

Systematic Review

Comprehensiveness of Outcome Reporting in Studies of Articular Cartilage Defects of the Knee

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Purpose: To assess the comprehensiveness of outcome reporting after treatment of focal articular cartilage defects in the knee. **Methods:** A systematic review of literature published over the past 5 years (October 2010 to October 2015) in 5 high-impact orthopaedic journals was completed to identify all recent clinical studies tracking outcomes after surgery for focal articular cartilage defects in the knee. A metric reporting score was calculated for each study, according to reporting of 6 cardinal domains: pain, satisfaction, osteoarthritis progression, subjective knee function, objective knee function, and patient-reported outcomes. **Results:** Of the 122 studies included for review, 117 (96%) tracked patient-reported outcomes during follow-up. Nearly two-thirds of studies (63%) monitored progression of osteoarthritis at follow-up. Fewer than half of studies (39%) specifically monitored pain outcomes in patients. One-third of studies (30%) tracked patient satisfaction. Only 21% of studies monitored subjective knee function using proxies such as return to play, and only 17% of studies reported on objective knee function during return visits to the clinic. The average metric reporting score of all studies was 2.6, and nearly half of studies (48%) reported on only 1 or 2 domains of interest. **Conclusions:** There is substantial variability in outcome reporting after cartilage surgery in high-impact orthopaedic journals. Furthermore, most studies do not comprehensively track outcomes across domains. Both factors hinder comparison of results across studies. Future outcome metrics should focus on patient-centered factors to improve both accuracy of results reporting and standardization across studies. **Level of Evidence:** Level IV, systematic review of Level I-IV studies.

Despite a multitude of technological and biological advances, focal articular cartilage defects of the knee continue to present a clinical challenge. Many affected patients are young and have limb-related comorbidities, such as ligament deficiency or mechanical malalignment, which further complicates treatment algorithms. Therefore, accurate outcome reporting is essential in evaluating the efficacy of various treatment techniques and algorithms. Unfortunately, as has been

shown in rotator cuff disease¹ and anterior cruciate ligament tears,² outcome reporting may be highly variable, even in high-impact literature. Given the multitude of options for reporting outcomes after treatment in focal articular cartilage disease,³ it is important to assess reporting variability in these patients as well.

When considering outcome reporting in patients with focal articular cartilage defects, there may be several primary goals in treatment. These include resolution of pain, prevention of further articular cartilage degradation, return to preinjury level of activity and function, and even improvement in quality of life.⁴⁻⁶ Therefore, clinical studies of this patient population should ideally address many—if not all—of these outcome domains.

The goal of this study was to assess the comprehensiveness of outcome reporting after treatment of focal articular cartilage defects of the knee. We hypothesized that there would be significant variability in both the types of outcomes reported and the comprehensiveness of reporting across high-impact studies.

Methods

All studies related to treatment of focal articular cartilage defects of the knee from 5 high-impact orthopaedic journals over a 5-year period (October 2010 to

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Table 1. Impact Factor and Included References by Journal

Journal	2014 Impact Factor	No. of Included References
<i>American Journal of Sports Medicine</i>	4.362	62
<i>Arthroscopy</i>	3.191	8
<i>Journal of Bone and Joint Surgery—American</i>	5.280	10
<i>Knee Surgery, Sports Traumatology, Arthroscopy</i>	3.053	34
<i>Clinical Orthopaedics and Related Research</i>	2.765	8

October 2015) were included for review (Table 1). This methodology has been used in several prior studies and was chosen to focus inclusion on high-impact orthopaedic literature.^{1,2,7,8} Six cardinal domains were considered in this literature review, comprising reporting of outcomes related to pain, satisfaction, objective knee function, subjective knee function, patient-reported outcomes (PROs), and progression of degenerative joint disease. Any article related to surgical treatment of patients with focal articular cartilage defects of the knee was included for review. The exclusion criteria included cadaveric or biomechanical studies, case reports, systematic reviews, meta-analyses, studies that did not report clinical outcomes, and studies of patients undergoing concomitant surgery (ligament reconstruction, meniscal transplantation, cartilage prosthesis, and mechanical realignment).

For each included study, the level of evidence was documented, along with the type of treatment included. In addition, any reporting of pain, satisfaction, objective knee function, subjective knee function, use of PROs, and progression of arthritis was noted and compared across studies. A metric reporting score (MRS) was assigned to all studies, ranging from 0 to 6 points, to reflect the number of these cardinal domains that were reported.

Results

A total of 122 studies met all inclusion criteria. The average number of patients in each study was 63 (range, 4 to 827 patients), with an average age of 33 years (range, 12 to 47 years) and an average follow-up time of 5.2 years (range, 0.75 to 21.8 years). In total, three-quarters of studies were Level IV, whereas only 15% of studies were either Level I or Level II (Fig 1). Although a variety of different treatments were performed, studies using autologous chondrocyte implantation were most commonly reported (Fig 2).

With regard to pain reporting, a total of 47 studies (39%) reported outcomes specifically related to pain (Fig 3). These included reporting of visual analog scale pain scores (40 studies, 33%), responses to a general

pain questionnaire (13 studies, 11%), and reports of pain during exercise (2 studies, 1.6%).

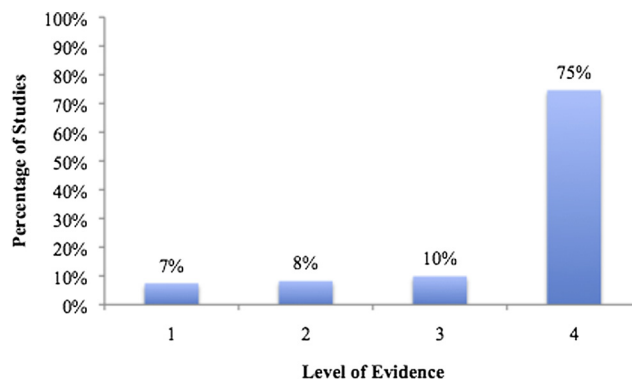
Only 36 studies (30%) reported on any satisfaction metrics. However, a number of different metrics were used to report patient satisfaction (Fig 4). The most commonly reported satisfaction metric was reporting of general satisfaction (20 studies, 16%). Fourteen studies (11%) reported on the likelihood of desiring to undergo the same operation again, and 7 studies (5.7%) reported a visual analog scale or numerical satisfaction score.

The third domain assessed was reporting of progression of arthritis or degenerative joint disease in patients (Fig 5). A total of 77 studies (63%) monitored progression of osteoarthritis after cartilage surgery. The most common modality used to report progressive degenerative findings was magnetic resonance imaging (63 studies, 52%), followed by histology or biopsy, second-look arthroscopy, radiography, and computed tomography scan.

Knee function was assessed in 3 categories: objective knee function, subjective knee function, and PROs. Objective knee function included assessment of examination findings or functional test outcomes monitored during clinic visits. This was the least commonly reported outcome, appearing in only 21 studies (17%) (Fig 6). The most commonly reported objective test was range of motion, which was documented in 11% of studies.

With regard to subjective knee function, a variety of metrics were reported. Any outcomes tracking return to preinjury knee function, including return to play, return to activity, and return to work, were considered proxies for subjective knee function. A total of 26 studies (21%) reported on subjective knee function (Fig 7). Among the studies that did report on this topic, return to sport was the most commonly asked question (17 studies, 14%). Within this subdomain, 14 studies (11%) reported on activity level after return to sport whereas 8 studies (6.6%) reported on time to return to sports.

PROs were by far the most commonly reported assessment of knee function, with 117 studies (96%)

**Fig 1.** Distribution of studies included by level of evidence.

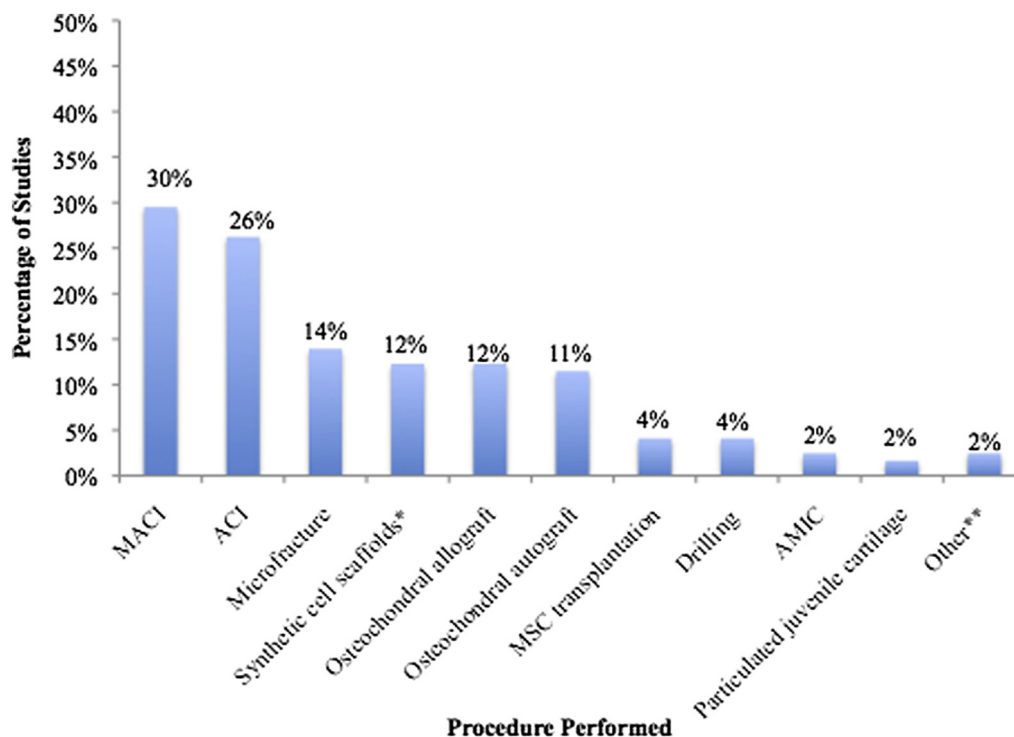


Fig 2. Distribution of the different types of knee cartilage surgery studies that were included in this systematic review. Over half of included studies reported on various techniques of chondrocyte implantation. Synthetic cell scaffolds (1 asterisk) were as follows: synthetic resorbable scaffold (1), cell-free collagen type I matrix (1), nano-composite multilayered biomaterial (3), biomimetic osteochondral scaffold (3), bone cartilage paste graft (1), extracellular matrix biomembrane with microfracture (1), Hyalograft C (Anika Therapeutics, Bedford, MA) (2), alginate beads containing human mature allogeneic chondrocytes (1), scaffold-based BST-CarGel (Piramal Healthcare, Quebec, Canada) (1), and MaioRegen scaffold (JRI Orthopaedics, Sheffield, England) (1). Other procedures (2 asterisks) comprised chondroplasty (1), TruFit Plug (Smith & Nephew, Andover, MA) (1), and abrasion arthroplasty (1). The aforementioned numbers in parentheses refer to the number, not percentage, of studies focusing on each surgical technique. (ACI, autologous chondrocyte implantation; AMIC, autologous matrix-induced chondrogenesis; MACI, matrix-induced autologous chondrocyte implantation; MSC, mesenchymal stem cell transplantation.)

using at least 1 PRO. In total, 24 different PROs were reported across all studies (Fig 8). Only 4 of 24 PROs appeared in more than 20% of studies, with the International Knee Documentation Committee (IKDC) score and Knee Injury and Osteoarthritis Outcome

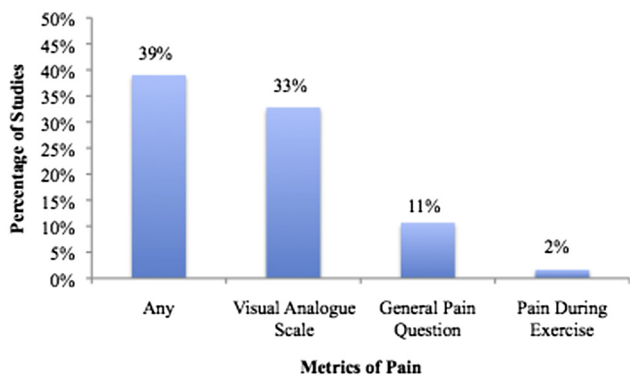


Fig 3. Distribution of pain reporting across various cartilage studies. Although a minority of studies reported on pain outcomes, there was low variability of pain measurements used.

Score (KOOS) being the scores most commonly reported (58% and 39%, respectively). Conversely, 18 of 24 PROs appeared in fewer than 10% of studies. Of all PRO scores measured, only the IKDC score,⁹ Lysholm score,^{10,11} and KOOS¹² have readily available evidence indicating that they are validated scores for patients with focal articular cartilage disease. Furthermore, only 9 additional PRO scores have been validated in the knee (Tegner, Cincinnati, Western Ontario and McMaster Universities Osteoarthritis Index, Knee Society Score, Marx, Kujala, Hospital for Special Surgery, Knee Outcome Survey of Activities of Daily Living, and Single Assessment Numeric Evaluation), whereas 2 have been validated for overall health (Short Form and EuroQol).

After we assessed the percentage of studies tracking each domain of interest (Fig 9), we graded all studies according to comprehensiveness of reporting inclusion (MRS, Fig 10). One point was awarded for each domain included, with a maximum possible score of 6 points for any study that reported outcomes related to the focus domains of pain, satisfaction, progression of arthritis, objective knee function, subjective knee function, and

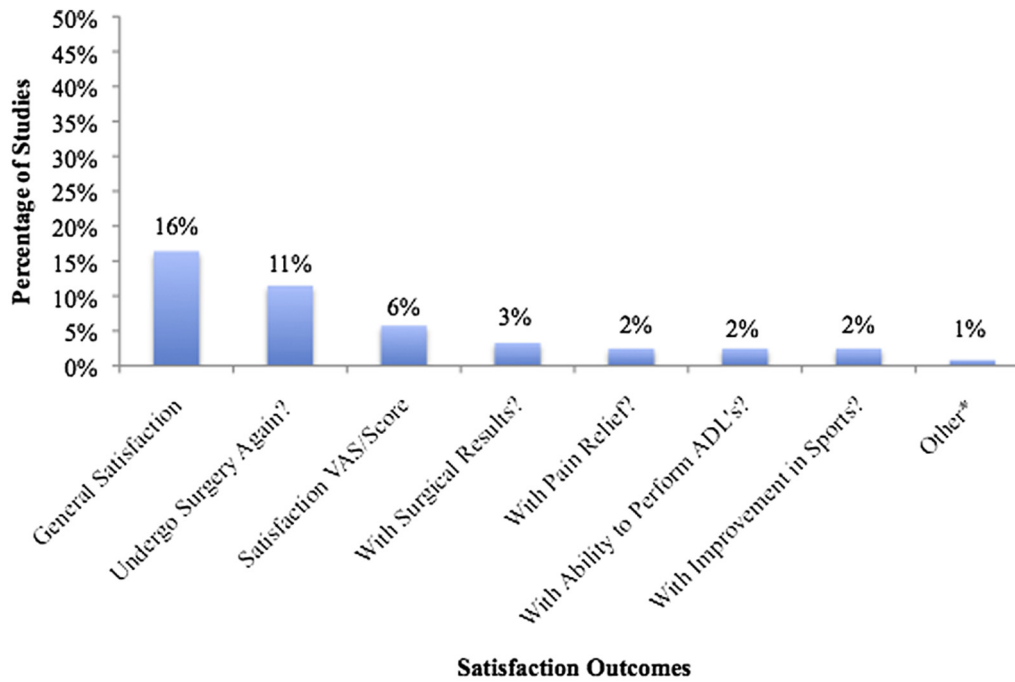


Fig 4. Metrics of patient satisfaction reported for cartilage surgery of the knee. Patient satisfaction was infrequently reported, with high variability in questions asked. Other outcomes (asterisk) were as follows: satisfaction with ability to undertake recreational activities (1), level of sports involvement allowed (1), would patient recommend this surgery to others (1), surgeon satisfaction (1), and general rating of surgery (1). The aforementioned numbers in parentheses refer to the number, not percentage, of studies focusing on each surgical technique. (ADLs, activities of daily living; VAS, visual analog scale.)

PROs. The average MRS across studies was 2.63 ± 1.06 points. Every study reported on at least 1 domain of interest. The highest proportion of studies had an MRS of 2 or 3 points, which represented 34% and 30% of studies, respectively. Only 1 study reported on all 6 domains. In total, 17 studies (14%) reported on just 1 of the focus domains.

Discussion

The results of this study confirm that outcome reporting of focal articular cartilage defects of the knee

in high-impact literature is highly variable. Twenty different PROs were each used in fewer than 20% of included studies. Moreover, most studies only reported outcomes for 3 or fewer categorical domains. Incomplete reporting by these studies may inadequately

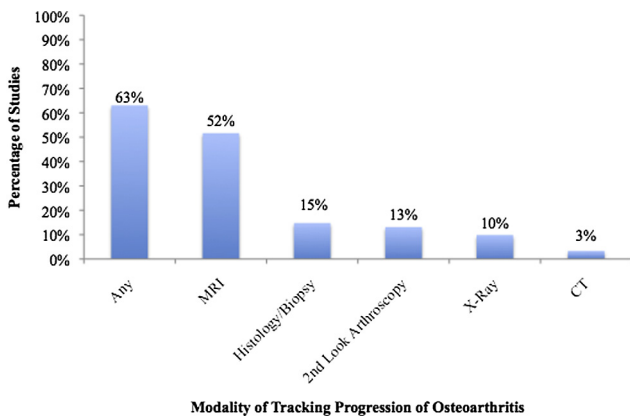


Fig 5. Modalities of monitoring progression of osteoarthritis in included studies. Nearly two-thirds of studies monitored progression of osteoarthritis during follow-up. (CT, computed tomography; MRI, magnetic resonance imaging.)

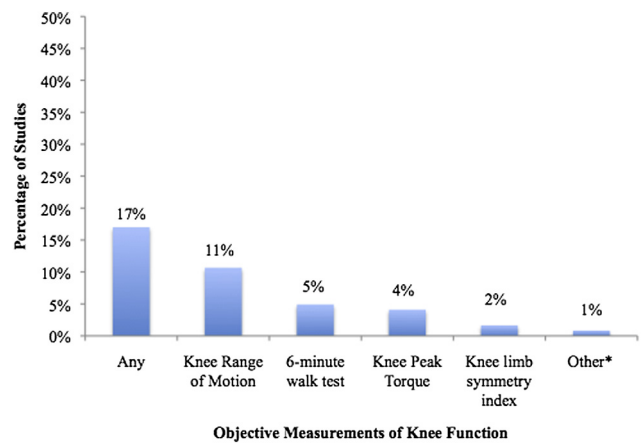


Fig 6. Objective measurements of knee function during follow-up visits to clinic. Fewer than one-fifth of studies reported on objective clinical findings during follow-up. Other measurements (asterisk) were as follows: patellar translation (1), three-repetition maximum straight leg raise (1), hamstring-quadriceps (HS-quad) strength ratio (1), effusion level (1), assessment of jumping on 1 leg (1), assessment of climbing stairs (1), and assessment of crouching (1). The aforementioned numbers in parentheses refer to the number, not percentage, of studies focusing on each surgical technique.

Fig 7. Subjective assessments of knee function reported in included studies. Fewer than a quarter of studies reported on subjective assessments, with high variability among those that did report. Other definitions of function (asterisk) were as follows: visual analog scale of stability (1), visual analog scale of function (1), numeric analog scale of function (1), general knee function score (1), general knee score compared with preinjury (1), and functional score (1). The aforementioned numbers in parentheses refer to the number, not percentage, of studies focusing on each surgical technique.

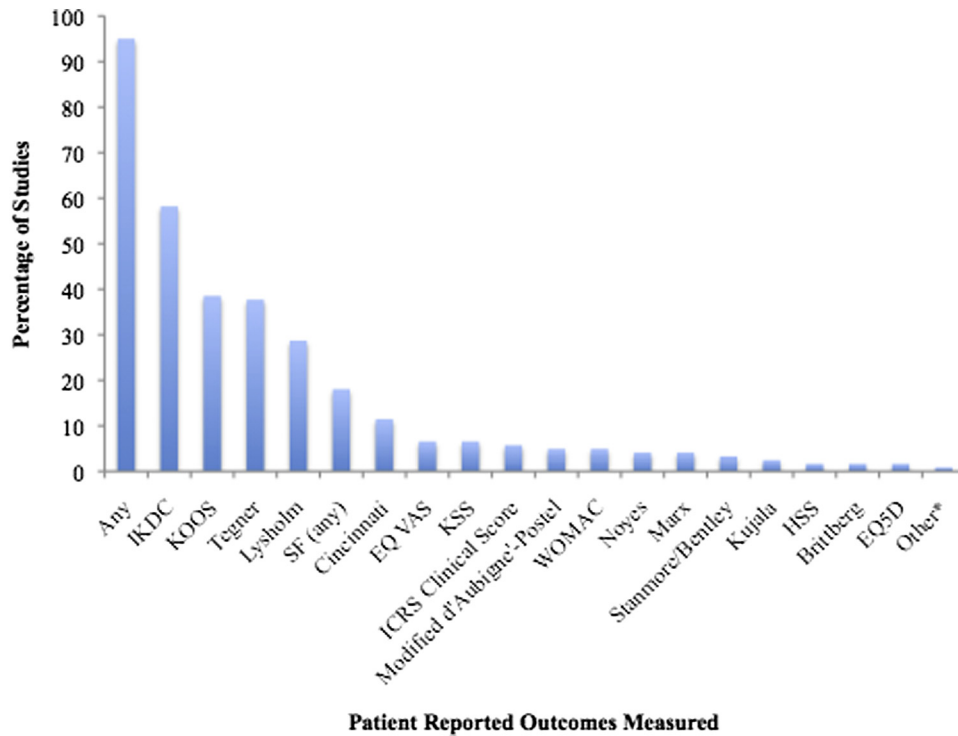
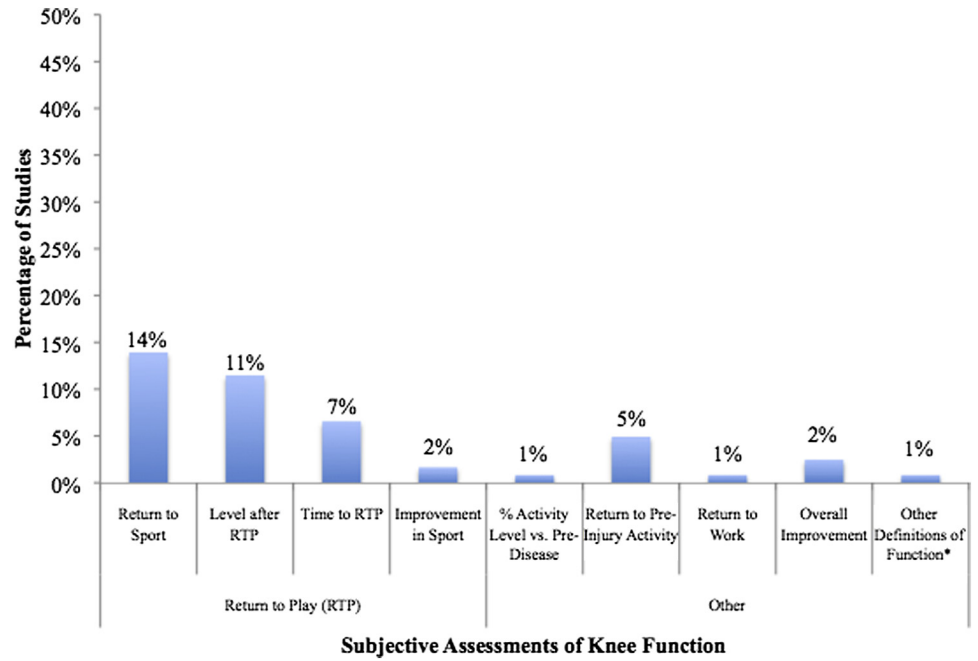


Fig 8. Patient-reported outcomes measured in cartilage outcomes studies. Whereas most studies tracked patient-reported outcomes, there was high variability in reporting of this metric. Other outcomes (asterisk) were as follows: Single Assessment Numeric Evaluation (1); Knee Outcome Survey of Activities of Daily Living (1); Fulkerson (1); Meyer (1); University of California, Los Angeles Activity Score (1); and rating scale of “excellent,” “good,” “moderate,” and “poor” (1). The aforementioned numbers in parentheses refer to the number, not percentage, of studies focusing on each surgical technique. (EQ VAS, EuroQol Visual Analogue Scale; EQ5D, EuroQol 5D form; HSS, Hospital for Special Surgery score; ICRS, International Cartilage Repair Society; IKDC, International Knee Documentation Committee; KOOS, Knee Injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; SF, Short-Form 12 or 36; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.)

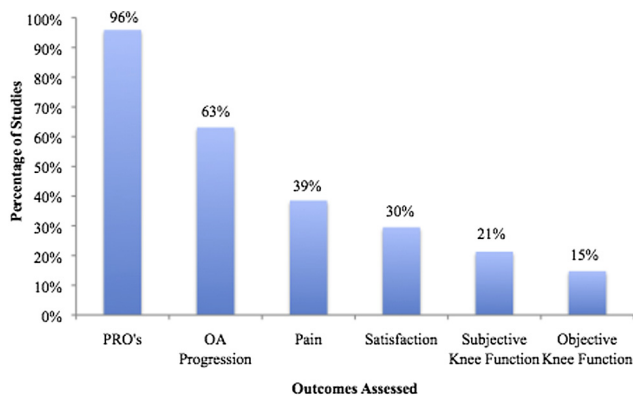


Fig 9. Percentage of included studies reporting on each domain of interest. Fewer than half of studies reported on 4 key domains of interest. (OA, osteoarthritis; PROs, patient-reported outcomes.)

convey outcomes after treatment, especially those that may be relevant to patients. Even within commonly reported metrics, such as PROs, inconsistency in type of PRO selected may hinder accurate comparison of results across different studies.

When considering quality of outcome reporting, it is imperative to focus on results that matter most to patients. In a recent study, Niemeyer et al.¹³ surveyed 118 patients undergoing autologous chondrocyte implantation regarding expectations after treatment. In total, 70% of patients expected to return to pain-free sports participation, and 20% of patients expected to have no restrictions while returning to high-impact sports. The results of our study indicate that only 14% of studies report any outcomes with regard to return to sport, with only 11% reporting on level after return to sport. Moreover, only 7% of studies report on time to return to play. This lack of reporting identifies a clear deficiency in the current state of outcome reporting of these active patients. However, the IKDC and KOOS forms both have been validated in patients with focal articular cartilage defects of the knee and were found to be the most reported forms in our group of studies. Therefore, continued emphasis on validated outcome tools should be encouraged.

There is increasing evidence that standardization of outcome reporting is beneficial for clinicians and patient alike.^{14,15} From a quality perspective, it affords the opportunity to truly compare results of various treatments across multiple different studies. Although criteria have been established by Coleman et al.¹⁶ to assess overall study methodology after surgery in the knee, articular cartilage surgery studies may exhibit a “pseudo-ceiling” effect when evaluated using generic knee surgery parameters because of unspecific and sometimes irrelevant metrics.¹⁷ Unlike the Coleman score, the MRS is intended only for outcome assessment after articular cartilage surgery

in the knee and to demonstrate the variability with current study reporting. Standardization of outcome reporting using the MRS alongside existing study methodology systems may decrease ambiguity when assessing the true impact of a given treatment. Finally, when attempting to report outcomes from a patient perspective, it is necessary to first understand what factors are important to patients with regard to their disease and recovery after treatment. Only then can accurate and comprehensive reporting metrics be defined.

Limitations

There are several limitations in this study. First, the domains selected for assessment (pain, satisfaction, progression of arthritis, objective knee function, subjective knee function, and PROs) were chosen by the study team. Therefore, the criterion used in this study has not been validated in other studies. However, it is the opinion of the study team, which is experienced in the treatment of focal articular cartilage defects, that these 6 domains comprise the most important expectations for this challenging patient population. Second, only a selective literature review was conducted of high-impact orthopaedic journals. This constriction likely excludes additional studies from consideration and inclusion. However, only high-impact studies were included to highlight the lack of standardization even at that level of impact. Therefore, inclusion of additional studies from lower-impact journals would likely reinforce the results of the study.

Conclusions

There is substantial variability in outcome reporting after cartilage surgery in high-impact orthopaedic journals. Furthermore, most studies do not comprehensively track outcomes across domains. Both factors hinder comparison of results across studies. Future outcome metrics should focus on patient-centered factors to improve both accuracy of results reporting and standardization across studies.

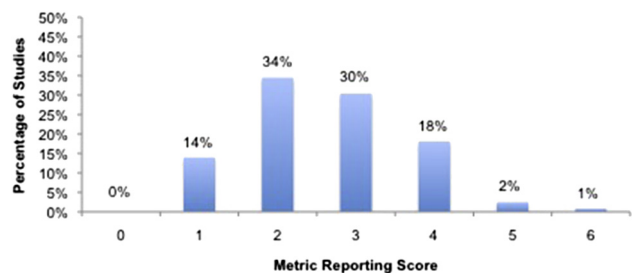


Fig 10. Breakdown of all studies by metric reporting score. Most studies reported on only 2 or 3 domains of interest.

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