005 the KNEEguru community was invited to participate in an online survey on

Return to activity after autologous chondrocyte implantation. This survey was designed to provide an opportunity for KNEEguru bulletin board members to share their experiences of returning to

# Background

See Karen's Own Site



# Who's online

There are currently 2 users and 88 auests online.

### **Online users**

Advertisement

Ads by Google Knee Pain

Knee Surgery

Knee Injuries

Advertisement

Knee Joint Injury

- · ACIMod
- mermaids

### Who's new

- buddy1741
- davesport
- Ts Mom
- floridanightingale
- SunStorm missouriairl

### Syndicate S

## My admin

- · Knee replacement
- · Recent posts
- · My account

ACI patients have or haven't returned to and why. This was a chance for ACI patients to provide their individual perspective on ACI surgery and rehabilitation and to help highlight areas that can be improved for ACI patients in the future.

sports and exercise activities after autologous chondrocyte implantation (ACI).

Over the last 10 years the vast majority of scientific studies on cartilage

repair have based a 'successful' outcome on what the graft looks like from either an MRI scan or on second look arthroscopy or by what the

new cartilage cells look like under the microscope. These are important factors, but just as important is whether having the ACI surgery helps the individual patient to return to the activities that they wanted to

The aim of this survey was to collate information about what activities

Thanks to all of you who gave up your time to take part in the survey. The quality of your responses was exceptional

### Results

participate in

There were 23 responses but 3 were excluded as it was less than 12 months after their ACI procedure. The average age was 34 years and the average time after ACI surgery was 29 months. An overview of the group is shown in the Table below.

DEMOGRAPHIC	S AND SURGERY CHARACTERISTICS	
No of Respondents	of Respondents 20 via on-line web based survey tool	
Male:Female	71% : 29%	
Mean Age at ACI	34 years (range 16-45 and SE 1.96)	
Mean FU Post ACI	29 months (range 13-48 and SE 2.65)	
Exclusions	3 as <12/12 post ACI	
ACI surgery location	59% Europe 23% USA 18% Australia	
Concomitant surgery	76% isolated 12% meniscal repair 6% ACL reconstruction 6% microfracture	
Lesion Location	53% single defect - 29% MPC 12% Patella 6% LPC 8% Tibla 35% multiple 12% didn't know	
Surgical Procedure	41% ACI using periosteum 29% ACI using collagen membrane 6% MACT 6% MACI 18% didn't know	

### Notes

FU = Follow Up, MFC = Medial Femoral Condyle, LFC = Lateral Femoral Condyle, MACI = Matrixinduced Autologous Chondrocyte Implantation, MACT = Matrix-associated Autologous Chondrocyte

http://www.kneeguru.co.uk/KNEEnotes/node/713



31/05/2011 11:14

health information: erify here

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- Keyword (tag) cloud
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Implantation

### Why choose to have ACI surgery?

One of the first questions in the survey was 'why did you choose to have ACI surgery?' and the main reasons that you gave for choosing to have ACI surgery in the first place were interesting:

- Lack of choice or limited options (47% of respondents)
- Sports/exercise activities (35% of respondents) Pain and/or other symptoms (29% of respondents)
- Surgeon recommendation (18% of respondents)
- To avoid/delay having a knee replacement (18% of respondents)

Almost half of you felt that either your options were restricted by things including the size of the cartilage damage; your age; prior knee surgery; or that you weren't given any other surgical options other than ACI.

Over a third of you said that sports and exercise activity was a key factor in why you decided to opt for ACI surgery in the first place. You wanted to return to an active life that ranged from taking part in competitive sports to playing with the children. The interesting point here is that more of you cited return to sports and exercise than cited pain and/or other symptoms such as swelling, locking or giving way as the main reason for your choice to have ACI.

However, there was a huge range in your responses with some individuals who were only going through the ACI surgery to be able to play sports to other individuals who quite openly stated that they never intended to go back to playing sports again and just wanted to be pain free.

### How did you rate your outcome?

The Brittberg Rating is a scale that was developed in 1990s to measure clinical outcome after cartilage repair surgery. If we take a look at how you rated your ACI outcome based on the Brittberg rating 59% of you reported excellent or good results as you can see in the pie chart below.

### Patient Reported Brittberg Rating



ian = Good: I experience mild aching with stren activity but I don't have any swelling or locking

any pain, swelling or locking with strenuous

- Good: l experience mild aching with strenuous activity but I don't have any swelling or locking.
- moderate pain with strenuous activity and occasional swelling but don't have any locking
- at rest and swelling and locking.

Previous studies have reported excellent and good outcomes for 55-90% of patients so the results from this survey are at the lower end of this range. It is not possible to say why this is the case from the survey but there are a couple of potential reasons. Firstly, the ratings weren't by the surgeon they were by you, the patient, and they were supplied anonymously so perhaps some of you were more honest in your answers. Secondly, the KNEEguru community isn't representative of the general population as there are proportionally more people who have poor knee surgery results or continuing problems in the community and therefore it would be expected that outcomes results would be lower.

### What activities did you return to?

Despite the fact that almost half of you (41%) rated your outcome as 'fair' or 'poor' in actual fact only 18% of you didn't return to sport at all. This is positive as it shows that even if your clinical outcome isn't as good as you may have hoped it shouldn't necessarily stop you from taking part in sports and exercise activities altogether

However, only 18% of you made a full return to your original sport or exercise activity. Twothirds of you found that you had to either return to your original activity with limitations or that

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### Return to activity after ACI - survey results | KNEEguru notebook

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you had to switch to a different sport/exercise activity.

### Patient Reported Return to Sport Status



The most common change of sporting activity was to switch from a high impact activity such as football, basketball, running or baseball to a lower impact sport such as cycling, walking and golf. For those of you who didn't change sports and exercise activities many of you found ways to compensate for limitations due to your knee problems including:

- Reducing how often you take part in that sport or exercise activity.
  Lowering the level at which you play.
  Allowing more time for your knee to recover between sessions.
- . Increasing the amount of strengthening work at home or at the gym.

In terms of the reasons for returning or not returning to your main sport or exercise activity there were a few schools of thought. Some of you returned to sports and exercise activities despite still experiencing symptoms. Whilst others with minimal symptoms took a different perspective on things and chose not to return to your main activity as you thought that it may cause more damage to your knee joint over the long term.

There was also a general feeling that ACI rehabilitation takes a lot of effort, both mentally and physically, and that you didn't want to risk having to go through it all again and/or weren't prepared to put your families and friends through it again.

### How well informed were you?

Rehabilitation after articular cartilage repair is quite different to a lot of other surgical procedures. The researcher therefore felt that it was important to find out how well informed patients thought they were before they had their ACI surgery about the rehabilitation process. The results of how well you thought you were informed are shown in the graph below.



How well informed were you before the surgery about the rehabilitation for ACI?

Almost half of you felt that they were fully informed about the rehabilitation for ACI before you

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had the surgery.

However, the other half of the group felt you received some information but that you were generally not very well informed.

### Would you opt for ACI surgery again?

If we now look at whether people would opt for ACI surgery again 76% of you said yes you would, 23% no and 6% were unsure.

What was interesting was that those people who said that they wouldn't opt for ACI surgery again tended to be the ones who considered that they weren't very well informed about the rehabilitation for ACI. It is not possible to draw any direct conclusions from this trend but it may suggest that informed patients tend to be more satisfied with their treatment than those people or were under or ill informed about ACI rehabilitation.

### How can ACI rehabilitation be improved?

When you were asked how ACI rehabilitation could be improved you identified five key areas:

- Psychological preparation & support (59% of respondents)
- Knowledge/education (47% of respondents)
- Communication (29% of respondents)
- Rehabilitation programmes (29% of respondents) Muscle strengthening (24% of respondents)

Over half of you felt that there was a need for better psychological preparation and support including pre-operative counseling, confidence building and the medical profession adopting a more holistic approach with patients.



Just under half of you thought that enhancing knowledge and education would improve the experience.

Interestingly the knowledge and education enhancement was predominantly focused on physiotherapists with a number of you stating that your physiotherapist had either never heard of ACI or knew nothing about the procedure.

Linking in with the previous area was the need for improved communication between the surgeon and physiotherapist as well as between the surgeon and the patient.

You expressed a general need for clearer, more structured rehabilitation guidelines that could be personalised to your own individual needs and goals.

Muscle strengthening was one of the components of the rehabilitation programme that was specifically highlighted for improvement. It was felt that there should be a greater emphasis on muscle strengthening in the ACI rehabilitation programme especially preoperatively.

### **Advice from ACI Patients**

The ACI patients who took part in this survey had the following advice for anyone considering ACI surgery

- Read as much information as you can.
- . Find a physiotherapist prior to your surgery who can work with you long term. Ask about the potential complications of ACI surgery.
- Start looking at local gym facilities prior to your operation.
- Try to get in the best shape possible before your operation.
- Be realistic about your expectations.
- Realise that rehabilitation is slow be prepared for a long recovery.
- Make sure you are attached to a physiotherapist who knows what ACI is. Choose a surgeon who has a good track record in ACI surgery.
- · Understand what you are getting yourself into.

### **Final Thoughts**



ACI rehabilitation is long and demanding, both physically and mentally. Individuals choose to undergo ACI surgery for a range of reasons but many want to, and do, return to an active lifestyle.

ACI rehabilitation is a process, a journey. You may start off the journey with full intentions of returning to your main sport or exercise activity but at the end of the journey you may have changed your mind, possibly more than once as you react to the experience.

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Anyone reading this article must bear in mind that the survey was of a small sample of 20 KNEEguru bulletin board members and that the KNEEguru community is not representative of the general population. It is therefore not possible to apply the results of this study directly to the general population.

Finally it is worth remembering that despite some of the issues regarding ACI rehabilitation that this survey has raised and the variance in individual expectations three-quarters of the people who took part in this survey said that they would opt for ACI surgery again.

The results from this survey were presented at the following conference in January 2006:

Hambly, K. Cartilage repair rehabilitation: The human factor. Paper presented at: 6th International Cartilage Repair Society Congress, 2006; San Diego, USA.

A larger prospective study looking at return to sports and exercise activities following ACI is being planned using the information gained from this KNEEguru survey.

Click here to read the KNEEinsights review of articular cartilage repair.

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# b) Screen shot: What symptoms and disabilities are important to articular

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### What symptoms and disabilities are important to articular cartilage repair patients? - survey update

Submitted by ergomaniac on February 29. 2008 · 3:38pm. abrasion arthroplasty ACI ACT cartilage repair hambly MACI MACT microfracture mosaicplasty OATS open survey osteochondral allograft osteochondral autograft outcomes survey reports

## Positive first response from medical community...

In June 2007 the KNEEguru website started a survey looking at 'What symptoms and disabilities are important to articular cartilage repair patients?'. The first 58 responses from the survey were anonymously collated, analysed and submitted as a clinical article to the American Journal of Sports Medicine. Earlier this month the authors received confirmation that the paper has been accepted for publication in a forthcoming issue of the American Journal of Sports Medicine.

The feedback from one of the reviewers was ....

This is a very interesting and clinically relevant study that can potentially help researchers and clinicians to select a more appropriate instrument for patient-based outcome measures in patients with articular cartilages repair surgeries.

A link to the abstract for the publication will be posted on the Survey Reports section of the KNEEguru Information Hub once the article has gone to press.

This survey will be staying open for the foreseeable future so that more responses can be collected with a view to gaining a more in depth insight into what symptoms are important to articular cartilage repair patients.

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# c) Screen shot: News Box update on KNEEguru Bulletin Board


# d) Screen shot: IKDC or KOOS? Which measures symptoms and disabilities

# most important to postoperative articular cartilage repair patients?

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### **IKDC or KOOS? Which Measures** Symptoms and Disabilities Most **Important to Postoperative** Articular Cartilage Repair Patients?

Submitted by admin on June 26, 2008 - 1:22pm. articular cartilage repair | cartilage repair hambly IKDC KOOS outcome measures scoring systems tegner

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#### Hambly K and Griva K. IKDC or KOOS? Which Measures Symptoms and **Disabilities Most Important to** Postoperative Articular Cartilage Repair Patients?. Am J Sports Med. 2008;epublication ahead of print.

This author has approached the KNEEguru bulletin

board members and elicited their co-operation in evaluating two scoring systems widely used by orthopaedic surgeons and researchers. Her objective was to ask the people who had had a cartilage repair procedure to rate how each element of the scoring systems related to their own personal symptoms and disabilities.

Fifty-eight bulletin board members gave up their time to answer the online questionnaire. The questions were a consolidation of the questions of the IKDC and KOOS scoring systems, and the author later separated the results to allow a comparison of the two scoring systems. IKDC (International Knee Documentation Committee) and KOOS (Knee injury Osteoarthritis Outcome Score) are what are known as QOL (Quality of Life)

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IKDC or KOOS? Which Measures Symptoms and Disabilities Most Import...perative Articular Cartilage Repair Patients? | KNEEguru notebook

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scoring sytems and are used to measure the effect of the medical problem on the patient's quality of life *as evaluated by the patient*.

The study was undertaken because the authors have recognised that there is a problem in the field of medical research - researchers are trying to compare the outcomes of different types of treatment, but there is no standardisation of scoring systems, so it can be very difficult to decide whether one type of treatment is better than another. This is true also of QOL scoring systems. One of the scoring systems may be very relevant to cruciate ligament patients, for example, but less relevant to patients with cartilage damage.

Karen Hambly's special research interest is cartilage repair. She was aware of the paper published in 2007 (ref 1) where the author concluded that the most representative of the OOL scoring systems for knee patients in general were the IKDC and KOOS systems. The IKDC had been designed to measure symptoms, function, and sports activity in patients who have one or more of a variety of knee conditions, including ligament, meniscal, articular cartilage, arthritis, and patellofemoral injuries. The KOOS had been designed with the purpose of evaluating short-term and long-term symptoms and function in subjects with a variety of knee injuries that could possibly result in osteoarthritis. The authors set out in this study to determine which of these two scoring systems better reflected the specific concerns of the postoperative cartilage repair patient.

In addition to IKDC and KOOS, the authors also built into the questionnaire the elements of the Tegner scoring system. The Tegner evaluates the activity levels of the patient and also their involvement in sporting activities.

The carefully-designed survey (approved by the London Metropolitan University's ethics committee) was posted on the KNEEguru bulletin board. The 58 responses were analysed taking note of both the frequency of a symptom and also how important that symptom was to the patient. The results highlighted that although both the IKDC and the KOOS scoring systems had a large number of questions of relevance and importance to this postoperative articular cartilage repair patient group, the IKDC scoring system better reflected their concerns.

#### References

1 Tanner SM, Dainty KN, Marx RG, Kirkley A. Knee-specific quality-oflife instruments: which ones measure symptoms and disabilities most important to patients? Am J Sports Med. 2007;35(9):1450-1458.

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