Return to sport following lateral ankle ligament repair is under-reported: a systematic review

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ABSTRACT

Importance Ankle sprains are the most commonly occurring musculoskeletal injury. Reconstruction of the lateral ligament complex is often required for athletes with recurrent instability, or high-grade acute sprains, in order to return to their preinjury level of sport.

Objective The purpose of this systematic review was to evaluate the spectrum, prevalence and quality of evidence regarding return to sport timeline following lateral ligament surgery.

Evidence review A search was conducted of Embase and Medline databases from the earliest possible entry to November 2016. Studies reporting a timeline regarding return to play (RTP) following lateral ankle ligament reconstruction were included in this review.

Findings Of 3184 total articles, 20 articles evaluating 489 athletes met the criteria and were included for review. Thirteen of the 20 papers were used to calculate a weighted mean time to RTP of 4.7 months. Overall, both the frequency and quality of RTP criteria and reporting were very low.

Conclusions and relevance The current review identifies a clear deficiency in the literature pertaining to consistent, meaningful postoperative RTP timeline following lateral ankle ligament repair. Published studies vary considerably in the metrics used for measuring patient-reported outcomes, and very few actually track them. Further studies on outcomes following ankle ligament repair should include clear and consistent metrics for return to sport and level of play. Standardised and reproducible criteria for reporting RTP for athletes will improve the utility and applicability of outcomes data as surgical and rehabilitative techniques continue to advance.

Level of evidence Systematic review of level I–IV studies, level IV.

What is already known

- There is extensive literature describing techniques and outcomes for lateral ankle ligament repair and reconstruction.
- There is existing literature to support the ability of athletes to return to play (RTP) following lateral ankle ligament stabilisation, but timeline of return is generally not included in those reports.
- There is a need to understand rates and timing of return to sport following lateral ligament repair in order to compare treatments, procedures and rehabilitation techniques.

What are the new findings

- These articles suggest a rate of return to sport of 85% following lateral ankle ligament repair in athletes, at an average of 4.7 (+/–1.5) months.
- There are more than 360 manuscripts describing a postoperative clinical outcome of lateral ankle ligament repair, yet only 5.5% of these detail an RTP timeline as a reported outcome metric, indicating a clear deficiency in the literature.
- We propose a better defined structure and protocol for assessing the readiness of athletes to RTP.

INTRODUCTION

Ankle sprains (particularly inversion sprains involving the lateral ligament complex) are exceedingly common injuries, with an incidence of 2.15 per 1000 person-years in the US general population.[1] The incidence of injury increases with exposure to sport, with ankle sprains comprising 31% of all injuries in soccer and 45% of all injuries in basketball.[2] In a cohort of 10 393 basketball participations, the rate of ankle injury was 3.85 per 1000 participations.[3] Although more common in collision sports, ankle sprain remains the most common musculoskeletal injury regardless of sport or exposure type.[3–6]

Ankle sprains are most commonly caused by inversion of a plantar flexed foot, resulting in injury to the lateral ligament complex of the ankle joint.[7] Sandelin *et al*[8] observed that 75% of ankle ligament sprains were of the lateral ligament complex. Hawkins *et al*[9] had similar findings, with 80% of sprains being to the lateral ligament complex. Lateral ankle stability is ordinarily maintained by the surrounding ligamentous structures, including the anterior talofibular ligament (ATFL), calcaneofibular ligament (CFL) and the posterior talofibular ligament. The ATFL prevents anterior talar displacement and is the primary structure injured in an ankle sprain; it has been observed that 2/3 of all ankle injuries are isolated to the AFTL.[10] The CFL prevents excessive inversion and is the second structure injured during an ankle sprain.[10] Broström[11] observed combined injury of the ATFL and CFL in 20% of ankle sprains and that the CFL was never ruptured alone.

Several surgical techniques have been described for repair of the lateral ligament complex. In 1966, Broström[12] was the first to describe direct repair

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of a remnant ATFL ligament with suture. In 1980, Gould *et al*[13] modified this procedure with advancement of the inferior extensor retinaculum; this procedure was further modified by Hu *et al*,[14] who used bone tunnels or suture anchors to repair both the ATFL and CFL back to the fibula. Patients whose ligament's remnants are preserved are good candidates for reconstruction with the modified Broström-Gould procedure. Additional techniques describe reconstruction with an alternative tendon graft, such as allograft or autograft, and arthroscopic techniques for primary ligament repair.

Surgical intervention of acute ankle sprains has not consistently been shown to improve long-term function.[15] However, in 20%–40% of ligamentous ankle injuries, chronic ankle instability develops, resulting in short-term and long-term functional deficits[16] and risk to other structures,[17] necessitating surgical correction.[18 19] In these cases, without surgical intervention, improvement in symptoms is unlikely.[20] Patients intending to return to their preinjury level of sports participation may elect for surgery in order to maximise recovery and function. Surgical outcomes for lateral ligament reconstruction are highly favourable in the general population; however, data regarding rates of return to preinjury sports participation following lateral ankle ligament injury and surgery are limited. Even less often reported is the timeline of return to play (RTP). The highly competitive nature of modern sports and the associated multifaceted pressures for rapid RTP following injury underscore the importance of understanding surgical procedures and rehabilitative techniques that may lead to a consistent and predictable return protocol during management of injured athletes. Moreover, our ability to compare novel surgical and rehabilitation techniques is predicated on consistent use of outcome measures and RTP metrics. Proper diagnosis and early intervention may facilitate an earlier return to sport and decreased reinjury rates.

This systematic review aims to evaluate all available literature regarding postoperative return to sport following surgical repair of the lateral ankle ligament complex. The primary purpose was to evaluate the current literature describing an RTP timeline following lateral ankle ligament repair, including how often an RTP timeline is being measured and the metrics being used to describe the RTP timeline.

METHODS

Literature search

A systematic literature search was conducted for articles on surgical repair of lateral ankle ligaments for acute sprain or chronic instability. Articles for review were obtained from a search of Medline and Embase databases, from 1953 up to November 2016, using the search headings 'ankle ligament surgery' and 'ankle sprain instability repair'. Information collected included year of publication, number of athletes, surgical technique, RTP metric, RTP timeline, RTP performance data, patient-reported outcomes measures and functional outcome measures.

Study selection

We independently identified and screened published studies by their title and abstract. Only articles written in English were considered. Initial exclusion criteria included (1) no abstract; (2) no reported clinical outcomes (eg, basic science, radiographic, anatomical study); and (3) a review paper (eg, review or meta-analysis). Manuscripts with abstracts including clinical outcomes from surgical stabilisation (varying procedures) of the lateral ankle ligaments were read fully to assess for RTP timeline metrics. To be included in this review, the study must have contained (1) patient(s) who participate in athletic activities; (2) RTP timeline as an outcome metric or result; and (3) clinical outcome(s) following lateral ankle ligament repair. Once inclusion criteria were met and papers read fully, those bibliographies were searched for additional relevant papers.

Statistical analysis

Using descriptive statistics from the articles included in this review, the weighted mean and weighted SD for time to RTP were calculated. Rate of RTP was described by percentage of all athletes who were able to return fully.

RESULTS

Literature search

The Medline search yielded a combined 2481 results and the Embase search yielded an additional 703 independent results. Of the 3184 total results, 360 articles (11.3%) were identified as having any clinical outcome postlateral ankle ligament stabilisation. Articles that did not report an RTP timeline were then excluded, leaving 54 papers (15.0%) that discussed an RTP timeline in some capacity. Twenty (5.5%) of the RTP timeline papers met the secondary criteria for inclusion in this review article. The other 34 papers were excluded primarily because they did not report an RTP timeline as a result or outcome metric. Most commonly, the RTP timeline was only described as part of a postoperative protocol without report of outcome, which did not meet the standards for inclusion in this review (figure 1).

RTP metrics

Studies were not uniform in their descriptions of RTP timeline. Twelve studies reported an average time to return to sport for all athletes (10 studies[21–30] included a range, 2 studies[31 32] did not). Three studies[33–35] described mean time to returning to various different exercises (eg, jogging, jumping and running) for all athletes but lacked explicit report of return to sport. Two studies[36 37] reported the specific return time for each individual athlete. Two studies[38 39] reported the number of athletes returning to sport at specified time intervals. One study[40] reported a range time for all athletes. RTP metrics and results for all included studies are shown intable 1.

For the purposes of calculating a weighted mean and weighted SD for time to RTP, 13 of the 20 papers provided adequate data to include in this review. Three papers, all written by the same author, were excluded from statistical analysis because they only measured time to return to specific activities, not to sport.[33–35] One article[38] was excluded because RTP was measured as the number of athletes able to return by a specified time (without providing a mean time), and three papers[21 25 29] were excluded because the numbers of athletes returning to play were not specified. For those articles that reported on whether or not athletes were able to return to preinjury level of participation, only those reporting athletes who were able to return fully were included in the weighted mean. Thirteen articles with a total of 281 athletes resulted in a weighted mean time to RTP of 4.7 months, with a weighted SD of 1.5. Articles that reported time in weeks and days were converted to months using the following conversions: 1 day is 0.033 months; 1 week is 0.23 months. Full results are reported in table 2.

Data specifying ability to RTP, independent of timeline, were available for a total of 489 athletes (16 articles), of which 414 were reported to have returned to preinjury level of sports participation at follow-up, producing a pooled RTP rate of 85%, as shown in table 3.

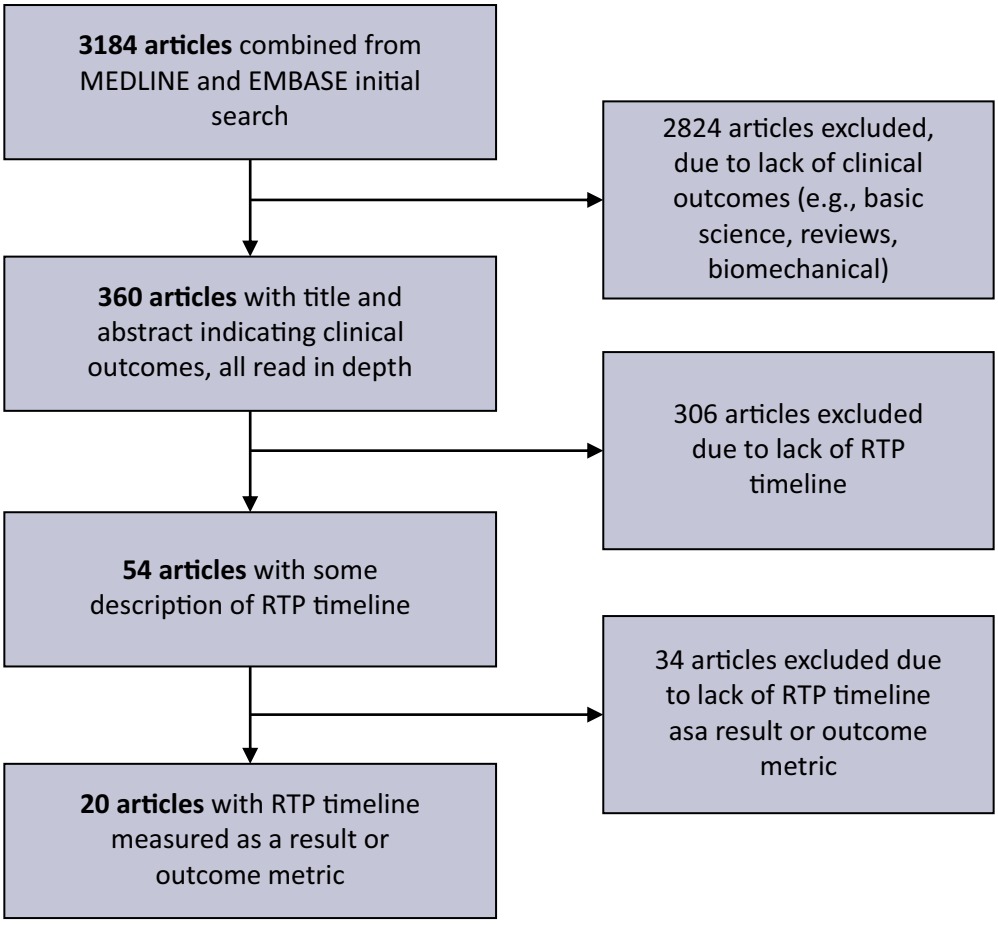

Figure 1 Literature search results ('RTP = return to play').

Comparison by intervention, injury and sport

Five of the 20 articles included some type of comparison between different groups and the outcome on RTP timeline. Four articles discussed differences in surgical techniques and one article discussed differences in injury pattern. Cho *et al*[34] compared suture anchor and suture bridge group reattachment techniques for mean period to return to exercise and found that the suture bridge group returned to jumping earlier when compared with the suture anchor group (10.6 weeks vs 13.8 weeks; p=0.038). Takao *et al*[29] compared functional treatment alone (F) with functional treatment with surgical repair (RF), for RTP both with and without the external support of soft ankle orthosis. With external support, the elapsed time between injury and return to full athletic activity was 6.3 weeks (F) and 5.7 weeks (RF) (p=0.0498). Without external supports, the elapsed time between injury and return to full athletic activity was 16.0 weeks (F) and 10.1 weeks (RF) (p<0.0001). Matsui *et al*[26] compared arthroscopic (A) and open (O) repairs, and found no significant difference in mean time to return to sports activities for the two groups (16.5 weeks (A) vs 17.1 weeks (O); p=0.07). Yoo and Yang[38] compared arthroscopic Broström with an internal brace to arthroscopic Broström without an internal brace. They found a significant difference in the rate of returning to sports at 12 weeks (81.8% with internal brace vs 27% without internal brace; p<0.001). White *et al*[30] compared isolated lateral ligament injuries with lateral ligament injuries with associated injuries (eg, OCL, deltoid). They found median time to return to training was different for isolated (57 days) and associated (86 days) injuries (p<0.001). Additionally, median time to RTP was different for isolated (72 days) and associated (105) injuries (p<0.001).

There were extremely limited data comparing RTP by sport, as articles generally reported aggregated mean time to RTP across all athletes included in the study, regardless of sport. Kramer *et al*[39] noted in their study that soccer players were less likely to RTP, and those who were able to return did so later than athletes who return to other sports. Buerer *et al*[21] found no relationship between RTP timeline and sport, yet they did not describe the types of sports included in their study.

Patient-reported outcome measures

For the purposes of evaluating the use of patient-reported outcomes, we analysed all articles that mentioned an RTP timeline, including the 20 articles considered for this review and the 34 articles that only discussed a postoperative protocol without providing data on return to sport. In these 54 articles, no single patient-reported outcome measurement was used more than 50% of the time. The most often used was the American Orthopedic Foot and Ankle Society Scales (AOFAS) (n=22; 41%), followed by the Karlsson scale (n=11; 20%), the Visual Analogue Scale (VAS) (n=8; 15%), the Foot and Ankle Outcome Score (n=7; 13%) and the Sefton scale (n=5; 9%). An additional 12 outcomes metrics were used in other papers. Full results are in table 4.

DISCUSSION

In general, the RTP timeline is primarily of concern for elite-level athletes. However, collecting data on all patients participating in

Table 1 Summary of articles and RTP metrics used in systematic review

Author	Year	RTP metric	RTP timeline data	RTP performance data/notes
Matsui	2016	Mean time for all athletes (with range)	1. Arthroscopic group: 16.5 weeks (range 12–22) 2. Open group: 17.1 weeks (range 13–22)	No recurrence of instability in either group; possibly first study to compare open versus arthroscopic for lateral instability of ankle
White	2016	Median time to training and full sport (with range)	1. Median time to return to training: isolated injuries (57 days, range 49–110), associated injuries (86 days, range 63–152), p<0.001 2. Median time to return to play: isolated injuries (72 days, range 56–127), associated injuries (5 days,* range 82–178), p<0.001	All professional athletes returned to preinjury levels (2/42§)
Yoo	2016	Number returned to sport at specified time intervals	Percent returned to sports activity at 12 weeks: 1. with internal brace (81.8%) 2. without internal brace (7%†); p<0.001	N/A
Cho*	2015	Mean time to return to specific exercises, based on VAS	Jogging (0.2 weeks*), sprint running (3.8 weeks*), jumping (11.4 weeks)	N/A
Cho†	2015	Mean time to return to specific exercises, based on VAS	Jogging (8.4 weeks), spurt running 2.5 weeks*), jumping (9.2 weeks)	N/A
Cho‡	2015	Mean time to return to specific exercises, based on VAS	1. suture bridge: jogging (9.8 weeks), spurt running (3.8 weeks*), jumping (0.6 weeks*) 2. suture anchor: jogging (0.4 weeks*), spurt running (4.5 weeks*), jumping (13.8 weeks)	Statistically significant difference in jumping; 44/45 athletes returned to preinjury level
Giannini	2015	Mean time for athletes (with range) back to preinjury level	(6 months — for 26/31 patients) (–8 months§)	5/31 did not return to preinjury level; 3 professional players resumed full activity
Jung	2015	Mean time for all athletes (with range)	3.1 months (6 weeks–12 months)	N/A - no specifics on number of athletes
Buerer	2012	Mean time for all athletes (with range)	.7-month average§ (–12 months†)	No correlation with sport and RTP time; no specifics on number of athletes
Takao	2012	Mean time for all athletes (with range)	1. With external support — functional treatment (6.3 weeks, range 3–12 weeks), surgery (5.7 weeks, range 3–8 weeks) 2. Without external support: functional treatment (6.0 weeks,* range 8–48 weeks), surgery (0.1 weeks,* range 8–15 weeks)	N/A — no specifics on number of athletes in each group
Ibrahim	2011	Mean time for all athletes (with range)	6.8 months (range 4–11 months)	N/A
Kramer	2011	Number returned to sport at specified time intervals	28 of 35 athletes at a median of 6 months (95% CI, 2.8–7.2 months) breakdown: 3 months,† 4 months (9), 5 months (0*), 6 months (9*), 7 months (0†), 9 months (1†), 12 months (28)	9 not at the same level as before their injury, 6/9 due to voluntary discontinuation of sport; soccer players less likely to return and more likely to return later
Morelli	2011	Mean time for all athletes (with range)	12 of 14 patients RTP after mean follow-up of 6 months (range 4–8 months)	The six professional athletes all reported a full recovery of their preoperative activity level; two reported a return to lower demanding sports activity, because of residual occasional pain occurring during high-level performances
Jones	2007	Specific time for individual athletes	3 months for 4/4 patients	2/2 athletes returned to sport, 2/2 recreational fitness returned to previous activity level
Coughlin	2004	Mean time for all athletes (with range)	(6.5 months) (–12 months‡)	4/28 patients had injury recurrence — still achieved eventual return to full activity
Solakoglu	2003	Mean time for all athletes	6 months	14/14 patients returned fully to amateur sports (basketball or football) or basic military training
Paterson	2000	Mean time for all athletes (with range)	Average time until return to sport was 12 weeks and all patients were able to return to sport, including 23/26 who were able to return to their preinjury level	Three did not return to preinjury level due lack of confidence in the ankle (2 people) or persistent pain (1 person)
Agoropoulos	1997	Range for all athletes	–6 months§	48/48 patients returned to sports without limitation
Hoy	1994	Mean time for all athletes	10 weeks, 18/25 athletes returned to preinjury level	Two patients did not return to sport
Leyshon	1982	Specific time for individual athletes	5 months, one athlete (case report)	Light training at 4 months, return to competition at 5 months

*Minimal invasive suture-tape augmentation for chronic ankle instability.
†A ligament reattachment technique for high-demand athletes with chronic ankle instability.
‡A prospective outcome and cost-effectiveness comparison between two ligament reattachment techniques.
RTP, return to play; VAS, Visual Analogue Scale for pain.

sport is necessary due to the dearth of available literature solely on professional athletes. RTP timeline data are necessary and useful for three purposes: (1) expectations for physicians and patients; (2) tracking milestone progression towards RTP post-surgery; and (3) linking RTP timeline with eventual outcomes.

1. Expectations: The review of current literature has illustrated significant variation in the RTP timeline depending on the injury pattern, surgical technique, sport played and use of external bracing. It is likely that other variations in the RTP timeline exist but have yet to be confirmed through scientific

Table 2 Mean time to return to play (RTP)

Author	Year	Athletes	RTP (months)
Matsui*	2016	19	3.8
Matsui†	2016	18	3.9
White	2016	30	2.4
Giannini	2015	26	6.0
Ibrahim	2011	14	6.8
Kramer	2011	28	6.0
Morelli	2011	12	6.0
Jones	2007	2	3.0
Coughlin	2004	28	6.5
Solakoglu	2003	14	6.0
Paterson	2000	23	2.8
Agoropoulos‡	1997	48	5.0
Hoy	1994	18	2.3
Leyshon	1982	1	5.0
Mean±SD			4.7±1.6

*Arthroscopic group.
†Open group.
‡Midpoint of 4–6 range chosen.

study. Expectations for ability to return to sport, especially when similar pre-existing conditions can be compared with previously established cases, can be of high utility to patients when evaluating their treatment options. The literature is especially weak on this reporting for elite-level athletes. Indeed, in a study on the RTP postacute lateral ankle ligament repair in professional athletes, White et al[30] indicated that there is a lack of available data to guide professional athletes in their recovery timeline.

2. Tracking progression: For those patients who have undergone surgery to repair the lateral ankle ligaments, it would be relevant to know where in their rehabilitation process they are relative to other comparable cases. Clanton et al[41] discussed the need for subjective and objective data in determining ability to RTP. Specifically, they called for assessments in functional testing to include range of motion, balance and proprioception, agility and strength. Pertinent to our subject of interest, the Lower Extremity Functional Scale is an objective score whose use has specifically been validated in athletic subjects with ankle sprains.[42] Rehabilitating postsurgical athletes should be tracked using both subjective and objective assessments to determine the relationship between these assessments and the RTP timeline. As of now, no study reviewed for this article included any measurement of clinical outcome scores at the time of RTP.
3. Linking to outcomes: Early RTP is important to high-level athletes, yet the long-term outcomes of the impact of an earlier or later RTP are not known. In general, there is literature to support the efficacy of repair and the ability of athletes to eventually return to preinjury level of play.[43–45] In particular, Maffulli et al[44] reported long-term results following a Broström procedure, indicating that 58% of athletes were able to return to their full activity level, while the remaining 42% were still able to be physically active (16% of whom were still able to compete but at a lower level). However, it is not possible to relate these data to when athletes return to play and if that impacted their eventual outcome. Overall, this trend of reporting on ability to RTP but lacking RTP timeline data is also noted by White et al.[30]

Table 3 Rate of return to play

Author	Year	All athletes	Full return
Matsui	2016	37	37
White	2016	30	30
Yoo*	2016	22	18
Yoo†	2016	63	17
Cho‡	2015	45	44
Giannini	2015	31	26
Takao§	2011	54	54
Ibrahim	2011	14	14
Kramer	2011	35	28
Morelli	2011	14	12
Jones	2007	2	2
Coughlin	2004	28	28
Solakoglu	2003	14	14
Paterson	2000	26	23
Agoropoulos	1997	48	48
Hoy	1994	25	18
Leyshon	1982	1	1
Totals		489	414
Return percentage		85%	

*Returned at 12 weeks with internal brace.
†Returned at 12 weeks without internal brace.
‡Ligament reattachment technique.
§All surgical patients, including those using external bracing.

Table 4 Patient-reported outcome scales

AOFAS	22	41%
Karlsson	11	20%
VAS	8	15%
FAOS	7	13%
Sefton	5	9%
Tegner	4	7%
JSSF	3	6%
FAAM	2	4%
Good	2	4%
Ahlgren and Larsson	1	2%
CAIS	1	2%
CAIT	1	2%
Elerud and Molander	1	2%
Hamilton	1	2%
Kaikkonen	1	2%
Modified Weber	1	2%
SF-12	1	2%

AOFAS, American Orthopedic Foot and Ankle Society Scales; CAIT, Cumberland Ankle Instability Tool; CAIS, Chronic Ankle Instability Score; FAAM, Foot and Ankle Ability Measure; FAOS, Foot and Ankle Outcome Score; JSSF, Japanese Society for Surgery of the Foot ankle-hindfoot score; SF-12, Short-Form 12 Health Survey; VAS, Visual Analogue Scale for pain.

Generally, there is substantial variability in the measurement of patient-reported outcome measures in the RTP literature. This trend is very similar to the broader foot and ankle literature, where Hunt and Hurwit[46] found the AOFAS scale was used most frequently (55.9%), followed by the VAS scale (22.9%). While the AOFAS scale is commonly used, it has not been found to accurately quantify or compare patient outcomes and is not a validated patient outcome measure.[47] In lieu of the AOFAS scale, we suggest a movement towards the use of concise, validated patient-reported outcome measures. The VAS is a widely accepted and validated outcome measure for pain and should

continue to be used.[48] In the context of chronic ankle instability, the Foot and Ankle Ability Measure is a validated outcome measure that should be incorporated in the standardisation of patient outcome measures,[49] and the PROMIS scales are gaining popularity as an efficient set of outcomes tools in orthopaedics. Having a more consistent use of validated clinical outcome measurements will increase the utility and applicability of data reporting.

The dearth of available data sufficiently describing RTP following orthopaedic surgery applies to other areas as well. For example, in a systematic review of 48 articles describing resumption of sport following ACL repair, only nine studies were found that included an RTP timeline with an average resumption of sport at 7.3 (range 2–24) months.[50] Consistent with our findings, there appears to be a deficiency in consistent reporting of RTP timeline reporting following ACL repair. In addition, while there are no pooled data on RTP following Bankart repair (shoulder stabilisation), one paper on 16 athletes reported an average RTP of 4.4 months.[51] It is clear that the paucity of RTP timeline data is not just isolated to ankle ligament reconstruction, but to other common surgically treated sports injuries as well.

Limitations

This study has several limitations. Lack of consistency in reporting data and outcomes metrics across manuscripts did not allow for complex comparative statistical analysis. None of the papers included in this systematic review reported effect sizes, such as ORs, risk ratios or the associated 95% CIs, which made conducting a meta-analysis unfeasible. Therefore, quantitative analysis was limited to reporting on descriptive statistics. In addition, the overwhelming majority of articles describing outcomes for lateral ligament repair are in the chronic instability population, so we pooled the one paper describing acute repair with the remaining articles that chronic instability. Lastly, the low number of included articles impacts the strength of any findings.

CONCLUSION

The results of this review demonstrate that while 360 manuscripts describe a postoperative clinical outcome of lateral ankle ligament repair, only 20 (5.5%) detail an RTP timeline as a reported outcome metric, indicating a clear deficiency in the literature. These articles suggest a rate of return to sport of 85% of athletes at an average of 4.7 (+/−1.5) months. In future studies involving athletes, increased attention should be placed on detailing the time until the athletes can RTP and the level of play to which the athletes returned. In addition, these data would optimally be stratified by activity or sport, so that athlete and physician expectations for return to sport can be based on sport-specific data. While some manuscripts broke down their patient populations by sport played, the RTP timeline was reported in an aggregated mean time to RTP across all athletes included in the study, regardless of sport, reducing the utility of their data. In addition, as acute ligament repairs become increasingly common with less invasive techniques, stratifying outcomes by chronicity (acute vs chronic) and by technique has become increasingly important. Moreover, there is currently no well-defined structure and protocol for assessing the readiness of athletes to RTP. We propose that athletes should be returned to play following a scheme similar to what van Eekeren *et al*[52] have suggested for talar osteochondral lesions, following a four-phase progression of increasing intensity, including walking, jogging, return to non-contact sports and return to contact sports. Our ability to better describe clinical and return-to-sport outcomes in patients will dramatically improve the science supporting novel advances in ankle ligament repair techniques and rehabilitation.

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Contributors KJH was responsible for study design, data analysis, manuscript preparation and revision, and overseeing the project. RSF and BSS contributed to the review of the literature, data abstraction and writing of the manuscript. HP and PD contributed to study design, and manuscript preparation and revision.

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Provenance and peer review Commissioned; externally peer reviewed.

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