The Current Evidence for Treatment of ACL Injuries in Children Is Low

A Systematic Review

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Background: There is no consensus on the management of anterior cruciate ligament (ACL) injuries in skeletally immature children, and the methodological quality of published studies is questionable. The transphyseal reconstructions, physeal-sparing reconstructions, and nonoperative treatment algorithms that are advocated have little support in the literature. The purpose of this study was to systematically review the methodological quality of the literature on the management of ACL injuries in skeletally immature children.

Methods: We performed a literature search with use of PubMed to identify prospective or retrospective studies whose primary aim was to assess the outcome after operative or nonoperative treatment of ACL injuries in skeletally immature children. To be included in the analysis, a study had to have a mean duration of follow-up of at least two years and a minimum of ten children in the study had to be verified to be skeletally immature. The methodological quality of the included studies was evaluated with use of the Coleman Methodology Score.

Results: No randomized controlled trials, two prospective cohort studies, and twenty-nine retrospective studies met the inclusion criteria. The Coleman Methodology Score averaged 44.7 ± 9.2 out of 100 (range, 28 to 62). The methodological deficiencies were most evident with regard to the number of included children, the study design, and the description of rehabilitation protocols, outcome criteria, and outcome assessments.

Conclusions: Caution is necessary when interpreting the results of studies on the treatment of ACL injuries in skeletally immature children because of widespread methodological deficiencies. There is a need for appropriately sized prospective studies and detailed descriptions of rehabilitation programs.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

The increased focus on the health benefits of regular physical activities highlights the importance of youth participation in sports[1]. However, there is a concern that participation in sports exposes children to musculoskeletal injuries that may negatively influence their long-term health[2,3]. During the past two decades, there have been an increasing number of studies on anterior cruciate ligament (ACL) injuries in skeletally immature children[4]. The main dilemma is whether surgical treatment can provide an adequate functional outcome without harming the physis or whether nonoperative treatment should instead be advocated until skeletal maturity is reached. Nonoperative management has been associated with an increased risk of secondary injuries and future disability[5-7]. Two recent publications, a systematic review[8] and a meta-analysis[9], have concluded that surgical treatment is safe and provides a good functional outcome. Although concerns have been raised regarding the quality of studies on this topic, the methodological quality of these studies has not been assessed[4,8,9].

In the present study, we review the literature on the treatment of ACL injuries in skeletally immature children with use of the Coleman Methodology Score, which has recently

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been used to evaluate the methodological quality of studies on a variety of other orthopaedic treatments[10-17].

Materials and Methods

To be eligible for inclusion, published studies had to be randomized controlled trials, prospective studies, or retrospective studies on operative or nonoperative treatment of an intrasubstance ACL injury in skeletally immature children. In addition, the study population had to have a minimum of ten children who were verified to be skeletally immature, and the mean duration of follow-up had to be at least two years. Studies had to be in English, German, or a Scandinavian language.

Search Strategy and Study Selection

Two systematic searches were performed with use of PubMed, and studies published between 1966 and May 2011 were included. The search strategies are shown in the Appendix. The first search (search #13 in the Appendix) aimed to identify studies on surgical treatment of ACL injury in skeletally immature children, and the second search (search #14 in the Appendix) aimed to identify studies on nonoperative and postoperative rehabilitation after ACL injury in this population. The abstracts of the identified studies were reviewed independently by two of the authors to assess eligibility. If an abstract did not provide sufficient information, the full text of the article was reviewed. Additionally, the reference lists of included studies were reviewed to identify additional studies that had not been found through the initial searches. Inclusion of the studies was determined by consensus between the two reviewers. The full text of the included articles was retrieved and assessed for methodological quality. Each included study was categorized, on the basis of the primary treatment described, as involving (1) transphyseal reconstruction, (2) physeal-sparing reconstruction, or (3) nonoperative treatment.

Study Quality Assessment

The Coleman Methodology Score[12] was used to assess the methodological quality of the included studies. This instrument consists of two parts with seven and eleven criteria, respectively, and the total score can range from 0 to 100. Part A has a maximum possible score of 60, and part B has a maximum score of 40 (see Appendix). A high score indicates a study with few confounding factors or other biases. The criteria for the Coleman Methodology Score were developed on the basis of the CONSORT (Consolidated Standards of Reporting Trials) statement[12,18].

In the present study, some of the scoring criteria in part A were modified: (1) the study size (question 1) was altered from the number of tendons to the number of patients; (2) the mean duration of follow-up (question 2) was altered to the minimum duration of follow-up, and the corresponding time criteria were changed from more than twenty-four months to more than five years, from between twelve and twenty-four months to between two and five years, and from less than twelve months to less than two years; (3) the type of study (question 4) was modified to include case series, which were assigned a score of 0 (the same score as retrospective cohort studies); and (4) the description of rehabilitation (question 7) was modified to omit compliance with rehabilitation from the scoring criteria. No modifications were made to the criteria in part B. The studies were scored independently by the reviewers, and any scoring discrepancies were discussed until consensus was achieved.

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Results

A flow diagram of the study selection process is shown in Figure 1, which is based on the PRISMA (Preferred

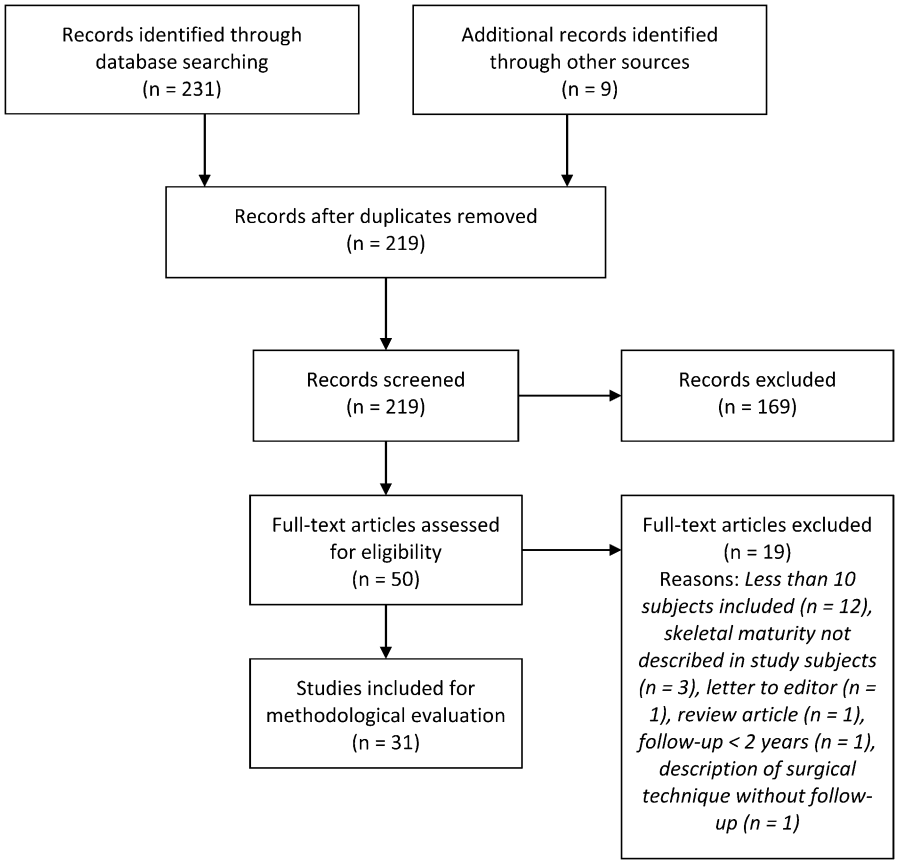

Fig. 1
Flow diagram showing the identification of potentially applicable studies and evaluation of their eligibility.

TABLE I Overview of the Included Studies, Sorted According to the Total Coleman Methodology Score

Study	No. of Patients	Treatment Algorithm*	Mean Age at Inclusion (Range) *(yr)*	Mean Follow-up (Range) *(yr)*	Coleman Methodology Score		
					Part A, Maximum = 60	Part B, Maximum = 40	Total, Maximum = 100
Liddle (2008)	17	T	12.1 (9.5-14.0)	3.8 (2.1-8.3)	37.0	25.0	62.0
Kocher (2007)	59	T	14.7 (11.6-16.9)	3.6 (2.0-10.2)	34.0	26.0	60.0
Nikolaou (2011)	94	T	13.7 (11.6-15.9)	3.2 (2.0-5.0)	37.0	23.0	60.0
Kocher (2005)	44	P	10.3 (3.6-14.0)	5.3 (2.0-15.1)	34.0	26.0	60.0
Janarv (1996)	28	P	13.1 (9.9-15.0)	Minimum, 3.0	29.0	28.5	57.5
Cohen (2009)	26	T	13.3 (11-15)	3.8 (2.0-7.0)	26.0	24.5	50.5
Steadman (2006)	13	P	13 (10-16)	5.8 (2.2-9.4)	27.0	23.0	50.0
Moksnes (2008)	26	N	10.3 (5.2-12.7)	3.8 (2.0-9.0)	19.0	30.5	49.5
Fuchs (2002)	10	T	13.2 (9-15)	3.3 (2.2-5.0)	22.0	26.0	48.0
Shelbourne (2004)	16	T	14.8 (13.1-15.8)	3.4 (std. dev., 1.1)	25.0	23.0	48.0
Bonnard (2011)	57	P	12.2 (6.8-14.5)	5.5 (2.0-14.0)	29.0	19.0	48.0
Woods (2004)	13	N	13.8 (11.0-16.0)	5.8 (1.8-24.5)	23.0	25.0	48.0
Courvoisier (2011)	38	T	14.0 (11.0-15.0)	3.0 (2.0-4.0)	26.0	21.5	47.5
Lipscomb (1986)	24	P	13.5 (10-15)	2.9 (2.0-5.0)	26.0	21.5	47.5
Aronowitz (2000)	21	T	13.4 (11-15)	2.1 (1.0-5.0)	29.0	17.5	46.5
Seon (2005)	11	T	14.7 (13.1-15.5)	6.5 (3.8-10.9)	22.0	24.5	46.5
Marx (2009)	55	T	13.4 (8.4-16.6)	3.2 (1.0-7.5)	27.0	18.0	45.0
Kopf (2010)	14	T	14.4 (11-16)	7.0 (1.9-11.1)	15.0	27.5	42.5
Anderson (2004)	12	P	13.3 (std. dev., 1.3)	4.1 (2.0-8.1)	22.0	19.5	41.5
Mizuta (1995)	18	N	12.8 (10-15)	4.3 (0.8-8.3)	17.0	24.5	41.5
Aichroth (2002)	45	T	13 (11-15)	4.1 (1.0-8.0)	30.0	11.0	41.0
McIntosh (2006)	16	T	13.6 (11.2-14.9)	3.4 (2.0-9.3)	15.0	24.5	39.5
Edwards (2001)	20	T	13.7 (11.8-15.6)	2.8 (1.4-7.4)	19.0	19.5	38.5
Gaulrapp (2006)	53	T	13.9 (9-16)	6.5 (3.0-11.0)	19.0	17.5	36.5
Streich (2010)	31	T	11 (9-12)	5.8 (3.4-7.1)	21.0	15.0	36.0
Henry (2009)	56	T	12.4 (5.0-16.8)	2.3 (1.0-6.8)	17.0	18.5	35.5
Gebhard (2006)	40	P	11.9 (7-14)	2.8 (1.1-17.0)	14.0	20.0	34.0
Micheli (1999)	17	P	11 (2-14)	5.5 (2.1-14.0)	22.0	11.0	33.0
McCarroll (1994)	60	T	13.7 (13-15)	4.2 (2.0-7.0)	17.0	15.0	32.0
Arbes (2007)	20	T	13.9 (9-15)	5.4 (0.5-10.5)	10.0	21.0	31.0
Graf (1992)	12	N	14.5 (11.7-16.3)	Minimum, 2.0	13.0	15.0	28.0

*T = transphyseal reconstruction, P = physeal-sparing reconstruction, and N = nonoperative treatment.

Reporting Items for Systematic Reviews and Meta-Analyses) statement[19]. The systematic search on operative treatment identified 209 potentially eligible abstracts, and twenty-one of the studies[7,20-39] were included. The search on rehabilitation identified twenty-two abstracts, and one of the studies[40] was included. Nine additional studies[5,6,41-47] were identified from manual searches of journals and the reference lists of the included studies and were also included.

Two of the thirty-one included studies were prospective cohort studies[27,30], and the remaining twenty-nine (94%) were retrospective studies; no randomized controlled trials were identified. The total number of participants in the included studies was 966, and the mean number of children per study was 31.2 (range, ten to ninety-four). The nineteen studies on transphyseal reconstruction had a mean of thirty-five children (range, ten to ninety-four), the eight studies on physeal-sparing reconstruction had a mean of twenty-nine children (range, twelve to fifty-seven), and the four studies on nonoperative treatment had a mean of seventeen children (range, twelve to twenty-six). The characteristics of all included studies are presented in the Appendix.

Methodological Quality

The results of the study quality assessments are presented in Table I. None of the studies fulfilled all of the criteria, and the mean Coleman Methodology Score (and standard deviation) was 44.7 ± 9.2. The lowest score was 28[38], and the highest was 62[30]. The mean score was 23.3 ± 7.1 for part A and 21.4 ± 4.9 for part B. The mean scores for the individual sections are shown in Table II. The highest mean scores in part A were for "diagnostic certainty" (4.8 out of 5) and "description of treatment given" (4.3 out of 5), and the lowest score was for "type of study" (0.6 out of 15). The highest score in part B was for "description of

TABLE II Coleman Methodology Score, Mean Section Scores

Section Score (Maximum)	Mean	Range	Standard Deviation
Part A (60)	23.3	10-37	7.1
1. Study size—number of patients (10)	3.5	0-10	
2. Minimum follow-up (5)	1.3	0-2	
3. Number of different treatment procedures included (10)	5.8	0-10	
4. Type of study (15)	0.6	0-10	
5. Diagnostic certainty (5)	4.8	0-5	
6. Description of treatment given (5)	4.3	0-5	
7. Description of preop. and postop. rehabilitation and/or conservative treatment (10)	2.9	0-10	
Part B (40)	21.4	11-30.5	4.9
Outcome criteria (10)	4.7	0-10	
8. Outcome measures clearly defined (2)	1.7	0-2	
9. Timing of outcome assessment clearly stated (2)	0.2	0-2	
10. Use of outcome criteria that has reported good reliability (3)	2.0	0-3	
11. Use of outcome with good sensitivity (3)	0.9	0-3	
Procedure for assessing outcomes (15)	3.9	0-15	
12. Subjects recruited (5)	0.5	0-5	
13. Investigator independent of surgeon/therapist (4)	0.3	0-4	
14. Written assessment (3)	2.4	0-3	
15. Completion of assessment by subjects themselves with minimal investigator assistance (3)	0.7	0-3	
Description of subject selection process (15)	12.8	8-15	
16. Selection criteria reported and unbiased (5)	4.8	0-5	
17. Recruitment rate reported (≥80% = 5; <80% = 3) (5)	4.5	3-5	
18. Eligible subjects not included in the study satisfactorily accounted for (5)	3.4	0-5	
Total score (100)	44.7	28-62	9.2

subject selection process" (12.8 out of 15). Table III compares the Coleman scores of the three different treatment algorithms.

The study by Liddle et al.[30] had the highest Coleman score. That study involved prospective follow-up of seventeen children who had undergone identical ACL reconstructions with a transphyseal technique and hamstring tendon grafts. The study also reported specifically on the postoperative rehabilitation program and secondary injuries, and it used adequate outcome measurements. The two studies by Kocher et al.[7,21] and the recent study by Nikolaou et al.[5] had the next-highest scores. The studies by Kocher were performed with identical designs and are good examples of how retrospective studies can have a sound methodological design. The 2005 study involving physeal-sparing reconstruction and the 2007 study involving transphyseal reconstruction had clear inclusion criteria, relatively large homogenous populations (forty-four and fifty-nine children, respectively), and a treatment algorithm based on physiological maturity and knee function. The

TABLE III Coleman Methodology Score According to Treatment Algorithm*

Section score (Maximum)	Transphyseal (N = 19)	Physeal Sparing (N = 8)	Rehabilitation (N = 4)
Part A (60)	23.6 (10-37)	25.4 (14-34)	18.0 (13-23)
Part B (40)	21.0 (11-27.5)	21.1 (11-28.5)	23.8 (15-30.5)
Outcome criteria (10)	4.8 (0-7)	4.2 (0-8.5)	5.5 (0-10)
Procedure for assessing outcomes (15)	3.4 (0-11)	4.5 (0-12)	4.5 (0-15)
Description of subject selection process (15)	12.7 (8-15)	12.4 (8-15)	13.8 (10-15)
Total score (100)	44.6 (31-62)	46.4 (33-60)	41.8 (28-49.5)

*Values are given as the mean, with the range in parentheses.

study by Nikolaou et al.[5] involved ninety-four skeletally immature children who underwent transphyseal reconstruction with good results as assessed with use of functional questionnaires and return to sports. In these four highest-rated studies, 4.2% (nine) of the 214 grafts sustained a rerupture, and growth disturbance was reported in 0.5% (one) of the patients. Furthermore, 47% (101) of the patients had 104 concomitant meniscal injuries, 67% (seventy) of which were treated with surgical repair. The meniscal repair failed during the follow-up period in 14% (ten) of those patients. However, only 10% (three) of the thirty-one included studies[32,38,43] included validated outcome measures, such as magnetic resonance imaging (MRI) or arthroscopy, for evaluating secondary meniscal tears or cartilage injuries.

Treatment Algorithms and Rehabilitation

Eleven of the nineteen studies on transphyseal reconstruction used hamstrings tendons, two used bone-patellar tendon-bone autograft, four used diverse techniques, one used bone-patellar tendon-bone allograft, and one used Achilles tendon allograft. The eight studies on physeal-sparing reconstruction involved ten different surgical methods. Three of the four studies on nonoperative treatment included a description of an unambiguous algorithm involving primary nonoperative treatment, with optional delayed surgical treatment, in all subjects. None of the studies on nonoperative treatment provided well-described rehabilitation protocols. Rehabilitation guidelines were adequately described in only 3% (one[37]) of the thirty-one included studies. Rehabilitation was inadequately described in 58% (eighteen) of the studies and not described in 39% (twelve). Two studies (6%) included functional preoperative outcome measurements[27,30], whereas the remaining twenty-nine studies (94%) did not include any data on baseline or pretreatment knee function.

Discussion

This systematic review illustrates that studies on the treatment of skeletally immature children with ACL injury have major deficiencies with regard to methodological quality. Thirty-one studies with a total of 966 children were included, but none were randomized controlled trials, two had a prospective study design, and the remaining twenty-nine had a retrospective design. The included studies had a mean Coleman Methodology Score (and standard deviation) of 44.7 ± 9.2 out of a maximum possible score of 100, which suggest that the knowledge base for the management of ACL injuries in skeletally immature children is weak. The present review showed that the published studies have major weaknesses in methodological quality, particularly with regard to study size, study design, and the description of rehabilitation protocols (in part A of the Coleman score) and with regard to the assessment of knee function with adequate measurement tools (in part B of the Coleman score).

The Coleman score evaluates the quality of studies with regard to study design (part A) and the assessment of outcomes, recruitment, and compliance (part B). The included studies had a mean score 23.3 ± 7.1 out of 60 on part A and 21.4 ± 4.9 out of 40 on part B, suggesting that the main deficiencies regarding methodological quality in the literature on the management of ACL injuries in the skeletally immature population involved study design (part A).

Coleman et al.[12] reported a mean Coleman score of 37.3 ± 15.9 for studies on the outcome of surgical treatment of patellar tendinopathy, and Watsend et al.[15] reported a mean score of 52.1 ± 14.0 for studies on posterior cruciate ligament tears. Note that the "operation-specific" nature of Coleman scores for different procedures means that this score should not be used to compare the methodological quality of studies of different medical conditions, and that was not a goal of the present study. To our knowledge, the highest Coleman scores reported are from studies on different techniques of microfracture cartilage repair[11] and collagen meniscus implantation[10], with mean scores of 58.2 ± 3.6 and 67.1 ± 18.6, respectively. In 2005, Jakobsen et al.[14] evaluated the quality of studies on cartilage repair and found a mean Coleman score of 43.5 ± 12.5, with scores of 35.7 ± 9.3 for part A and 7.8 ± 4.7 for part B. Øiestad et al.[16] reported a mean modified Coleman score of 52.2 ± 13 out of 90 for studies involving long-term follow-up of adults with ACL injuries; the mean score was 31.1 ± 9.6 out of 50 for part A and 21.1 ± 6.9 out of 40 for part B. Comparison of the mean Coleman score for the studies in the present review with the scores in the previous studies shows the methodological quality of the studies on treatment of ACL injuries in skeletally immature children to be among the lowest reported. The main difference between the present systematic review and the other reviews is in part A, suggesting that greater attention in future research should be focused on designing adequately sized prospective studies.

Methodological deficiencies in the included studies were found in five criteria in particular: "study size," "type of study," "description of rehabilitation protocols," "outcome criteria," and "procedure for assessing outcomes." The main limitation involving study size and study type was the lack of randomized controlled trials and prospective studies. Thus, there is a need to perform high-quality prospective observational studies on this patient population that describe treatment algorithms, interventions, and outcomes in detail. Manchikanti et al.[48] and Hoppe et al.[49] emphasized that the results of observational studies are particularly valuable for investigating questions regarding etiology, prognosis, and estimates of potential risks. Furthermore, prospective long-term observational studies are suitable for detecting rare or late adverse effects of interventions, and they are more likely to provide an indication of what is accomplished in daily health care practice[50,51]. Thereafter, randomized controlled trials should be performed to compare the effects of different interventions. We recognize that there are practical and ethical limitations because of the low number of pediatric ACL injuries, but well-planned multicenter studies with uniform inclusion criteria and outcome measures should be performed.

The rehabilitation programs, including exercises and progression milestones, were also not well described in the majority of the included studies. Postoperative restrictions involving weight-bearing and knee motion were provided in some studies, but rehabilitation protocols describing exercise selection, dose, progression, and criteria for return to sports on the basis of functional performance were not.

The primary purpose of the published studies was to describe and evaluate surgical techniques. The majority of the studies had adequate descriptions of the surgical techniques, as reflected by the mean score of 4.3 out of 5 for the Coleman criterion "description of treatment given." Although the focus was on the surgical technique, the Coleman score highlights the importance of describing rehabilitation programs because of the known impact of rehabilitation on the functional outcome after orthopaedic surgical treatments. In future studies, there should be an increased focus on describing and assessing compliance with the rehabilitation programs to enhance the strength and clinical relevance of the results.

The major deficiencies involving outcome criteria were the absence of predefined and homogeneous timing of follow-up assessments and the lack of validated outcome measures with good sensitivity. All of the studies except the two with a prospective design had large variations in the time between inclusion or surgical treatment and the follow-up assessment, which significantly reduces the generalizability of the reported results. Additionally, 90% (twenty-eight) of the thirty-one included studies did not document adequate outcome measures for assessing secondary meniscal tears or cartilage injuries at the time of follow-up. Because arthroscopy or MRI was not included in the follow-up examinations, only secondary injuries that were treated during the follow-up period were documented in those studies. Thus, the number of secondary injuries may be underestimated in the published studies on surgical as well as nonoperative treatment and should be interpreted with caution.

Outcome measures with good sensitivity are also needed for young children with ACL injuries; although there is a need for reliable and validated self-reported questionnaires, none of the questionnaires that are frequently used have been validated in this population. There have been conflicting reports on how the International Knee Documentation Committee (IKDC) subjective knee evaluation form (2000 version) is understood by children[52-55]. Good reliability, validity, and responsiveness have recently been reported for the newly developed Pedi-IKDC[56]. Most of the studies in the present review used functional questionnaires, but few studies included performance-based outcome measures. Furthermore, the majority of studies included radiographs as an outcome measure, although only sixteen (52%) received points for having sufficient radiographic evaluations including standing longitudinal radiographs (question 11), which are a requirement for examining lower limb alignment and growth disturbances[57]. MRI has been suggested to be a good radiation-free method to determine skeletal maturity in the future[58], although further validation of this measure is needed[59].

Single-leg hop tests are reliable outcome measures for healthy adults and adults who have undergone ACL reconstruction[60,61]. Single-leg hop tests are recommended in combination with isokinetic strength measurements for functional evaluation of knee stability and ability to return to sports[62,63]. Additionally, isokinetic strength measurements have been documented to be reproducible and reliable in children six to fifteen years of age[64,65], and they are the preferred outcome measure for evaluation of quadriceps and hamstring muscle strength[66]. Three (10%)[27,37,40] of the thirty-one included studies used performance-based functional outcome measures to evaluate knee function at the time of final follow-up.

In the outcome assessment portion of the Coleman score, only three (10%)[27,40,41] of the thirty-one studies received points for reporting consecutive recruitment of patients (question 12); in the other twenty-eight studies, medical records or surgeon files had been searched to identify skeletally immature children with ACL injuries. Additionally, only two (6%) of the studies[27,40] received points for using investigators who were independent of the surgeon or therapist (question 13). Furthermore, only seven (23%) of the studies[7,21,29,39-41,43] included a clear statement that completion of the written assessments were performed by the patients themselves with minimal investigator assistance (question 15). Ultimately, reporting following the guidelines in the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement is essential to enable other researchers and clinicians to compare results[51].

We recognize that the present review has limitations. The electronic search was performed with use of only one database; however, because of the small number of published studies and the few research centers publishing on the topic, we are confident that all relevant studies have been included.

An important caution should be noted: although the methodological quality of the published studies was low, that does not mean that the quality of the treatments given in the studies was equally low. The purpose of this paper was not to assess the effect of the treatments applied. Because of the low methodological quality, clinicians and researchers should practice caution when deciding on the treatment recommendations to be given to skeletally immature children who have sustained an ACL injury. There are no studies with solid scientific evidence that can justify advising one treatment algorithm over others. The child and parents should be individually assessed and informed on the basis of a clinical examination, imaging, performance-based functional testing, and an initial rehabilitation program before conclusive advice on treatment of an ACL injury in a skeletally immature patient is provided.

In conclusion, this systematic review demonstrated that the methodological quality of the current literature on treatment of skeletally immature children with ACL injuries was generally low, as measured with use of the Coleman Methodology Score. The four studies with the highest scores reported good functional results with a low rate of growth disturbance. More attention should be paid to methodological quality when designing, performing, and reporting studies on treatment of skeletally immature children with ACL injuries. Particular attention should be given to the design of prospective studies, the inclusion of homogenous populations, detailed reporting of rehabilitation protocols, and the use of adequate outcome measures.

Appendix

eA Tables summarizing the Coleman Methodology Score, the included studies, and the number of studies identified

with use of each of the search terms are available with the online version of this article as a data supplement at jbjs.org. ■

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