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Are Prospective Criteria or Objective Clinical Measures Utilized in Return to Play (RTP) Decision Making After Ankle Surgery? A Scoping Review

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Abstract

Background: Manuscripts discussing return to play (RTP) following ankle surgery are common. However, the definition for RTP and the method by which it is determined remains unclear. The purpose of this scoping review was to clarify how RTP is defined following ankle surgery in physically active patients, to identify key factors informing RTP decision making (such as objective clinical measures), and make recommendations for future research.
Methods: A scoping literature review was performed in April 2021 using PubMed, EMBASE, and Nursing and Allied Health databases. Thirty studies met inclusion criteria: original research following ankle surgery reporting at least 1 objective clinical test and documentation of RTP. Data were extracted for study methods and outcomes (RTP definition, RTP outcomes, and objective clinical tests).
Results: The scoping review found studies on 5 ankle pathologies: Achilles tendon rupture, chronic lateral ankle instability, anterior ankle impingement, peroneal tendon dislocation, and ankle fracture. RTP criteria were not provided in the majority of studies (18/30 studies). In the studies that provided them, the RTP criteria were primarily based on time postsurgery (8/12) rather than validated criteria. Objective clinical outcome measures and patient-reported outcome measures (PROMs) were documented for each surgery when available. Both clinical outcomes and PROMs were typically measured >1 year postsurgery.
Conclusion: In physically active patients who have had ankle surgery, RTP remains largely undefined and is not consistently based on prospective objective criteria nor PROMS. We recommend standardization of RTP terminology, adoption of prospective criteria for both clinical measures and PROMs to guide RTP decision making, and enhanced reporting of patient data at the time of RTP to develop normative values and determine when the decision to RTP is not safe.

Level of Evidence: Level IV, scoping review.

Keywords: ankle, foot, chronic ankle instability, Achilles tendon, return to play, return to sport

Introduction

It is well documented that ankle injuries are common in sport.[17,21] Of particular interest, severe ankle injuries requiring surgical intervention can have sweeping effects on the athlete, causing lost time in training and competition, lost opportunity, lost income, and incurred medical costs.[5,44] Fortunately, surgical techniques have evolved greatly over the last 15 years and may offer improved clinical outcomes (such as faster return to sport, higher percentage of patients

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who are able to return to sport) to those who require surgery after failed conservative management.[36]

Postoperatively, the goal of the medical team is to return the athlete to participation as quickly and safely as possible. This postoperative return to play (RTP) should take into account multiple factors, including, but not limited to, soft tissue healing timelines, rehabilitation progress defined by objective clinical measures (eg, full range of motion [ROM], strength 90% of uninjured limb), subjective patient-reported instruments, sport risk assessment, and psychological readiness.[10,47] The decision should be made with contributions from within the medical team (eg, physician, physical therapist, athletic trainer) as well as the athlete's performance support system (eg, sport coach, strength coach). Historically postsurgical RTP decisions were primarily influenced by the surgical procedure performed and soft-tissue healing time frames, whereas modern sources recommend inclusion of these factors into a more comprehensive approach.[1,10,19,47] Data to support readiness for sport can be drawn from the results of validated subjective and objective outcomes measures, sport-specific testing, and psychological readiness tools.[1,10,19,47] However, it does not appear that recommendations for criteria-based RTP decision making are being fully implemented after ankle injury. For example, one systematic review of nonoperative lateral ankle sprains failed to identify a single study that used a prospective, criteria-based RTP decision-making process.[47] A similar review of operative management of common ankle injuries has not been performed to date.

Furthermore, there is a lack of clarity and great variability in how RTP and return to sport (RTS) are defined. Is RTP the point at which the athlete participates in their first day of restricted training? Is it once the athlete can engage in unrestricted training? Or is it back to preinjury competitive levels? It has been proposed that the RTP process should be viewed as a continuum through several steps.[47] Tassignon et al[47] applied a set of operational definitions[1] for athlete status post ankle injury, providing a progression from (1) the time the athlete is still in rehabilitation but beginning to participate in their sport perhaps in a controlled environment, and at a level lower than his or her return to sport goal (return to participation [RTPa]), through (2) the time when the athlete is playing without restrictions but not at his or her desired performance (return to sport [RTS]), and finally (3) when the athlete is performing at or above his or her preinjury level (return to performance [RTPf]). In musculoskeletal injuries treated surgically, the surgeon typically provides orthopaedic clearance for the introduction of athletic activity (aligning with the concept of RTPa), identifying that it is safe to *begin* the process of return to athletic activity, whereas ongoing rehabilitation and the transition to RTS are commonly led by the physical therapist and/or athletic trainer. Resources and level of sport (eg, professional vs recreational) will affect the composition of the athlete's medical team as they progress through RTPa, RTS, and RTPf. Although the definitions proposed by Tassignon et al[47] may be helpful in the future, current research often uses RTP or RTS interchangeably without specifying the exact stage in the continuum. We will use the term RTP where a more precise definition is lacking.

Scoping reviews are a relatively new concept in the research literature and aim to determine the coverage of the body of literature on a certain topic.[32,48] They can be especially useful to clarify key concepts or definitions in the literature (eg, RTP) and to identify key characteristics or factors related to a concept (eg, RTP criteria or measurement).[32] In contrast, a systematic review typically focuses on the outcomes of the reviewed studies, which was not the focus of the current research question.[32] Therefore, a scoping review design was adopted. The purpose of this scoping review was to clarify how RTP is defined following ankle surgery in physically active patients, to identify key factors informing RTP decision making, and make recommendations for future research.

Methods

Literature Search

We conducted a scoping review, in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for scoping reviews.[48] The search query was performed on April 12, 2021, in the following registries: PubMed, EMBASE, and Nursing and Allied Health Database. Studies were limited to the past 15 years (published between January 1, 2006, and April 2021). Results were restricted to peer-reviewed literature published in the English language. Key words were organized into 3 strings—string 1: *ankle* OR *talocrural* OR *hindfoot* OR *rearfoot* OR *tibiotalar* OR *subtalar*; string 2: *surgery* OR *operative* OR *open repair* OR *arthroscopy*; and string 3: *return to sport* OR *return to play* OR *return to performance*. Each string was connected in the search using the Boolean operator "AND." A representative search strategy is shown in Figure 1.

Inclusion and Exclusion Criteria

Studies were included if they met the following criteria: (1) patients are adults (>18 years old) engaged in any level of physical activity or sport; (2) patients underwent surgery in the region of the ankle joint (eg, Achilles repair, lateral ligament repair or reconstruction, peroneal tendon repair, and fracture fixation); (3) the study reports at least 1 objective clinical test (eg, ROM, strength measure, balance test, and functional test); (4) the study reports RTP data regardless of how it was labeled, including RTS, RTPa, RTPf (eg, RTP

#	Search terms	Pubmed	Nursing & Allied Health	Embase
1	Ankle	70,814	53,849	81,313
2	Talocrural	465	636	414
3	Rearfoot	1,210	1,193	985
4	Hindfoot	3,933	2,766	3,802
5	Tibiotalar	1,064	987	1,044
6	1 OR 2 OR 3 OR 4 OR 5	72,550	54,313	74,786
7	Surgery	2,938,087	534,888	3,047,409
8	Arthroscopy	31,756	21,415	31,195
9	Open repair	4,762	58,670	5,710
10	Surgical	1,244,341	414,075	1,243,509
11	Operative	290,528	119,867	319,434
12	7 OR 8 OR 9 OR 10 OR 11	3,329,481	713,991	3,351,102
13	Return to play	2,533	4,773	3,046
14	Return to sport	3,185	3,781	4,169
15	Return to performance	47	71	54
16	13 OR 14 OR 15	5,034	7,330	3,046
17	6 AND 12 AND 16	254	1,437	402

Figure 1. Representative search strategy.

criteria, time to RTP, or % RTP); and (5) the study is original research including randomized controlled trial, cohort, case-control, or case series in design.

Studies were excluded if they were (1) not in English, (2) not available as a full-text manuscript (eg, published abstract only), (3) not-peer reviewed, (4) did not report surgical outcomes, (5) were not published in the last 15 years, or (6) were a review, commentary, or case-study. We limited criteria to studies published in the last 15 years as surgical techniques and associated healing times are constantly evolving and we aimed to capture relatively recent trends.[36]

Study Selection

The results of the search strategy were compiled into a spreadsheet. Duplicate entries and search results that were clearly not full-text articles (eg, published abstracts, conference proceedings) were removed. In the first round of screening, 2 independent reviewers with subject knowledge and research experience screened the title of all publications for relevance to the topic and appropriate article type (full-text, original research). Publications deemed irrelevant (not related to surgical outcomes at the ankle region), abstracts (not full-text), and review articles (not original research) by both reviewers after screening the title were removed from the search.

All remaining publications were retained for a second round of review. In the second round, the same 2 independent reviewers screened the title and abstract of all remaining publications for inclusion or exclusion eligibility criteria. Publications deemed ineligible by both reviewers after screening the title and abstract were removed from the review, and any disagreements were resolved by discussion. All remaining publications were retrieved for full-text review. After full-text review, publications deemed ineligible by both reviewers were removed from the review, and the reason for removal was documented. Any disagreements were resolved by discussion. All remaining publications were included in the review. Results are shown in Figure 2.

Data Extraction

Following approval for inclusion, 2 independent investigators (CJW and ABJR) extracted the relevant data, including study design, pathology, patient characteristics, surgical procedures, criteria for patient to be released to RTP, time until RTP, percentage of cohort that RTP, name and type of objective clinical measures obtained, timing of objective clinical measures, and type of patient-reported outcome measures (PROMs) reported. Results were synthesized descriptively and utilizing frequency counts.

Evaluation of Study Quality

Study quality was assessed using one of 3 National Institute of Health quality assessment tools: (1) the tool for controlled intervention studies, (2) the tool for case-control studies, or (3) the tool for case series studies.[43] Study design dictated which tool was used. For all tools, higher scores indicated higher study quality.

Results

Characteristics of Included Studies

After applying the inclusion criteria, 30 studies were included in this scoping review (Figure 2). Study characteristics are detailed in Table 1, study methods are detailed in Tables 2 to 4. Although all ankle surgical procedures

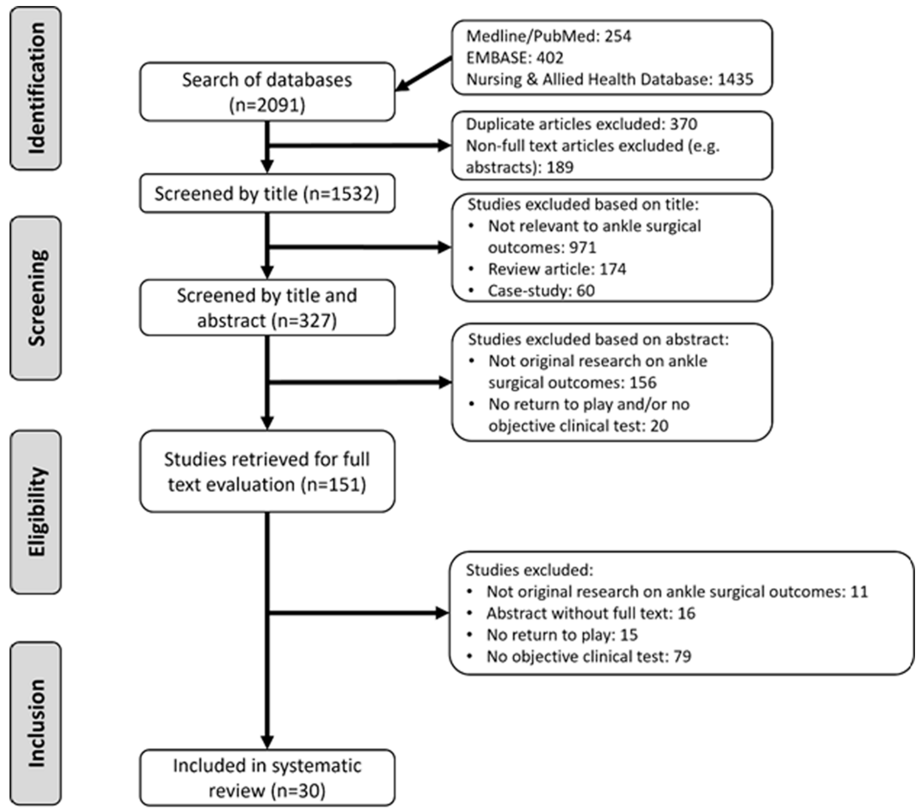

Figure 2. Systematic search and screening process.

were eligible for inclusion, only 5 conditions were represented within the included studies: Achilles tendon rupture (16 articles),[4,6-8,12,20,26-29,34,39,40,45,46,49] chronic ankle instability (9 articles),[9,15,16,18,23,25,37,50,52] anterior ankle impingement (2 articles),[14,30] peroneal tendon dislocation (1 article),[13] and ankle fracture (2 articles).[31,42] There were 1442 patients across all studies, with individual studies averaging 48.1 ± 32.5 patients (range: 8-126). Surgical procedures varied by pathology. Study designs were most commonly cohort (19 studies) or case series (10 studies), with just 1 randomized controlled trial. Within the limitations of study design, study quality was typically moderate (average quality score 86.8% ± 11.4%, range 55-100; Supplemental Table).

RTP Decision Making After Surgery for Achilles Tendon Rupture

Criteria for release to RTP. There were 16 studies in the Achilles tendon rupture subgroup. Criteria for release to RTP was provided in 5 of the 16 studies (Table 2).[6,7,26,34,46] Specifically, 3 studies provided purely time-based criteria for allowing RTP, each with a different time interval (ranging from 3 to 6 months).[7,34,46] One study allowed RTP if both time and a clinical measure were met (eg, >6 months as strength allowed).[26] Another study allowed RTP if both time and a subjective criterion were met (eg, >3 months then based on patient comfort).[6] The time until RTP was reported in 11 studies.[4,8,12,26,27,34,39,40,45,46,49] The percentage of the cohort to return to sport was reported in 14 studies.[4,6,7,12,20,26-29,39,40,45,46,49] Of these 14 studies, 8 specified that the RTP was at preinjury levels,[6,7,12,20,27,28,39,45] whereas 6 did not specify the level at which patients RTP.[4,26,29,40,46,49]

Objective clinical measures obtained. The most common objective clinical measurements were calf circumference (n=11), strength (n=9), heel rise test or height (n=8), ROM (n=8), jump or hop test (n=3), and the Achilles tendon resting angle (n=2). All other measures were used in a single study, including Matles test,[28] ultrasonographic depth and length of tendon,[29] 3-dimensional gait analysis,[46] and Achilles Tendon Performance Test.[46]

PROMs. The most common PROM utilized was the American Orthopaedic Foot & Ankle Society Score

Table 1. Included Studies' Characteristics.

Article	Pathology	Patients Characteristics	Activity Level[a]	Study Design	Surgical procedures
Baumfeld et al, 2019[4]	Acute Achilles tendon rupture	38 patients total (3 ♂, 35 ♀; mean age: 47 y) Open repair group, n=20 Percutaneous repair group, n=18	Recreational	Retrospective comparative study	Open vs percutaneous Achilles repair
Carmont et al, 2020[7]	Achilles tendon rupture	18 patients total (17 ♂, 1 ♀). Delayed presentation group, n=9 (8 ♂, 1 ♀; age: 48.4±14.9) Acute presentation group, n=9 (9 ♂; age: 47.7±14.6 y)	Recreational	Retrospective case-control study	Both groups: Minimally invasive Achilles tendon repair
Carmont et al, 2017[6]	Acute midportion Achilles tendon rupture	70 patients (58 ♂, 12 ♀; age: 42±8 y)	Competitive or recreational	Prospective cohort study	Four-strand vs 6-strand Achilles tendon repair
Choi et al, 2017[8]	Acute Achilles tendon rupture	68 patients total. Four-strand group, n=35 (29 ♂, 4 ♀; age: 37.8±8.6 y) Two-strand group, n=33 (30 ♂, 5 ♀; age: 36.5±6.4 y)	Competitive or recreational	Retrospective cohort study	Two-stranded single vs 4-stranded double Krackow technique for open Achilles tendon repair
De Carli et al, 2009[12]	Spontaneous Achilles tendon rupture	20 patients (14 ♂, 6 ♀; mean age: 39.7 y, range 28-57)	Recreational	Retrospective consecutive cohort study	Mini-open surgical repair of Achilles
Holzgrefe et al, 2020[20]	Acute Achilles tendon rupture	36 patients (26 ♂, 10 ♀; mean age: 35.0 y, range 22-49)	Competitive or recreational	Retrospective cohort study	Open direct locked suture repair or percutaneous Achilles repair system techniques
Maffulli et al, 2011[26]	Acute Achilles tendon rupture	17 patients (13 ♂, 4 ♀; age: 34.2±13.1 y)	Elite	Retrospective case series	Percutaneous Achilles tendon repair (8 strand)
Maffulli et al, 2017[27]	Achilles tendinopathy	47 (36 ♂, 11 ♀; age: 35.0± 9.5 y)	Recreational	Prospective consecutive cohort study	Minimally invasive Achilles tendon stripping
Manegold et al, 2018[28]	Acute Achilles tendon rupture	118 patients (102 ♂, 16 ♀; median age: 42 y, range 24-73)	Recreational	Retrospective cohort study	Percutaneous Achilles tendon repair using the Dresden instrument
Manent et al, 2019[29]	Acute Achilles tendon rupture	23 patients total. Percutaneous group, n=11 (10 ♂, 1 ♀; mean age: 41 y, range 18-50) Open group, n=12 (11 ♂, 1 ♀; mean age: 40.5 y, range 28-51)	Recreational	Randomized controlled clinical trial	Percutaneous vs open Achilles tendon repair
Nam et al, 2019[34]	Acute Achilles tendon rupture	41 patients total. Immobilization group, n=25 (21 ♂, 4 ♀; age: 39.3±7.4 y) Functional group, n=16 (14 ♂, 2 ♀; age: 37.7±6.6 y)	Not specified	Retrospective cohort study	Minimally invasive Achilles tendon repair (with percutaneous Achilles repair system)

(continued)

Table 1. (continued)

Article	Pathology	Patients Characteristics	Activity Level[a]	Study Design	Surgical procedures
Ryu et al, 2018[39]	Acute Achilles tendon rupture	112 patients (80 ♂, 32 ♀; mean age: 43.1 y, range 22-62)	Recreational	Retrospective cohort study	Open repair (tenorrhaphy) of the Achilles tendon
Seker et al, 2016[40]	Chronic Achilles tendon ruptures	21 ♂ patients (mean age: 32.1 y, range 17-45)	Recreational	Consecutive case series	Reconstruction of Achilles tendon ruptures with gastrocnemius flaps
Talbot et al, 2012[45]	Achilles Tendon rupture	15 patients (13 ♂, 2 ♀; mean age: 39.5 y, range 30-59)	Recreational	Consecutive case series	"Suture frame" repair of Achilles tendon
Taşatan et al, 2016[46]	Acute Achilles tendon rupture	20 patients (18 ♂, 2 ♀; mean age: 39.3 y, range 21-55)	Not specified	Consecutive case series	Mini-open Achilles repair
Usuelli et al, 2017[49]	Chronic Achilles tendon rupture	8 patients (5 ♂, 3 ♀; age: 50.5±7.5 y)	Competitive or recreational	Consecutive case series	Minimally invasive Achilles reconstruction with semitendinosus graft augment
Coetzee et al, 2018[9]	Chronic ankle instability	81 patients (30 ♂, 51 ♀; median age: 34 y, range 18-62)	Not specified	Retrospective cohort study	Open Brostrom repair augmented with InternalBrace
Feng et al, 2020[15]	Chronic ankle instability	68 patients total Horizontal mattress group, n=31 (19 ♂, 12 ♀; age: 28.6±11.2 y) Free-edge group, n=37 (23 ♂, 14 ♀; age: 30.4±9.2 y)	Not specified	Retrospective cohort study	All-inside arthroscopic Brostrom-Gould with horizontal mattress suture vs free-edge suture
Feng et al, 2021[16]	Chronic ankle instability	84 patients total. Repair group, n=49 (32 ♂, 17 ♀; age: 33.3±8.4 y) Nonrepair group, n=35 (21 ♂, 14 ♀, age: 35.6±9.9 y)	Not specified	Retrospective cohort study	All-inside arthroscopic Brostrom-Gould either with or without ATFL remnant repair
Hanada et al, 2020[18]	Chronic ankle instability	18 patients (9 ♂, 9 ♀; median age: 26 y, range 14-60)	Not specified	Prospective cohort study	Arthroscopic Brostrom-Gould
Kramer et al, 2011[23]	Chronic ankle instability	43 patients (34 ♀, 9 ♂; mean age: 19.7 y, range 14-32)	Competitive or recreational	Retrospective cohort study	Variation of the Chrisman-Snook lateral ligament reconstruction
Li et al, 2020[25]	Chronic ankle instability	51 patients total. One-anchor group (11 ♂, 9 ♀; age: 34±10 y) Two-anchor group (23 ♂, 8 ♀; age: 31±6 y)	Competitive or recreational	Cohort study	Arthroscopic ATFL repair with 1 or 2 anchors
Petrera et al, 2014[37]	Chronic ankle instability	49 patients (23 ♂, 26 ♀; mean age: 25 y, range 18-37)	Not specified	Case series	Modified open Brostrom repair
Wei et al, 2019[50]	Chronic ankle instability	29 patients (21 ♂, 8 ♀; age: 34.3±10.3 y)	Recreational	Consecutive case series	Modified all-inside arthroscopic ATFL repair

(continued)

Table 1. (continued)

Article	Pathology	Patients Characteristics	Activity Level[a]	Study Design	Surgical procedures
Yoo and Yang, 2016[52]	Chronic ankle instability	85 patients (85 military ♂; mean age = 23 y, range 19-44) Internal brace group, n=22, No internal brace group, n=63	Not specified	Retrospective consecutive cohort study	Arthroscopic modified Brostrom repair with or without an internal brace
Deng et al, 2019[13]	Recurrent peroneal tendon dislocation	44 total patients. Bone block group, n=24 (18 ♂, 6 ♀; age: 22.5±9.2 y) Reattachment group, n=20 (17 ♂, 3 ♀; age: 25.2±10.1 y)	Not specified	Consecutive series	Bone block procedure vs reattachment of the superior peroneal retinaculum
Devgan et al, 2016[14]	Anterior ankle impingement	14 patients (12 ♂, 2 ♀; mean age: 26.2 y, range 19-38)	Competitive or recreational	Prospective case series	Arthroscopic debridement of anterior ankle impingement (osseous or soft tissue)
McCrum et al, 2018[30]	Anterior ankle impingement	29 patients (29 ♂; age: 28.1±2.9 y)	Elite level	Retrospective cohort study	Arthroscopic debridement of anterior ankle impingement
Mishra et al, 2021[31]	Transitional (Tillaux and triplane) distal tibial fracture	49 patients total (mean age: 13.4 y, range 11-16) K-wire group, n=18 (12 ♂, 6 ♀) Screw group, n=31 (24 ♂, 7 ♀)	Not specified	Retrospective consecutive cohort study	K-wire vs screw fixation after open reduction of transitional distal tibia fractures
Steinmetz et al, 2016[42]	Ankle fracture, syndesmotic injury, and lateral instability	126 patients (77 ♂, 49 ♀; age: 45.0± 15.7 y, range 16-87)	Not specified	Retrospective cohort study	Open surgical treatment of distal tibiofibular joint injuries by temporary screw fixation and ATFL repair

Abbreviations: ATFL, anterior talofibular ligament; ♂, males; ♀, females.
[a]Activity level was defined on a spectrum from recreational (lowest) to competitive to elite (highest). Not specified indicates the article omitted any information about level of activity in their methods or return to sport data.

(AOFAS, n = 10),[4,8,28,29,34,39,40,45,46,49] Achilles Tendon Rupture Score (ATRS, n = 10),[4,6-8,12,26,29,34,45,49] Tegner activity scale (n = 4),[6,7,20,28] visual analog scale (VAS, n = 4),[12,28,34,40] and Victorian Institute of Sports Assessment–Achilles (n = 2).[27,29] All other PROMs were used in a single study, including Trillat,[46] Halasi,[7] patient perception of performance,[7] Physical Activity Score,[7] Arner-Lindholm,[39] Foot and Ankle Disability Index,[40] patient satisfaction.[45]

Timing of clinical measurements. Objective clinical measures and PROMs were commonly collected 1-2 years postoperatively (range 6 weeks–10 years).

RTP decision making after surgery for chronic ankle instability

Criteria for release to RTP. There were 9 studies in the chronic ankle instability subgroup.[9,15,16,18,23,25,37,50,52] Criteria for release to RTP was provided in 7 of the 9 studies (Table 3).[15,16,18,23,37,50,52] Specifically, 3 studies provided clinical criteria for allowing (eg, start RTP when no swelling present with jogging, full-ankle ROM and strength, >90% strength).[18,23,37] Four studies provided purely time-based criteria for allowing RTP (eg, postoperative week 8, after 3 months).[15,16,50,52] The time until RTP was reported in 6 of the 9 studies.[9,15,16,18,23,50] Eight of 9 reported the percentage

Table 2. Summary of Return to Play Criteria in Studies of Surgical Management of Achilles Tendon Rupture.

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures[a]	PROMs
Baumfeld et al, 2019[4]	Not defined	RTP Time: Average 9 mo % Cohort RTP: 95% (36/38)	• Plantarflexion and dorsiflexion isokinetic peak torque and work (units not specified)	Mean 33 mo po; 12 mo minimum po	• AOFAS • ATRS
Carmont et al, 2020[7]	Time based: Plyometric exercises were permitted at 3 mo; no other RTP restrictions were defined.	RTP Time: Not reported % Cohort RTP: Tegner same or improved: Delayed group: 44% (4/9) Acute group: 44% (4/9)	• Achilles tendon resting angle (degrees) • Calf circumference (mm) • Heel Rise Height Index (cm, % of contralateral) • Heel Rise Repetition Index (reps, % of contralateral)	At 6 wk and 3, 6, 9, and 12 mo po	• ATRS • Halasi • Patient perception of performance • Physical Activity Score • Tegner Scale
Carmont et al, 2017[6]	Time based and subjective: No running until 3 mo; then based on patient comfort	RTP Time: Not reported % Cohort RTP: Tegner same or improved: Four-strand group: 53% (n=8) Six-strand group: 55% (n=32)	• Heel-rise height (% of contralateral) • Heel-rise repetitions (% of contralateral side) • Achilles tendon resting angle (degrees) • Calf circumference (cm)	At 1.5, 3, 6, 9, and 12 mo po	• ATRS • Tegner Scale
Choi et al, 2017[8]	Not defined	RTP Time: Four-strand group: 18.7±2.0 wk Two-strand group: 17.8±1.9 wk % Cohort RTP: Not reported	• Plantarflexion and dorsiflexion isokinetic peak torque and work (units not specified)	At 3, 6, and 12 mo po	• AOFAS • ATRS
De Carli et al, 2009[12]	Not defined	RTP Time: mean 5 mo (range 3-8) in subgroup that did RTP % Cohort RTP: 85% (17/20) RTP; 71% (12/20) resumed same sport at preinjury level	• Calf circumference (cm) • Ankle ROM (degrees) • Jumping evaluation, (1) squat jump, (2) countermovement jump, and (3) repetitive jump (all flight time in seconds)	Mean 52 mo po (range 20-95 mo)	• ATRS • VAS
Holzgrefe et al, 2020[20]	Not defined	RTP Time: Not reported % Cohort RTP: 31% (11/36) returned to same Tegner; 58% (21/36) returned within 1 Tegner	• Isokinetic strength score for plantar and dorsiflexion at 3 velocities (points 0-102)	Mean 1.8 y po (range 1-3.9 y)	• Tegner Scale

(continued)

Table 2. (continued)

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures[a]	PROMs
Maffulli et al, 2011[26]	Criteria and time based: goal to RTP by 6 mo po, as strength allowed	RTP Time: 4.8±0.9 mo (range 3.2-6.5) % Cohort RTP: 100% (17/17) RTP	• Calf circumference (cm) • Isometric plantarflexion strength (N) • Single-leg heel raise	Mean 72 mo po (range 48-114 mo)	• ATRS
Maffulli et al, 2017[27]	Not defined	RTP Time: In subgroup who RTP: 3.5±0.6 mo (range 2-5) % Cohort RTP: 74% (35/47) RTP at the same level; 83% (41/47) RTP at same or lower level	• Calf circumference (cm) • Strength of both legs (N)	Mean 40.5±7.4 mo po (range 24-52 mo); minimum 2 y po	• VISA-A
Manegold et al, 2018[28]	Not defined	RTP Time: Not reported % Cohort RTP: 91% (108/118) RTP, but only 66% (78/118) RTP at preinjury level	• Calf circumference (cm) • Dorsiflexion ROM (degrees) • Plantarflexion ROM (degrees) • Matles test for Achilles tendon length (positive/negative)	Mean 33.45±21.67 mo (range 12-82 mo)	• AOFAS • Hannover score • Tegner Scale • VAS
Manent et al, 2019[29]	Not defined	RTP Time: Not reported % Cohort RTP: Percutaneous group: 82% (9/11) Open group: 92% (11/12)	• Heel rise for >3 sec (pass/fail) • Calf circumference (cm) • Resting plantarflexion (degrees) • Ultrasonographic depth of tendon (cm) • Ultrasonographic length of tendon (cm) • Plantarflexion strength (N)	Select measures: at 12 and 24 wk po; All measures: 52 wk po	• AOFAS • ATRS • VISA • VNRS
Nam et al, 2019[34]	Time based: No competitive running or jumping until 16 wk	RTP Time: Immobilization group: 141.4±74.7 d Functional group: 126.8±49.9 d % Cohort RTP: Not reported	• Calf circumference (cm) • Heel height (cm) • ROM difference (degrees)	At 6 wk, 3 mo, 6 mo, and 1 y po; Last follow-up: Immobilization group: 14.3±2.6 mo Functional group: 14.5±3.1 mo	• AOFAS hindfoot score • ATRS • VAS

(continued)

Table 2. (continued)

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures[a]	PROMs
Ryu et al, 2018[39]	Not defined	RTP Time: 1 patient reported RTP at 10 wk; time not reported for entire cohort % Cohort RTP: 86% (96/112) RTP at preinjury level; 14% (16/112) RTP at lower level or different sport	• Calf circumference (cm) • Dorsiflexion ROM (degrees) • Plantarflexion ROM (degrees) • Single limb heel raise (yes/no) • Hopping (yes/no) • Plantarflexion peak torque (% contralateral)	At 1 y post op; subgroup for isokinetic testing: mean 19.8 mo (range 12-30 mo)	• AOFAS • Arner-Lindholm Score
Seker et al, 2016[40]	Not defined	RTP Time: mean 14.1 mo (range 9-20 mo) % Cohort RTP: 100% (21/21) RTP	• Plantarflexion and dorsiflexion peak torque (Nm) • Dorsiflexion ROM (degrees) • Plantarflexion ROM (degrees) • Calf circumference (cm)	Mean 145.3 mo po (range 121-181 mo); minimum 10 y follow-up	• AOFAS • FADI • VAS
Talbot et al, 2012[45]	Not defined	RTP Time: mean 4.8 mo (range: 6 wk–12 mo) % Cohort RTP: 66% (10/15) RTP at same level; 26% (4/15) RTP at lower level	• Dorsiflexion ROM (degrees) • Plantarflexion ROM (degrees) • Isokinetic muscular torque in plantarflexion and dorsiflexion (% contralateral)	Mean 34 mo po (range 14-70 mo)	• AOFAS • ATRS • Satisfaction (0-10)
Taşatan et al, 2016[46]	Time based: Jogging at 12 wk, demanding sports at 6 mo	RTP Time: Not reported % Cohort RTP: 100% (20/20) RTP	• 3D gait analysis including: ankle power (N-m); dorsiflexion (degrees); plantarflexion (degrees); cadence (steps/min); single support (s); step length (m); double support (s); walking speed (m/s) • Achilles tendon performance test • 1-min stand on tiptoe test (pass/fail) • Single-extremity jump landing test (not defined)	At 12 mo po	• AOFAS • Trillat scale
Usuelli et al, 2017[49]	Not defined	RTP Time: mean 7.0 mo (range 6.7-7.2) % Cohort RTP: 75% (6/8) RTP	• Endurance test (no. of heel rise until fatigued) • Calf Circumference (cm)	Mean 27.9 mo po (range 24-34 mo)	• AOFAS • ATRS

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society Score; ATRS, Achilles Tendon Rupture Score; FADI, Foot and Ankle Disability Index; po, postoperative; PROMs, patient-reported outcome measures; ROM, range of motion; RTP, return to play; VAS, visual analog scale; VISA-A, Victorian Institute of Sports Assessment–Achilles; VNRS, verbal numeric rating scale.

[a]If data were available for multiple time points (eg, at 6 and 12 months), only data at last follow-up were included here.

Table 3. Summary of Return to Play Criteria in Studies of Surgical Management of Chronic Ankle Instability.

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures	PROMs
Coetzee et al, 2018[9]	Not defined	RTP Time: Mean 84 d % Cohort RTP: Not reported	• Anterior drawer (grade) • Ankle dorsiflexion ROM (cm) • Ankle plantarflexion ROM (degrees) • Functional single-leg hop test (distance % of contralateral limb) • Calf girth (cm)	Mean 11.5 mo po (range 6-27 mo)	• AOFAS • FAAM-ADL • FAAM-Sport • SF-12 • VAS
Feng et al, 2020[15]	Time based: ~8 wk begin running and functional activity	RTP Time: Horizontal mattress group: 10.4±2.0 wk (range: 8-12) Free-edge group: 8.6±2.3 wk (range: 8-12) % Cohort RTP: Horizontal mattress group: 68% (21/31) RTP Free-edge group: 68% (25/37) RTP	• Anterior tibial translation (mm) • Active joint position sense (degrees)	At 1 y po and 2 y po	• AOFAS • KAFS • VAS
Feng et al, 2021[16]	Time based: physical activity encouraged after 6 wk	RTP Time: Repair group: 8.2±2.4 wk (range 6-10) Nonrepair group: 8.4±3.1 wk (range 6-10) % Cohort RTP: Repair group: 69% (34/49) RTP Nonrepair group: 69% (24/35) RTP	• Anterior tibial translation (mm) • Active joint position sense (degrees)	At 1 y po and 2 y po	• AOFAS • KAFS • VAS
Hanada et al, 2020[18]	Criteria based: after 2-5 wk NWB, start RTP when no swelling and effusion with jogging	RTP Time: No cartilage damage group: median 4 mo (range 2-6) Cartilage damage present group: median 6 mo (4-12) % Cohort RTP: No cartilage damage group: 100% (11/11) RTP Cartilage damage present group: 57% (4/7) RTP	• Talar tilt angle (degrees) • Talar anterior drawer distance (mm)	At approximately 1 y po	• Japanese Society for Surgery of the Foot score • KSS
Kramer et al, 2011[23]	Criteria based: >4 wk po, when full ankle ROM and strength	RTP Time: Median 6 mo % Cohort RTP: in athlete subgroup 80% (28/35) RTP	• Dorsiflexion ROM • Plantarflexion ROM • Inversion ROM • Eversion ROM	4.4±2.1 y po (range 2-10.5 y)	• FAOS • Kaikkonen total score

(continued)

Table 3. (continued)

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures	PROMs
Li et al, 2020[25]	Not defined	RTP Time: Not reported % Cohort RTP: Two-anchor group: 68% (21/31) RTP at preinjury level One-anchor group: 30% (6/20) RTP at preinjury level Both groups: 100% (51/51) returned to ≥light activity	• Anterior drawer test (mm) • ROM (not specified)	Minimum 2 y po	• AOFAS • KAFS • Tegner Scale
Petrera et al, 2014[37]	Criteria based: full pain-free ROM, ≥90% ankle strength compared to contralateral side, pass sport-specific tests	RTP Time: Not reported % Cohort RTP: 94% (46/49) RTP at preinjury levels	ROM (not specified)	Not specified	• FAOS
Wei et al, 2019[50]	Time based: sport allowed after 3 mo	RTP Time: ≤3 mo po % Cohort RTP: 100% (32/32) RTP	• Talar tilt (degrees) • Anterior talar translation (mm)	33.7±4.5 mo po	• AOFAS • VAS
Yoo and Yang, 2016[52]	Time based: Internal brace: 4 wk No internal brace: 3 mo	RTP Time: Not reported % Cohort RTP: At 12 wk po. Internal brace group: 82% (18/22) No internal brace group: 27% (17/63)	Anterior drawer test (mm)	At 12 wk, and 24 wk po; Mean 7.4 mo po (range 6-9 mo); Minimum 6 mo	• AOFAS

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society Score; FAAM-ADL, Foot and Ankle Ability Measure–activities of daily living scale; FAAM-Sports, Foot and Ankle Ability Measure–sports scale; FAOS, Foot and Ankle Outcome Score; KAFS, Karlson Ankle Function Score; KSS, Knee Society Score; NWB, nonweightbearing; po, postoperative; PROMs, patient-reported outcome measures; ROM, range of motion; RTP, return to play; SF-12, 12-Item Short Form Health Survey; VAS, visual analog scale.

of the cohort to return to sport,[15,16,18,23,25,37,50,52] with 2 of these specifying that the RTP was at preinjury levels.

Objective clinical measures obtained. The most common objective clinical measurements were laxity (n=7) and ROM assessment (n=4). Other less common objective clinical measurements included joint position sense, hop test, and calf girth.

PROMs. The most common PROMs utilized were the AOFAS (n=6),[9,15,16,25,50,52] VAS (n=4),[9,15,16,50] and Karlsson Ankle Function Score (n=3),[15,16,25] and the Foot and Ankle Outcome Score (n=2).[23,37] Other less common objective clinical measurements included Tegner,[25] Foot and Ankle Ability Measure (FAAM),[9] Japanese Society for Surgery of the Foot score,[18] Kaikkonen total score,[23] and Knee Society Score[18] (each utilized in n=1 studies).

Timing of clinical measurements. Objective clinical measures and PROMs were most commonly collected 1-2 years postoperatively (range 12 weeks to 4 years).

RTP decision making after surgery for other ankle pathologies

Criteria for release to RTP. There were 5 studies in this category, which included pathologies such as anterior ankle impingement (2 studies),[14,30] peroneal tendon dislocation (1 study),[13] and ankle fracture (2 studies).[31,42] Criteria for release to RTP was not provided in any of the articles in this category (Table 4). The time until RTP and percentage of the cohort to RTP were reported in all studies (n=5).

Objective clinical measures obtained. All articles reported measuring ankle ROM (n=5).[13,14,30,31,42] Only 1 article

Table 4. Summary of Return to Play Criteria in Studies of Surgical Management of Other Ankle Pathologies.

Article	Criteria for Release to RTP	RTP Data Reported	Objective Clinical Measures Obtained (units)	Timing of Clinical Measures	PROMs
Deng et al, 2019[13]	Not defined	RTP Time: Bone block group: median 6 mo Reattachment group: median 5 mo % Cohort RTP: Bone block group: 79% (19/24) Reattachment group: 90% (18/20)	• Dorsiflexion ROM • Plantarflexion ROM • Inversion ROM • Eversion ROM (all reported as n deficient)	Bone block group: 42.5±16.7 mo po Reattachment group: 35.8±15.3 mo po	• Ankle Activity Score • AOFAS
Devgan et al, 2016[14]	Not defined	RTP Time: 5.0±1.5 mo % Cohort RTP: 93% (13/14)	• Plantarflexion ROM (degrees) • Dorsiflexion ROM (degrees)	Mean 15 mo (range 12-26)	• AOFAS • VAS
McCrum et al, 2018[30]	Not defined	RTP Time: 8.4±4.1 wk (range 2-20) % Cohort RTP: 100% (29/29)	• Dorsiflexion (degrees)	>1 season po	• AOFAS • VAS
Mishra et al, 2021[31]	Not defined	RTS Time: K-wire group: 4.7±2.2 mo Screw group: 5.2±3.1 mo % Cohort RTS: 100% (49/49)	• Talocrural ROM (degrees) • Gait analysis	Mean 7.5 mo po (range 4-24 mo)	• None
Steinmetz et al, 2016[42]	Not defined	RTS Time: Of athlete subgroup, 10±6.7 wk (range 2-48) % Cohort RTS: Of athlete subgroup, 83% (76/92) RTS at preinjury level	• Plantarflexion ROM (% of contralateral) • Dorsiflexion ROM (% of contralateral)	5.9±5.7 y po (range 2.9-10.5 y)	• AOFAS • Olerud-Molander Ankle Score • VAS

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Score; po, postoperative; PROMs, patient-reported outcome measures; ROM, range of motion; RTP, return to play; VAS, visual analog scale.

reported additional clinical measures, and they reported gait analysis.[31]

PROMs. The most common PROMs were AOFAS (n=4),[13,14,30,42] then VAS (n=3).[14,30,42] The Ankle Activity Score[13] and Olerud-Molander Ankle Score[42] were each used once.

Timing of clinical measurements. Objective clinical measures and PROMs were all collected 4 months to 10.5 years postoperatively.

Discussion

The purpose of this scoping review was to clarify how RTP is defined following ankle surgery in physically active patients, to identify key factors informing RTP decision making, and make recommendations for future research. Overall, the review found no definitions of RTP, few provided prospective RTP criteria, and there was inconsistent use of objective clinical outcome measures. Our findings suggest that gaps in the literature may impact RTP decision making and the ability to provide accurate postoperative expectations after injury.

Definition of RTP in Ankle Surgical Literature

Past research has found variability in the literature relative to the definition (or lack thereof) of the term RTS or RTP. None of the 30 studies included in this review defined RTP, so it is unknown if the studies were using the term RTP to refer to the stage in the athlete's progression when they reached RTPa, RTS, or RTPf (using the classification system proposed by Tassignon et al[47]). This can cause unequal comparisons. For example, in a prior meta-analysis of RTP after Achilles rupture, Zellers et al[53] found that studies that did not use criteria to determine or define RTP reported an 11% higher RTP among their cohort than studies who did use criteria. This may indicate that it was easier to classify a patient as fully RTP when not held to prospectively defined criteria or definitions. Future research should utilize more precise terms. We (the 3 orthopaedic surgeon authors) prefer to use the term "orthopaedically cleared" at time of RTPa when releasing a postoperative patient to their physical therapist or athletic trainer's care.

Criteria for Release to RTP in Ankle Surgical Literature

In Achilles repair literature, only 6 studies (33%) reported prospective criteria for release to RTP. Criteria included time alone,[7,34,46] time and strength (although no objective strength target was specified),[26] and time and patient comfort.[6] In contrast, most chronic ankle instability surgical outcomes studies (n=7, 78%) reported prospective criteria for release to RTP.[15,16,18,23,37,50,52] Again, most studies reporting criteria included time,[13,15,16,18,23,52] although some additionally included criteria such as full ROM, ≥90% ankle strength, and/or functional tests.[15,18,23,37] None of the ankle impingement, peroneal tendon, or ankle fracture studies reported criteria for RTP clearance.[13,14,30]

Even for studies in which criteria for RTP included objective clinical measures or PROMs, no data were provided *at the time of* RTP. For example, if strength were a criteria, the study might report an objective clinical measure of strength an average of 72 months postoperatively, whereas RTP occurred at approximately 5 months postoperatively.[26] Only a minority of studies (n=6, 20%) reported objective clinical data or PROMs in a time frame that may have corresponded to RTP (eg, at 6 weeks, 3 months, or 6 months).[6-8,29,34,52] Although their data offer clinically useful information closer to the *likely* time of RTP, it would be preferred if these type of data were reported at the *actual* time of RTP.

None of the included studies included objective data on workload from tools such as global positioning system (GPS) or other activity monitoring systems that are increasingly being used in elite sports. Utilizing GPS technology to capture workloads and translate the understanding of sport demands to enhancing RTP has been a topic in recent literature.[24,38] We believe GPS technology or other activity monitoring systems could provide valuable information toward safe and effective RTP progression, and should be included in future research.

Objective Clinical Tests Used in Ankle Postsurgical Outcomes Studies

The objective clinical tests reported trended toward reflecting the unique aspects of each pathology and subsequent surgical procedure. For example, surgical management of Achilles rupture requires rehabilitation to minimize tendon elongation and maximize plantarflexion strength to withstand the demands of load required in sport.[3,51,54] As such, it is no surprise that the 3 most common objective clinical tests were calf circumference (a measure of atrophy), strength measures, and the heel rise test. Similarly, the most common objective clinical tests used in the chronic ankle instability literature were laxity and ROM, likely reflecting the primary goal of these procedures to restore joint stability. Surgical interventions of anterior ankle impingement and ankle fracture also focused on ROM, which fits with the surgical indications. However, the only objective clinical measure reported following peroneal tendon dislocation was ROM (not peroneal strength). Thus, although the objective clinical tests reported trended toward reflecting the unique aspects of each pathology, the trend was not consistent across all reports.

PROMs Used in Ankle Postsurgical Outcomes Studies

All but 1 study[31] used at least 1 PROM. Across all conditions, the 4 most common PROMs were the AOFAS[22,33] (n=20), ATRS[35] (n=10), VAS (n=11), and Tegner activity scale (n=6). Although the AOFAS was the most commonly used PROM, it has several issues—including validation and a noted ceiling effect.[11,33] If using validated instruments, PROMs should be a helpful tool to identify patient status at the time of RTP. Future research should identify PROMs that provide the clinician tasked with evaluating readiness to RTP with valuable data to inform decision making. The ideal PROM will be validated for a specific injury or body region and be able to capture the highest level of function that meets the athlete's goals. Additionally, evidence suggests that PROMs are also important in evaluating psychological factors that may affect athletes' confidence to RTP.[2,41] However, psychological readiness instruments were not used in any of the studies in this review.

Limitations

Our scoping review was limited to studies reporting postoperative RTP, excluding conditions that may be managed conservatively. Additionally, our search was limited to English-language articles that may induce bias. The study quality was varied, which may impact results. However, the impact of study quality is limited by our study design, as we were not analyzing surgical outcomes directly but rather analyzing RTP criteria and objective clinical outcomes measures.

Conclusions

In physically active patients post ankle surgery, RTP remains largely undefined and is not based on prospective objective criteria. Additionally, there is large variation in selection and timing of clinical measures and PROMs. We recommend that future research provide prospective RTP criteria that uses both objective clinical measures and validated PROMs obtained at the time of RTP decision making to evaluate readiness to RTP.

Ethical Approval

Ethical approval was not sought for the present manuscript because it is a scoping review, and thus ethical approval is not needed. No new patient/participant data were collected; rather all data were obtained from previously published studies.

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Supplemental Table. Quality Assessment of Included Studies.

Article	Assessment tool	Item 1	item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Percentage Yes[a]
Baumfeld et al, 2019[4]	Case-control[b]	Y	Y	N	NR	Y	Y	NR	Y	Y	Y	N	N			58
Carmont et al, 2020[7]	Case-control	Y	Y	Y	Y	Y	Y	NR	Y	Y	Y	N	N			75
Carmont et al, 2017[6]	Case series[c]	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Choi et al, 2017[8]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
De Carli et al, 2009[12]	Case series	Y	Y	Y	Y	Y	Y	Y	N	N						78
Holzgrefe et al, 2020[20]	Case series	Y	Y	Y	NR	N	Y	Y	Y	Y						78
Maffulli et al, 2011[26]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Maffulli et al, 2017[27]	Case series	Y	N	Y	NR	Y	Y	Y	Y	Y						78
Manegold et al, 2018[28]	Case series	Y	Y	Y	NR	Y	Y	Y	Y	Y						89
Manent et al, 2019[29]	Controlled intervention[d]	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	93
Nam et al, 2019[34]	Case series	Y	Y	NR	NR	Y	Y	Y	Y	Y						78
Ryu et al, 2018[39]	Case series	Y	Y	NR	Y	Y	Y	Y	Y	Y						89
Seker et al, 2016[40]	Case series	Y	Y	NR	Y	Y	Y	Y	Y	Y						89
Talbot et al, 2012[45]	Case series	Y	N	Y	NR	Y	Y	Y	Y	Y						78
Tasatan et al, 2016[46]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	N						89
Usuelli et al, 2017[49]	Case series	Y	Y	Y	NR	Y	Y	Y	NA	Y						88
Coetzee et al, 2018[9]	Case series	Y	Y	N	Y	Y	Y	Y	Y	Y						89
Feng et al, 2020[15]	Case series	Y	Y	Y	NR	Y	Y	Y	Y	Y						89
Feng et al, 2021[16]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Hanada et al, 2020[18]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Kramer et al, 2011[23]	Case series	Y	Y	NR	Y	Y	Y	Y	Y	Y						89
Li et al, 2020[25]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	N						89
Petrera et al, 2014[37]	Case series	Y	Y	NR	Y	Y	Y	Y	Y	N						78
Wei et al, 2019[50]	Case series	Y	Y	Y	NR	Y	Y	Y	Y	Y						89
Yoo and Yang, 2016[52]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Deng et al, 2019[13]	Case-control	Y	Y	N	Y	N	Y	NA	Y	N	Y	N	N			55
Devgan et al, 2016[14]	Case series	Y	Y	NR	Y	Y	Y	Y	Y	Y						89
McCrum et al, 2018[30]	Case series	Y	Y	Y	Y	Y	N	Y	Y	Y						89
Mishra et al, 2021[31]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	Y						100
Steinmetz et al, 2016[42]	Case series	Y	Y	Y	Y	Y	Y	Y	Y	N						88

Abbreviations: N, no; NA, not applicable; NR, not reported; Y, yes.

[a]Percentage yes was calculated as the number of *yes* answers divided by number of applicable items.

[b]Case-control items: (1) Clear question, (2) Study population, (3) Sample size, (4) Controls, (5) Inclusion/exclusion valid, (6) Case definition, (7) Random selection, (8) Concurrent controls, (9) Exposure timing, (10) Exposure measurement, (11) Blind assessors, (12) Confounding variables.

[c]Case series items: (1) Clear question, (2) Study population, (3) Consecutive cases, (4) Subjects comparable, (5) Clear intervention description, (6) Appropriate outcome measures, (7) Adequate follow-up, (8) Statistical methods, (9) Results well described.

[d]Controlled intervention items: (1) Randomized controlled trial, (2) Adequate randomization, (3) Concealed allocation, (4) Participants anonymized, (5) Assessor anonymized, (6) Baseline similarity, (7) Overall dropout rate, (8) Dropout between groups, (9) Adherence, (10) Cointerventions controlled, (11) Valid reliable outcomes, (12) Sample size, (13) Preplanned analysis, (14) Intention-to-treat analysis.