

# World Journal of *Orthopedics*

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## Management of achilles tendon injury: A current concepts systematic review

Vivek Gulati, Matthew Jaggard, Shafic Said Al-Nammari, Chika Uzoigwe, Pooja Gulati, Nizar Ismail, Charles Gibbons, Chinmay Gupte

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### Abstract

Achilles tendon rupture has been on the rise over recent years due to a variety of reasons. It is a debilitating injury with a protracted and sometimes incomplete recovery. Management strategy is a controversial topic and evidence supporting a definite approach is limited. Opinion is divided

between surgical repair and conservative immobilisation in conjunction with functional orthoses. A systematic search of the literature was performed. Pubmed, Medline and EmBase databases were searched for Achilles tendon and a variety of synonymous terms. A recent wealth of reporting suggests that conservative regimens with early weight bearing or mobilisation have equivalent or improved rates of re-rupture to operative regimes. The application of dynamic ultrasound assessment of tendon gap may prove crucial in minimising re-rupture and improving outcomes. Studies employing functional assessments have found equivalent function between operative and conservative treatments. However, no specific tests in peak power, push off strength or athletic performance have been reported and whether an advantage in operative treatment exists remains undetermined.

**Key words:** Orthopaedic surgery; Achilles tendon injury; Sports injury; Tendon rupture; Conservative management

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**Core tip:** Achilles tendon rupture is a common injury. Simmonds or Thomas' test is a reliable diagnostic tool with a sensitivity of between 0.89-0.93. Studies have not shown conclusive superiority of operative repair compared with non-operative and casting techniques. Non-operative management has a more favourable complication profile. There is emerging evidence that the traditional perception that non-operative management is associated with higher re-rupture rates no longer holds true for the new management strategies which assess tendon gap and use a dedicated "Achilles tendon management infrastructure". It is important that clinicians can recognize the injury and delayed diagnosis can lead to significant morbidity.

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## INTRODUCTION

The Achilles tendon is the most frequently ruptured tendon in the human body<sup>[1]</sup>. The incidence of rupture is on the rise and has been so since the 1980s. The yearly incidence of Achilles tendon rupture is rising and reported as 4.7/100000 in 1981 to 6/100000 in 1994 from a Scottish cohort, and 22.1/100000 in 1991 to 32.6/100000 in 2002 from a Danish cohort. The most rapid increase was noted in the male 30 to 39 age group<sup>[1,2]</sup>. The most hazardous sport appears to be badminton with 83% occurring in males. The mean age of presentation is 35 years with a male:female ratio of 20:1<sup>[3,4]</sup>. The classical patient is the novice sportsmen in his fourth decade engaging in unaccustomed sport.

The commonest site of rupture is in a region 3 to 6 cm above the os calcis which corresponds to a watershed region of poor vascularisation<sup>[5]</sup>. Perfusion in this region is further compromised during stretching and contraction<sup>[6,7]</sup>. With increasing age there is decreased collagen-crosslinking and weakening of the tensile strength of the tendon. Maffulli *et al*<sup>[8]</sup> and Järvinen *et al*<sup>[9]</sup> histologically observed significant collagen degeneration in patients with Achilles tendon rupture. Ruptured Achilles tendon have histologically demonstrated collagen degeneration with a greater content of collagen III and less collagen I<sup>[8,9]</sup>.

Both oral and intratendinous injection of steroids have been implicated in spontaneous tendon rupture<sup>[10]</sup>. Other risk factors for rupture of the Achilles tendon include steroid therapy, hypercholesterolemia, gout, rheumatoid arthritis, long-term dialysis, and renal transplantation<sup>[2,11-15]</sup>.

## PRESENTATION

The patient typically presents with pain, inability to weight bear and a clear popping sensation or sound after an episode of activity during which they sustain a forced dorsiflexion of the ankle. The injury can also be sustained during eccentric contraction. The patient frequently describes the sensation of being kicked, shot or even bitten on the back of the heel.

Acute Achilles tendon rupture can readily be detected on physical examination. Plantarflexion of the foot is understandably weak<sup>[16]</sup>. The Achilles tendon is best examined with the patient kneeling and the feet hanging over the edge of the chair. In this position soft tissues hang off the Achilles tendon like a tent ridge pole and defects can be readily visualised (Figure 1). There is frequently a visible defect in the Achilles tendon. This is accompanied by swelling due to peritendinous haematoma.

The defect in the Achilles tendon is typically palpable with a sensitivity of 0.71 and specificity of 0.89. Maffulli compared the sensitivity and specificity of the principal clinical tests designed to determine Achilles tendon rupture<sup>[17]</sup>. Specific tests include Simmonds or Thompsons' test with sensitivity of 0.98 and specificity of 0.93. Lesser known are the O'Brien and Copeland tests both with a sensitivities of 0.8. Early reports suggest that up to 20% of Achilles tendon injuries can be missed by clinical assessment alone<sup>[18]</sup>.

## RADIOLOGY

In patients with equivocal clinical signs diagnostic imaging is required.

Ultrasound is readily available, cheap, non-invasive but user dependant. Ultrasound has a diagnostic reported sensitivity, specificity and accuracy of 100%, 89.9% and 94.4% respectively<sup>[19]</sup>.

It can discriminate between and partial complete tears except those located at the proximal pole or musculotendinous junction of the tendon where sensitivity and specificity drop to 0.5 and 0.81 respectively<sup>[20]</sup>. An additional advantage in ultrasound in the dynamic observation of tendon gaps which have been shown to correlate strongly with those observed during operative repair<sup>[21]</sup>. Some authors argue that if the gap between the tendon ends is greater than 5 mm as assessed by ultrasound in full equinus than surgical intervention is indicated<sup>[22]</sup>.

Magnetic resonance imaging remains the gold standard for the diagnosis of the Achilles tendon rupture with a sensitivity of 100% and a specificity of 0.03<sup>[23]</sup>.

## TREATMENT

There is a dichotomy of therapeutic options: operative and conservative. Both are accepted forms of management for acute rupture and the optimal regimen remains contentious. The article discusses cases of acute tendoachilles rupture. In cases of delayed diagnosis the likely success of conservative management may be limited by a lack of apposition of the tendon ends due to scarring and retraction. Therefore, surgical repair is advocated<sup>[24]</sup>. Cases of chronic rupture of the tendoachilles by their very nature will not respond to conservative treatment and therefore will require repair utilising graft<sup>[25]</sup>.

### Conservative

The aim of non-operative means of treatment is restore and maintain contact between the two ends of the ruptured Achilles tendon to facilitate healing. Conservative treatment regimens vary greatly but commonly involve immobilisation with rigid casting or functional bracing. The foot is initially placed in full equinus (30° namely full plantarflexion). The foot is then brought into neutral sequentially over a period of 8-12 wk. Once ankle position





**Figure 1** View of the right and left Achilles tendon with the patient prone. The left is ruptured. The right Achilles tendon is well defined and soft tissues hang off it like a tent. The suspension of the soft tissues off the Achilles tendon is not visible on the left side as the tendon is ruptured.

permits it, weight bearing is allowed. There is currently no clinical consensus on whether the cast should extend above the knee or if a below knee cast is sufficient. The above knee plaster is applied with the knee in slight flexion which serves to defunction gastrocnemius, having an origin over the posterior aspect of the femora condyles. However, one study shows the position of the knee does not influence gap between the torn ends of the Achilles tendon<sup>[26]</sup>.

Little evidence exists to recommend one regimen over another. The current evidence is summarised in Table 1. These studies demonstrate that patients can be allowed to weight-bear early in an off-the-shelf orthosis/CAM walker/Sheffield splint with no detriment in any long term outcomes<sup>[27,28]</sup>. This has obvious practical advantages compared to the traditional treatment of prolonged non weight-bearing in a below knee equinus cast. This is particularly true for frail or elderly patients where non-operative treatment tends to be preferred. Petersen *et al* also suggest that this may also actually decrease the risk of re-rupture although this was not found to be significant ( $P = 0.066$ ). Saleh *et al*<sup>[29]</sup> also suggested that their splint allowed patients to regain mobility significantly more quickly and that patients preferred the splint to the cast. These findings are in keeping with the literature on operatively managed acute Achilles tendon ruptures which suggests that early weight bearing and mobilisation improve outcomes.

Newer splints for immobilisation have been developed with encouraging initial results. The Vacoped© is a cast in which the patient's ankle is supported by an air cushion which is then inflated. The cushion is encased in a robust shell. The design of the cast allows the degree of equinus to be dialled from 30° (full) to 15° (mid) and 0° (neutral). In addition there is latch which allows users the facility to perform a restricted range (-10°-10°) of plantar and dorsiflexion. The Vacoped regimen recommends 2 wk in full equinus followed by a further 2 wk in partial equinus. Then the ankle is held in neutral for 1 wk and then restricted (10°) dorsi- plantar flexion for the final week.



**Figure 2** Achilles tendon repair with plantaris tendon reinforcement.

The Vacoped allows the patient to touch weight bear for two weeks, and partial weight bear from for one week after that. Full weight-bearing is commenced at 3 wk<sup>[30]</sup>. In addition the periodic insufflations and deflation of air facilitates venous drainage theoretically reducing the risk of deep vein thrombosis. Furthermore, the support is buoyant and supple avoiding the risk of pressure areas.

### Operative

There are a variety of approaches to the surgical management of this injury. Contention exists over the surgical approach (open or percutaneous), suture repair method and suture type.

In addition to isolated direct tendon repair, various means of augmentation of the tendon have been described. Gastrocnemius augmentation involves raising a flap 2 cm wide by 8 cm long which is reflected across the repair and sutured. The Plantaris tendon can also be used (Figure 2). It is either weaved around the tendon or may be expanded into a membrane which is sutured around the repair. The evidence supporting augmentation is weak. Pajala *et al*<sup>[31]</sup> performed a large prospective study of tendoachilles repair and found no benefits between augmented and simple end-to-end repair.

Percutaneous repair has been described involving minimally invasive stab incisions on the medial and lateral aspect of Achilles tendon and a suture passer. Reduced infection rates have been shown compared to open repair<sup>[32]</sup>. Increased rates of Sural nerve injury have been demonstrated with this technique<sup>[33]</sup>.

Patient factors have been demonstrated to influence post-operative wound breakdown and infection rates. These included diabetes mellitus, steroid therapy, smoking and rheumatoid disease<sup>[34]</sup>.

**Post-operative regime:** Postoperatively the patient can progressively increase the extent of weightbearing. Typically, at 6 wk the patient commences active and assisted movement of the ankle. Isokinetic strengthening is commenced 2 to 4 wk. The patient can usually expect full strength and endurance 4 mo after surgery. Although

Table 1 Summary of evidence for non-operative management of acute tendo-achilles rupture

Ref.	Patient group	Study type (level of evidence)	Outcomes	Key results	Study weaknesses
Costa <i>et al</i> <sup>[27]</sup>	48 adult patients with acute achilles tendon rupture who chose to have non-operative treatment. Randomised to either six weeks in an off-the-shelf, carbon-fibre orthosis with three 1.5 cm heel raises that were encouraged to mobilise fully weight-bearing and move the ankle within the orthosis (trial group) or to six weeks in a below knee gravity equinus cast that were non weight-bearing (control group). This was followed by serial removal of heel raises or casting in increasing dorsiflexion over 6 further weeks. Immobilisation was discontinued at 12 wk. Reviews at 3, 6 and 12 mo	PRCT	<p>Numbers returning to sport</p> <p>Time to return to normal activities</p> <p>EuroQol health status questionnaire- EQoL</p> <p>Domain</p> <p>EuroQol health status questionnaire- ESD</p> <p>Domain</p> <p>Deficit in calf diameter in mm</p> <p>Loss of movement in degrees</p> <p>Deficit in total concentric and eccentric work</p> <p>Complications</p>	<p>No significant difference found (<math>P = 1.0</math>); 56% trial group <i>vs</i> 52% control group</p> <p>No significant differences found. Sport- (<math>P = 0.631</math>) 18 wk trial group <i>vs</i> 21 wk control group. Walking- (<math>P = 0.765</math>) 16 wk trial group <i>vs</i> 22 wk control group. Stair climbing- (<math>P = 0.484</math>) 16 wk trial group <i>vs</i> 22 wk control group. Work- (<math>P = 0.370</math>) 13 wk trial group <i>vs</i> 17 wk control group</p> <p>No significant differences found. 3 mo- (<math>P = 0.372</math>) 80 trial group <i>vs</i> 85 control group. 6 mo (<math>P = 0.598</math>) 89 trial group <i>vs</i> 88 control group. 12 mo- (<math>P = 0.122</math>) 85 trial group <i>vs</i> 91 control group</p> <p>No significant differences found. 3 mo- (<math>P = 0.450</math>) 0.73 trial group <i>vs</i> 0.69 control group. 6 mo- (<math>P = 0.810</math>) 0.80 trial group <i>vs</i> 0.80 control group. 12 mo- (<math>P = 0.888</math>) 0.85 trial group <i>vs</i> 0.85 control group</p> <p>No significant difference found (<math>P = 0.634</math>). 1.37 trial group <i>vs</i> 1.11 control group</p> <p>No significant differences found. Dorsiflexion (<math>P = 0.879</math>) -0.7 trial group <i>vs</i> 0.27 control group. Plantarflexion (<math>P = 0.248</math>) 4.13 trial group <i>vs</i> 7.27 control group</p> <p>No significant differences found</p>	Of the original 48 patients only 40 were available for review at one year. All patients who presented out of hours were initially placed in below-knee equinus plaster backslab
Peterson <i>et al</i> <sup>[28]</sup>	50 adult patients with acute achilles tendon ruptures. Randomised to either a CAM walker and were encouraged to weight bear (trial group) or to a below knee full equinus cast and were non-weight bearing (control group). Both groups were immobilised for 8 wk. Reviews at 4 and 12 mo	PRCT	<p>Re-rupture rate</p>	<p>1 re-rupture in trial group <i>vs</i> 1 re-rupture, 1 failure of tendon healing and 1 PE in control group</p> <p>No significant difference found (<math>P = 0.066</math>) but suggestive of a trend towards increased re-rupture in the control group. The risk of a type II error was 44% and it was thought likely that should the numbers of patients recruited have been larger this may have become a significant difference. 0% trial group, <i>vs</i> 17% control group</p> <p>No significant difference</p> <p>No significant difference found at 3, 6 or 12 mo</p>	Number lost to follow-up: 8. Length of time between injury and treatment not stated although delayed presentations were excluded
Saleh <i>et al</i> <sup>[29]</sup>	40 adult patients with acute achilles tendon ruptures. Randomised to either a below knee full equinus cast for 2 wk followed by, a mid equinus cast for 1 wk and then controlled early mobilisation in a Sheffield splint with full weight-bearing (trial group) or to a full-leg cast, with the ankle in full equinus, for four weeks, followed by two weeks in a below-knee cast with the ankle in mid-equinus, and then two more weeks with the ankle in the neutral position with weight-bearing allowed during the final two weeks only (control group). Review at 3, 6 and 12 mo. The Sheffield splint is an ankle-foot orthosis which holds the ankle at 15 degrees of plantar flexion, but allows some movement at the metatarsophalangeal joints. The orthosis is used in conjunction with an insole within an extra-depth shoe. It is removed to allow controlled movement during physiotherapy	PRCT	<p>Patient satisfaction</p> <p>Strength of plantar flexion</p> <p>Range of plantar flexion (degrees)</p> <p>Range of dorsiflexion (degrees)</p> <p>Time to walking indoors</p> <p>Time to walking outdoors</p> <p>Complications</p> <p>Patient preference</p>	<p>No significant difference found at 3, 6 or 12 mo</p> <p>No significant difference found at 3, 6 or 12 mo (<math>P &lt; 0.001</math>)</p> <p>Significantly quicker in trial group (<math>P &lt; 0.001</math>). 6 wk trial group <i>vs</i> 11 wk control group</p> <p>Significantly quicker in trial group (<math>P &lt; 0.001</math>). 9 wk trial group <i>vs</i> 15 wk control group</p> <p>1 re-rupture in each group</p> <p>All patients in the trial group preferred the time spent in the Sheffield splint to the time spent in the cast</p>	Randomisation method not stated

this represents the standard post-operative regimen, the optimum post-operative rehabilitation remains to be determined. Suchak *et al*<sup>[35]</sup> explored the effect of early weight bearing at 2 wk vs weight bearing at 6 wk in their randomised controlled trial. They observed that early weight-bearing had statistically significant improvement in quality of life indices (such as social functioning), vitality scores and physical functioning<sup>[35]</sup>. However, by 6 mo postoperatively there was no difference in the groups. Other sources of clinical controversy include post-operative early mobilisation versus rigid immobilisation for 6 wk. Kangas *et al*<sup>[36]</sup> explored this in a randomised controlled trial. They reported that early mobilisation was associated with improved isokinetic calf strength at 60 wk. The re-rupture rate was higher in the immobilisation cohort. However, the difference did not reach statistical significance<sup>[36]</sup>. Mortenson's group observed that patients who were allowed to perform early restricted motion had a shorter rehabilitation time when compared to a below knee cast for 8 wk<sup>[37]</sup>.

### **Conservative or operative: which is better?**

No published studies conclusively demonstrate the definitive superiority of one modality over another. Meta-analyses of studies have shown that the re-rupture rates are higher in cases of non-operative management: 13% for conservative management compared with 4% for surgically repaired Achilles tendons<sup>[31,38]</sup>. Meta-analyses report a re-rupture rate of 2% for percutaneous reparative techniques.

Tendon elongation and weaker plantar flexion are also associated with non-operative management. However, recent studies suggest that these benefits of operative repair over conservative management in plaster are only short-lived. Keating and collaborators in the recent prospective randomised trial found that operative repair was associated initially with increased range of ankle movement and plantarflexion power when compared with cast management<sup>[39]</sup>. However by 26 wk there was no difference between the two groups.

Plaster or simple immobilisation alone avoids the inherent risks of surgery. These include wound infection (4%), fistula formation, skin necrosis, suture granuloma and damage to the sural nerve<sup>[31,37]</sup>. The skin necrosis can result in significant morbidity and require extensive plastic soft tissue procedures to ensure coverage of the tendon. Operative repair is associated with more rapid rehabilitation and return to work.

Percutaneous operative techniques have been found to have a complication profile superior to that of both conservative and open operative techniques. Meta-analysis report a re-rupture rate of 2%<sup>[31,37]</sup>. Studies involving functional bracing suggest that the disparity between surgical and conservative management may not be as marked as originally suspected. More recent studies show that re-rupture rates in patients treated operatively vs functional bracing are comparative<sup>[19,40-42]</sup>. In a recent study the result of percutaneous operative

management were compared with those achieved by functional bracing using the Vacoped. Investigators found that the incidence of re-rupture to be 3.9% for percutaneous repair and 3.4% for functional bracing with the Vacoped<sup>[43]</sup>. The difference did not reach statistical significance. The Vacoped allows early weight-bearing. The protective effect of early weight-bearing appears to be reproduced when patients are allowed early ankle movements. A recent prospective randomised controlled trial observed no difference in rupture rates between operative and non-operatively managed Achilles tendon rupture when both groups are permitted early movement in a functional brace<sup>[29]</sup>.

Assessment of the gap between the ends of the tendon as determined by magnetic resonance imaging or ultrasound may influence re-rupture rates in patients managed conservatively. Kotnis *et al*<sup>[22]</sup> elected to manage conservatively only those patients whose gap in full equinus was less than 5 mm. All other were managed operatively. They observed no statistically significant difference in re-rupture rates between the groups<sup>[22]</sup>. Wallace *et al*<sup>[44]</sup> based in Belfast, Ireland and Sheffield, United Kingdom studied 875 non-operatively treated Achilles tendon ruptures. The decision to manage patients non-operatively was based on the presence of opposition of the tendon ends on dorsiflexion. The observed re-rupture rate was 2.9%. A recent series studied by the Swansea and Maudsley group used a protocol of dynamic ultrasound and a tendon gap of less than 1 cm in full equinus. Furthermore, a dedicated clinic and service was established to treat and rehabilitate the patients. They found only a single case of re-rupture (< 1%) in 151 conservatively treated patients since 2008. This was comparable to the single case in the operative group of 63 patients<sup>[45]</sup>. In two of these series the re-rupture rate is superior to any anything achieved in a published operative series.

In Wallace's published series of excellent non-operative results patients were managed in a dedicated "Tendo Achilles" clinic. Patients were placed in an equinus non-weight bearing cast for the first four weeks. For the next four weeks they were placed in a pneumatic walker with heel-raises, which were sequentially removed over a period of 4 wk. The combined time in the equinus cast and boot walker was 8 wk. After this patients engaged in a specialist physiotherapy programme involving gait training, strength and mobility training. Final assessment and discharge was at 14 wk from injury or 6 wk from the time of removing the walking boot. It is uncertain how much the dedicated Achilles tendon clinic contributed to the favourable outcome. Patients were attended to by a specialist physiotherapist and were only discharged when the latter deemed that ankle strength was satisfactory.

Some authors would argue the merits of operative intervention in high performing athletes. The rationale for this argument is the potential loss of power or push

off strength with conservative management which is lessened by operative repair. The most recent studies quoted using specific treatment and rehabilitation regimes do not identify a functional benefit to operative repair. It is possible that the cohort may not reflect the athlete group. Furthermore, the measurement tools and assessments may not be sensitive enough to detect a deficit at the high functioning sporting level. For this reason the authors would exercise caution in treating this cohort as it is difficult to draw definitive conclusions.

## CONCLUSION

Tendoachilles rupture causes significant burden. Recovery is slow and potentially incomplete. Simmonds is a sensitive and reliable test. Avoiding missed diagnosis is imperative in good outcome. Both MRI and Ultrasound have potential diagnostic value. The argument of conservative vs operative treatment will no doubt continue; evidence is beginning to shift towards underpinning the benefits of non-operative treatment. Tendon gap assessment may be an important tool in deciding treatment modality. Intensive and specific post-operative regimes are being employed with seemingly positive results. The relative impacts of these factors in not known but certainly it has been demonstrated that favourable re-rupture rates are achievable in the non-operative group.

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## Management of negative pressure wound therapy in the treatment of diabetic foot ulcers

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therapy (NPWT) is a useful adjunct in the management of chronic and complex wounds to promote healing and wound bed preparation for surgical procedures such as skin grafts and flap surgery. NPWT has shown remarkable results although its mechanisms of action are not completely understood. In this paper, we offer a complete overview of this medication and its implication in the clinical setting. We have examined literature related to NPWT concerning human, animal and *in vitro* studies, and we have summarized why, when and how we can use NPWT to treat DFUs. Further we have associated our clinical experience to scientific evidence in the field of diabetic foot to identify a defined strategy that could guide clinician in the use of NPWT approaching to DFUs.

**Key words:** Diabetes; Diabetic foot; Negative pressure wound therapy; Advanced medication; Wound healing

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**Core tip:** This paper represents a summary of the mechanism of action of negative pressure wound therapy and its effectiveness. Further, according to scientific findings and our experience, we propose a flow chart about its use addressed to the field of diabetic foot.

### Abstract

Diabetic foot (DF) is a common complication of diabetes and the first cause of hospital admission in diabetic patients. In recent years several guidelines have been proposed to reinforce the the management of DF with a notable increase in diabetes knowledge and an overall reduction of amputations. Significant improvements have been reached in the treatment of diabetic foot ulcers (DFUs) and nowadays clinicians have several advanced medications to apply for the best local therapy. Among these, negative pressure wound

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### INTRODUCTION

Diabetic foot ulcers (DFUs) are the main cause of hospitalization in diabetic patients and they are considered a worldwide health problem. In recent years, the



Figure 1 Diabetic foot ulcer treated by negative pressure wound therapy.

improvement in diabetes therapy and the reinforcement of guidelines have reduced the amputation rate<sup>[1]</sup>. Furthermore the increased knowledge in the approach to DFUs has allowed the availability of several medical options to ensure the best local condition and wound healing. In this overview, negative pressure wound therapy (NPWT) plays a key role.

NPWT is a non-invasive therapy system that uses controlled negative pressure using a vacuum device to promote wound healing by removing fluid from open wounds through a sealed dressing or a foam dressing connected to a collection container using sub-atmospheric pressure<sup>[2,3]</sup> (Figure 1).

There are some differences between the various systems concerning the filler material used (foam vs nonadherent antimicrobial gauze), the connecting suction catheter (integrated with pressure sensor vs flat drain) and the intensity of negative pressure (ranging from 50 to 200 mmHg) continuous or intermittent<sup>[3]</sup>.

Since the first publications, it has been documented that this tool has become a useful option for the treatment of acute and chronic wounds in diabetic foot (DF).

The aim of this review is to summarize the available literature on NPWT to describe mechanisms of action, clinical efficacy and when and how to use this device.

## MECHANISM OF ACTION

The mode of action is not completely clear, but several levels of evidence are available. NPWT promotes a moist environment, reduces edema, creates a positive wound environment by removing healing inhibitors, increases blood flow, stimulates angiogenesis and granulation tissue and causes mechanical stress in the bed of the wound promoting cell proliferation.

## MOIST ENVIRONMENT

As an occlusive wound dressing, NPWT provides a moist wound environment ideal for the process. A moist wound bed is favourable for reepithelialization, growth factor action, angiogenesis and granulation promotion. At the same time, a moist wound reduces

local pain, protecting the nerve endings and improving quality of life<sup>[4,5]</sup>.

## EDEMA REDUCTION

The edema reduction decreases interstitial pressure and positively effects microvascular occlusion and lymphatic drainage, increasing the availability of nutrients, oxygen and antibiotic therapy in the wound area. A few studies describe this mechanism. One article by Kamolz *et al*<sup>[6]</sup> presents a clinical case study about seven patients with bilateral burns on the hand. The authors observed an increase of drained fluid and an evident edema reduction in the NPWT-treated side compared to the controlateral side treated with silver sulfadiazine cream<sup>[6]</sup>. A second study observed one pig with bilateral lesions on the back: the authors compared a wound covered with a split-skin graft treated with tie-over bolster and a wound treated by NPWT. Histological analysis described less wound edema in the side treated with NPWT<sup>[7]</sup>.

## POSITIVE WOUND ENVIRONMENT

Wound healing is the result of balance between promoting cytokines, growth factors and inhibiting proteases<sup>[8,9]</sup>. Wound exudate often contains high quantities of metalloproteinases (MMP) and low levels of their inhibitors; this condition is associated with an unsuitable environment for wound healing. MMP play a key role in the remodeling and turnover of the extracellular matrix (ECM) in several tissues. Each MMP has a defined role in tissue repair, and sometimes, its activity is involved in the same processes of wound healing. When MMP are present in high levels in the wound bed, they degrade proteins that are not their normal substrate: growth factors, receptors and ECM proteins; excessive degradation of ECM would deprive cells of attachment sites and signals for migration, differentiation and proliferation; this condition affects the different phases of tissue repair. Among the different proteases, MMP-9 is involved in the degradation of ECM, and it promotes angiogenesis and cell migration. Neutrophil gelatinase-associated lipocalin (NGAL) is a stabilizer of active enzymes in the degradation of ECM, and it creates a complex with MMP-9, playing a key role in the control of MMP-9 action. MMP-2 (latent and active form) has a central role in the regulation of vascularisation and inflammatory response. Its increase in the wound bed could alter the tissue remodeling by an excessive degradation of ECM. Tissue inhibitor of metalloproteinases 1 (TIMP-1) is a tissue inhibitor of MMP, balancing their activity, promoting cell proliferation and reducing apoptosis effect. Some studies showed that NPWT promotes an improvement of balance between proteases and their inhibitors and a greater expression of healing factors. Moues *et al*<sup>[10]</sup> described significantly lower levels of pro MMP-9 and a lower total MMP-9/TIMP-1 ratio in NPWT-treated wounds in comparison to wounds treated conventionally. Greene *et al*<sup>[11]</sup> observed a reduction in

MMP-9/NGAL, MMP-9, latent MMP-2 and active MMP-2 by 15% to 76% in three patients treated with NPWT therapy. Although scientific evidences are few, several analyses suggest that NPWT influences cytokine modulation and promotes a positive wound environment.

## BLOOD FLOW

Several studies showed an increase of blood flow in wounds treated with NPWT therapy. Morykwas *et al.*<sup>[12]</sup> placed a laser Doppler probe inside the wounds of twenty five pigs and studied blood flow. NPWT was applied in increasing increments of 25 mmHg up to 400 mmHg and for fifteen minutes intervals, and they found that optimal pressure was 125 mmHg, which was a 4 times increase of blood flow. To maintain this result, they observed that pressure applied needed a pause of two minutes between each five minutes of application<sup>[12]</sup>. These data were used to establish the baseline setting for the treatment of different typologies of wounds. Wackenfors *et al.*<sup>[13,14]</sup> measured blood flow by laser Doppler technique blood flow to an inguinal and sternal wound model using 50 to 200 mmHg. They marked an increase in microvascular flow a few centimetres from wound edges and a relative hypoperfusion in the immediate proximity of the wound edge. The study detected that negative pressure is distributed differently in the soft and dense tissue, and a low negative pressure (75 for soft tissue and 100 for muscle) reduces the risk of ischemic effects<sup>[13,14]</sup>. Chen *et al.*<sup>[15]</sup> examined the blood flow in wounds experimentally created in the ears of white rabbits treated with vacuum-assisted closure therapy using the microcirculation microscope and the image pattern analyses. They observed an increase of blood flow that was due to an increase of vascular diameter, blood flow velocity and blood flow volume<sup>[15]</sup>. Considering all these elements, the optimal pressure setting depends on the tissue treated and ideal pressure levels; the mode of action needs to be further investigated.

## ANGIOGENESIS AND GRANULATION TISSUE

Fabian *et al.*<sup>[16]</sup> showed a significant increase of granulation tissue in the treatment of ischemic full-thickness wounds in a rabbit model treated with NPWT with suction vs foam without suction. Still, Chen observed in his experimental study, in the rabbits treated with NPWT the increase of blood flow promotes the endothelial proliferation and angiogenesis more than that of the control group and a higher integrity of endothelial membrane<sup>[15]</sup>. In a prospective clinical non-randomized study of traumatic wounds treated with NPWT or Epigard (polyurethane foam), Labler *et al.*<sup>[17]</sup> found higher levels of interleukin 8 and vascular endothelial growth factor (VEGF) in the group treated with TNP compared to the control group.

Interleukin 8 has a significant role in the chemotaxis of granulocytes in the site of infections and, moreover, it is an effective stimulator of angiogenesis, promoting the migration of endothelial cells. VEGF is a family of growth factors involved in the angiogenesis that promote the development of blood vessels in the vasculature near the lesion. The same study showed a neovascularisation in histological analyses of wounds treated by NPWT documented by the finding of CD31 and the von Willebrand factor (vWf)<sup>[17]</sup>. CD31 (cluster of differentiation 31) is a protein that allows the angiogenesis process, the leukocyte migration and the integrin activation. vWf is a glycoprotein that promotes platelet anchorage, playing a key role in the first step of wound healing. Nain *et al.*<sup>[2]</sup> conducted a study on 30 patients divided in two groups, one treated with NPWT and a second with conventional saline gauze dressing. They observed a statistically significant difference in the rate of appearance of granulation tissue that appeared earlier in the study group<sup>[2]</sup>. A recent paper reported that NPWT activity induces a mobilization of endothelial progenitor cells (EPCs), allowing the healing of complex chronic wounds through the formation of new small blood vessels in lesion area<sup>[18]</sup>. Several studies showed that EPCs are retrieved from bone marrow in the case of ischemia to allow the neovascularisation of hypoperfused tissues<sup>[19,20]</sup>. A recent study conducted by Yang *et al.*<sup>[21]</sup> showed that DFUs treated by NPWT developed granulated tissue with increased collagen deposition if compared to traditional gauze therapy. Further, immunohistochemical analysis revealed higher beta fibroblast growth factors (bFGF) in NPWT patients, highlighting the involvement of NPWT in the promoting of the healing phase. Therefore, an increase in the rate of angiogenesis and the promotion of granulation tissue are two mechanisms that may be attributed to NPWT.

## MECHANICAL STRETCHING OF BED WOUND AND CELL PROLIFERATION

When NPWT is applied, the foam in the wound bed transmits a negative force to surrounding tissues. This force deforms the extracellular matrix, and the tension exerts a stress effect. These effects activate tyrosine kinases, transport genes, stimulate calcium release, and induce early growth response genes<sup>[22]</sup>.

In a *vitro* study, Kremers *et al.*<sup>[23]</sup> observed that, in fibroblast cultures exposed to mechanical stress with intermittent NPWT, there was a significant increase of p38 protein kinase and appended transcription factor, which represents a marker of cell proliferation. Scherer *et al.*<sup>[24]</sup> treated full-thickness wounds in diabetic mouse models, and the group treated with NPWT revealed an increase of cell proliferation, a higher concentration of CD 31 and Ki-67 statistically significant compared to other group. In conclusion, these studies, and the evidence of granular tissue and angiogenesis promotion, imply that NPWT encourages cellular proliferation.

## WOUND CHEMOTHERAPY WITH NPWT

New devices are now available, more comfortable and easier to use. Moreover, fluid instillation associated with NPWT is currently used as a new modality to treat diabetic and non diabetic ulcers. New devices allow infusion and fluid removal with the simultaneous application of local negative pressure<sup>[25]</sup>. Several kinds of fluids can be applied, mainly antiseptic, topical antibiotic, insulin saline solution<sup>[26-28]</sup>. This system could be useful, especially for contaminated or infected wounds.

## INDICATIONS AND CONTRAINDICATION

The application of negative pressure therapy is indicated for acute and chronic wounds, and therefore to promote the healing of diabetic foot wounds, pressure ulcers, traumatic wounds, dehisced surgical wounds, partial thickness burns, flaps and grafts. NPWT can be used in any size wound, especially on deep, complicated, nonhealing wounds of mixed etiologies<sup>[29]</sup>. Several studies reported a positive effect of NPWT therapy in diabetic foot wounds. Authors observed a significant wound volume reduction<sup>[30-34]</sup> and a quicker healing time in wounds treated with NPWT vs the control group. NPWT in the treatment of diabetic foot ulcers is not indicated for ischemic and infected wounds. Wakenfors *et al.*<sup>[13,14]</sup>, using laser Doppler, observed a zone of relative hypoperfusion in the immediate proximity of the wound edges; Kairinos *et al.*<sup>[35,36]</sup> showed that perfusion of intact skin decreases if NPWT is applied and hypoperfusion increases for increasing the suction pressure. In general, a  $TcPO_2 > 40$  mmHg is desirable, and several case studies reported failure in patients with inadequate flow<sup>[37,38]</sup>. Nevertheless, in some cases of revascularization failure, it was reported a therapeutic success with the use of NPWT<sup>[39,40]</sup>. In this case, it could be useful to apply a low pressure to avoid an impairment of local ischemia. Further, in a recent paper, Lavery reported a high rate of wound closure also with low pressure in the treatment of DF wounds<sup>[41]</sup>.

In our experience, in the case of non-optimal peripheral perfusion, we use a low pressure (75 mmHg) if we have a  $TcPO_2 < 40$  mmHg and a higher pressure (100-125 mmHg) if  $TcPO_2$  is  $> 40$  mmHg. In infected wounds, a surgical debridement and an appropriate antibiotic therapy is necessary before NPWT application<sup>[42,43]</sup>, because of a high risk of worsening the infection using an occlusive dressing as NPWT. In our policy, we usually also treat the patients with NPWT in cases of infection that involve only the skin and subcutaneous tissue, without involvement of deeper tissues and without systemic signs of infection (grade 1-2 of PEDIS classification). In these circumstances, we perform a closer follow-up with a careful monitoring of the wound. Additional precautions are needed in patients on antiplatelet or anticoagulant therapy because they have a risk of bleeding, which is increased by topical suction.

## REQUIREMENT FOR TNP

NPWT should not be applied to a critical ischemic wound. Before the application, it is necessary to have a sufficient perfusion in the wound side; infection should be treated. A radical debridement and excision of all infected and devitalised tissue must first be done<sup>[44,45]</sup>. After debridement, an adequate local haemostasis must be performed. If there is a potential for local bleeding, it is recommended to wait at least 24 h before applying NPWT<sup>[46]</sup>. Once healthy granulation tissue has been promoted, skin graft or flap could be performed. In Figure 2, we summarize the indications for management of NPWT in DFUs that represent the result of literature evidence and our experience. We retain that this flow chart could be an easy and immediate reference for clinicians who work with NPWT in the field of DF.

## CONCLUSION

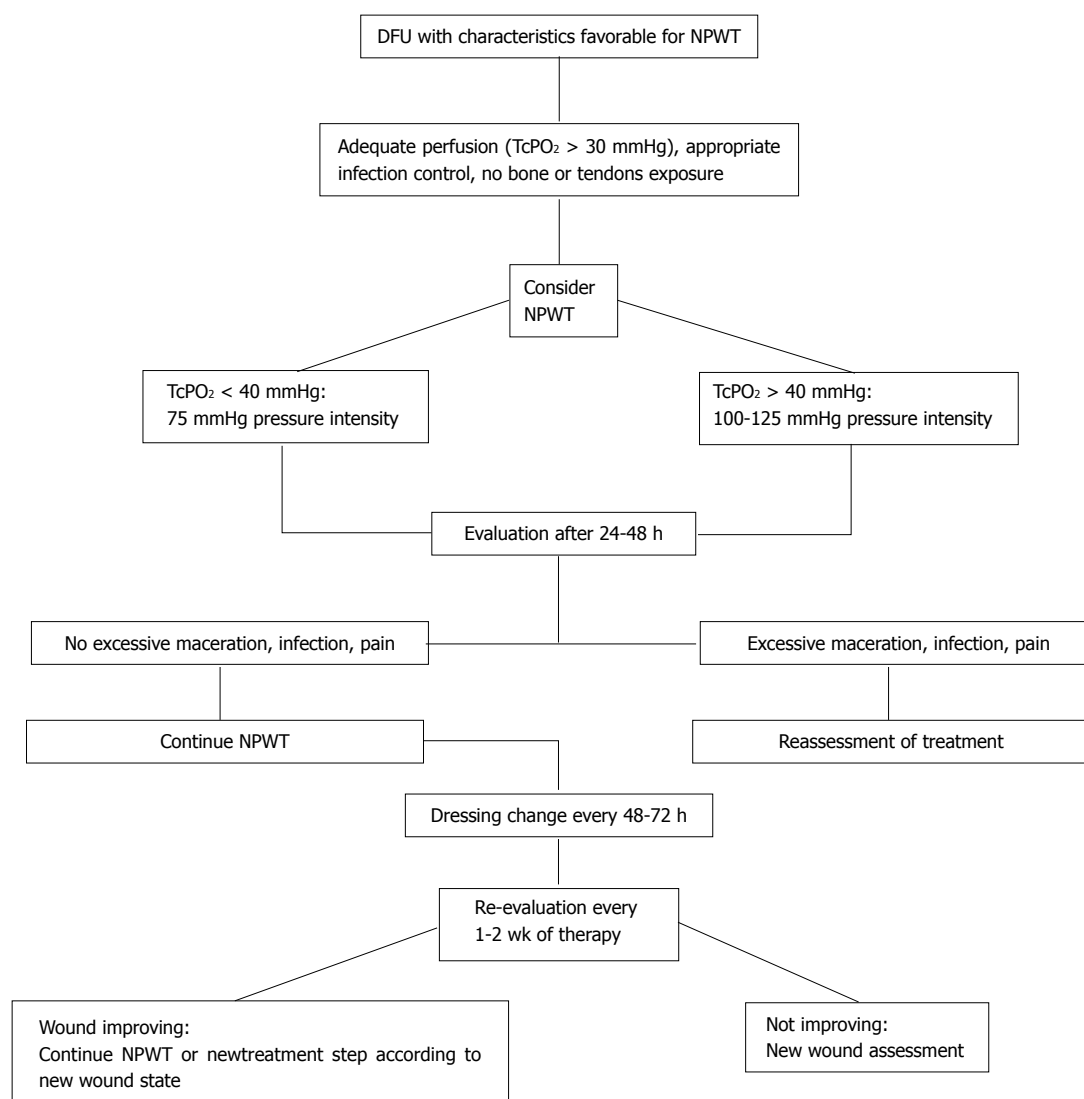
Research focused on understanding healing process of DFUs allowed the availability of targeted treatment according to wound phase, and new options such as skin substitutes, extracellular matrix proteins, negative pressure and growth factors have emerged as adjunctive therapies.

Therefore NPWT has become a useful option in the management of DFUs. It can be applied with effectiveness to treat acute, chronic and complex wounds, and several studies have shown it to be more effective than traditional moist therapy in terms of healing and rate of wound closure. Before the application, it is mandatory to apply the standard care, to ensure an adequate blood flow in the wound area and to exclude an infectious process that could affect the deeper tissues. The mechanism of action, partly unclear, determines a favourable wound environment to promote and accelerate the healing process. NPWT reduces perilesional edema, allows the removal of infected fluid and exudate, increases blood flow and stimulates angiogenesis, granulation tissue and cell proliferation. Furthermore this medication creates an appropriate wound bed for a possible application of skin graft and flap surgery. Although excellent results are documented with the use of NPWT, further studies are needed to better define its use, the optimal pressure level, the use of intermittent or continuous pressure and the filler material covering the wound. In conclusion, we retain that currently, between advanced dressing, topical negative pressure plays a leading role in the field of diabetic foot, and physicians can use this medication to treat chronic and complex wounds with excellent benefits.

## CLINICAL IMPLICATIONS, FUTURE DIRECTION AND LIMITATIONS

The availability of this device to treat inpatients and outpatients ensures clinicians a useful therapeutic option.





**Figure 2** Proposed flow chart for management of negative pressure wound therapy in the treatment of diabetic foot ulcers. DFU: Diabetic foot ulcer; NPWT: Negative pressure wound therapy; TcPO<sub>2</sub>: Transcutaneous oximetry.



**Figure 3** Model of lightweight and portable device that allows patients to perform daily activities.

DFUs managed with NPWT benefit from significant reduction in the ulcer size, increase in the granulation tissue, improvement with pain control and often a shorter treatment in comparison with ulcers treated with

with traditional gauze dressing. Other advantages are lower time requirements and lower costs for nursing staff and hospitalization. However, this data is often reported by small pilot studies and Randomized Control Trials with larger samples and adequate randomization are required to reinforce the role of NPWT<sup>[47-52]</sup>.

NPWT is also characterized by some limitations related both to the action and the management of the device. Pain and discomfort could be felt when suction is initially applied, a skin irritation from adhesive film can happen and the inadequate application of the foam can cause an abrasion. It is therefore mandatory that family members or caregivers are properly informed and educated on the use of this treatment because inappropriate use may result in an impairment of wound condition and discomfort for the patient. Nevertheless, new portable devices in smaller size and requiring reduced frequency of dressing changes that can be managed more easily and with good comfort are available for outpatients (Figure 3).



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Prospective Study

## Nerve compression and pain in human volunteers with narrow vs wide tourniquets

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**Author contributions:** Kovar FM and Kasprian G contributed equally to this work; Jaindl M, Prayer D and Kutscha-Lissberg F designed the research; Kovar FM, Oberleitner G and Breitensteher J performed the research; Kovar FM and Endler G analyzed the data; Kovar FM and Jaindl M wrote the paper.

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**Ethics approval:** The study was reviewed and approved by the IRB, Medical University Vienna, EK-1042/2011.

**Clinical trial registration:** The study is registered under NCT02023476 at <https://clinicaltrials.gov/ct2/show/NCT02023476?term=hemaClear&rank=1>.

**Informed consent:** All study participants provided informed written consent prior to study enrollment.

**Conflict-of-interest:** The present paper was supported by different sources: Volunteers honorary in the amount of 3.000 USD was supported by private funds of Kovar FM; HemaClear™ devices were provided by OHK Medical Device, Haifa, Israel. An agreement with representatives of Zimmer Inc. in Austria failed, for providing an A.T.S.® 3000 Automatic tourniquet system, as used by McEwen. We hereby certify that there are no other actual or potential conflicts of interest for the authors of the present paper. There are no other undisclosed financial or personal relationships with other people or organizations that could inappropriately influence our work. All other authors do not have a conflict of interest.

**Data sharing:** Technical appendix, statistical code, and dataset available from the corresponding author.

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### Abstract

**AIM:** To assess the clinical effects and the morphological grade of nerve compression.

**METHODS:** In a prospective single-center randomized, open study we assessed the clinical effects and the morphological grade of nerve compression during 20 min of either a silicon ring (group A) or pneumatic tourniquet (group B) placement variably on the upper non-dominant limb in 14 healthy human volunteers. Before and during compression, the median and radial nerves were visualized in both groups by 3 Tesla MR imaging, using high resolutional (2.5 mm slice thickness) axial T2-weighted sequences.

**RESULTS:** In group A, Visual analog pain scale was  $5.4 \pm 2.2$  compared to results of group B,  $2.9 \pm 2.5$ , showing a significant difference ( $P = 0.028$ ). FPS levels in group A were  $2.6 \pm 0.9$  compared to levels

in group B  $1.6 \pm 1$ , showing a significant difference ( $P = 0.039$ ). Results related to measurable effect on median and radial nerve function were equal in both groups. No undue pressure signs on the skin, redness or nerve damage occurred in either group. There was no significant difference in the diameters of the nerves without and under compression in either group on T2 weighted images.

**CONCLUSION:** Based on our results, no differences between narrow and wide tourniquets were identified. Silicon ring tourniquets can be regarded as safe for short time application.

**Key words:** Nerve compression; Magnetic resonance image; Wide tourniquet; Narrow tourniquet; Human volunteers

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**Core tip:** Nerve injury is a serious potential complication associated with clinical use of tourniquets in surgery. In a prospective single-center randomized, open study we assessed the clinical effects and the morphological grade of nerve compression during 20 min of either a silicon ring (group A) or pneumatic tourniquet (group B) placement variably on the upper non-dominant limb, visualized by 3 Tesla magnetic resonance imaging, using high resolutional (2.5 mm slice thickness) axial T2-weighted sequences. Based on our results, no differences between narrow and wide tourniquets were identified. Silicon ring tourniquets can be regarded as safe for short time application.

Kovar FM, Jaendl M, Oberleitner G, Endler G, Breitenseher J, Prayer D, Kasprian G, Kutscha-Lissberg F. Nerve compression and pain in human volunteers with narrow vs wide tourniquets. *World J Orthop* 2015; 6(4): 394-399 Available from: URL: <http://www.wjgnet.com/2218-5836/full/v6/i4/394.htm> DOI: <http://dx.doi.org/10.5312/wjo.v6.i4.394>

## INTRODUCTION

Nerve injury is a serious complication, associated with the clinical use of tourniquets, and influencing profoundly orthopedic surgery<sup>[1-3]</sup>. A bloodless operative field is considered mandatory for most surgical procedures on the upper and lower extremity, allowing surgical procedures to be performed with improved precision, safety and speed<sup>[1-7]</sup>.

The invention by McEwen in 1981, a modern microcomputer-based tourniquet system can be seen as a modified version of this basic idea of Cushing<sup>[2]</sup>. Following a different approach, OHK Medical Devices Inc. launched an elastic rubber ring with a stockinet and gained common approval.

Several studies related to tourniquet use have investigated various complications, the most frequent

one being nerve palsy<sup>[1-4,6,8,9]</sup>. In the current literature, the impact of the width of a tourniquet and as a consequence the pressure expansion, is discussed controversial<sup>[3,10-14]</sup>.

To the best of our knowledge, none of them used magnetic resonance image (MRI) as a visualization model, in healthy human volunteers, wearing two different tourniquet devices. Therefore we conducted the present study, to investigate differences between HemaClear™ blood free device and a standard pneumatic tourniquet.

## MATERIALS AND METHODS

We investigated 16 upper extremities in 16 volunteers during an eight months period in an IRB approved (EK 1042/2011) single centre randomized prospective, controlled study, by the standards of International Conference of Harmonisation and Good Clinical Practice. (Registered: NCT02023476) All individuals gave written consent to participate in the study. Two individuals, one male and one female, had to be excluded after study Day 1, due to the fact of violating the inclusion criteria between Day 1 and Day 2. In the remaining group of 14 volunteers, mean age was 24.3 years (range 22 to 28), 9 (64%) were males and 5 (36%) were females. All remaining individuals finished the study without nerve impairment or skin lesion.

Volunteers who meet the inclusion criteria and provide written informed consent were included. Main criteria for inclusion were the following: self defined Caucasian, clinically healthy, body mass index (BMI) of  $\leq 30$ , a systolic arterial blood pressure  $\leq 190$  mmHg, no rash or dermatologic condition or tattoos which may interfere with the placement site and no neurovascular impairment or previous surgery on the investigated limb. Self-defined Caucasian was implemented to guarantee an equal evaluation of possible skin lesions.

### HemaClear™ of OHK Medical Device (group A)

HemaClear™ consists of a silicon ring wrapped in a stockinet sleeve and pull straps (Figure 1). It performs three functions-blood removal (exsanguinations), arterial flow occlusion, and placement of sterile stockinet. The ring is placed on the extremity and then straps are pulled proximally. The silicone ring rolls up the limb and the stockinet sleeve unfolds onto the limb. During the rolling up process, the ring exerts pressure and squeezes the blood away from the limb. Pressure is exercised by only a single silicon ring, and therefore the profile is very small.

### Standard pneumatic tourniquet (group B)

As standard pneumatic tourniquet system, we used the following setting: an inflatable cuff (Tourniquet Cuff REF 20-64-711, 35 cm/14 in., VBM Medical Technique), with a width of 8 cm/6.5 in. and an air compression unit (fine pressure actuator tube connector 645-1708.2, Synthes REF 520.95) using the inner hospital 5 bar pipeline system for inflating the tourniquet. Due to





**Figure 1** HemaClear consists of a silicon ring wrapped in a stockinet sleeve and pull straps.

the containing metal of the air compression unit, we connected it with the tourniquet in the MRI room, using a flexible tube (PVC Extension Tubing, VBM Medical Technique) of 20 meter/187.4 in. length.

Defining the appropriate inflating pressure of the pneumatic tourniquet: In a similar approach like McEwen<sup>[2]</sup>, we detected the Limb Occlusion Pressure (LOP) with a handheld dopplers device (MD2/SD2, Dopplex® High Sensitivity Pocket Dopplers, Huntleigh Healthcare Limited, Cardiff United Kingdom). RTP (Recommended tissue pressure) feature was calculated as following: LOP + 40 mmHg if LOP < 130 mmHg, LOP + 60 mmHg if LOP 131-190 mmHg, and LOP + 80 mmHg if LOP > 190 mmHg. Calculated RTP was the pressure, used for inflating the pneumatic tourniquet.

### **MRI protocol**

Subjects were examined by a clinical high field (3 Tesla) MR system (Philips Achieva, Best, The Netherlands) in supine position. A flex medium surface coil was consistently placed on the non-dominant upper arm, with the tourniquet centering the field of view. Before, 5 min after application of the tourniquet a T2-TSE (turbo spin-echo sequence: TR (repetition time) 4808 ms. TE (echo time) 90 ms, flip angle 90°, FOV 130 mm × 164 mm, acquisition data matrix 260 × 316, reconstruction image resolution 0.2 mm, slice thickness 2.5 mm, NEX 1; The total imaging was 6:25 min) was acquired in an axial plane, covering the region 3.7 proximally and 4.8 cm distally to the tourniquet and 6.7 proximally and 7 cm distally to the narrow tourniquet position.

### **Practical setting**

The study was divided in three parts, screening visit (SV), study day 1 (Day 1) and study day 2 (Day 2). During SV, a physical examination, evaluation of the inclusion criteria and the device randomization (Group A-HemaClear™; Group B- standard pneumatic tourniquet) with a blinded envelope were performed. On Day 1, blood pressure, visual analog pain scale

(VAS) and faces pain scale (FPS) baseline scores and pictures of the upper limb were performed. According to the randomization process to groups were formed for further proceedings.

In group A, the volunteer was placed in a supine position on the MRI, and the baseline MRI sequence was performed. Before starting the T2 sequence, the HemaClear™ device was placed on the non-dominant upper arm, using the same measurements criteria for exact placement. After finishing the T2 sequence, the tourniquet was removed immediately.

In group B, LOP and RTP detection were performed in a sitting position, and the volunteer was placed in a supine position on the MRI. Then, bating of three layers, and the standard pneumatic tourniquet were placed on the non-dominant upper arm. The exact position for the placement site was half the way of a drawn line between the greater tubercle and the lateral supercondylar ridge. A baseline MRI sequence was performed, and inflating to the calculated RTP was conducted, seconds before starting the T2 sequence, guaranteeing a full inflated tourniquet. After finishing the T2 sequence, the tourniquet was removed immediately.

Subsequently, the following procedures were performed in both groups: detecting the grade of muscle strength for the compressed upper extremity on a scale from 5 to 0, and evaluating VAS and FPS. Pictures of the device placement site were taken (iPhone 4, Apple Inc., Cupertino, CA, United States) after the volunteer had left the MRI room. During a final check up, 30 min post removal, before the volunteer left the study site the following parameters were evaluated: blood pressure, VAS and FPS levels.

Day 2 was performed at least seven days after Day 1, but no longer than 2 wk after Day 1, with switched groups for each volunteer. At the end of Day 2 the volunteer was asked which device was more painful after all.

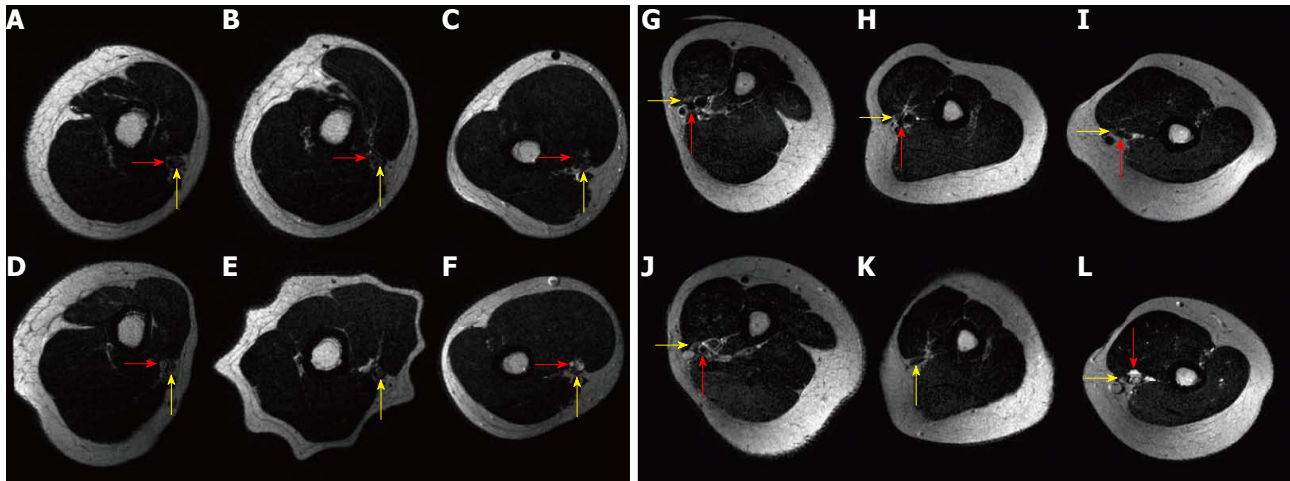
### **MRI measurements**

The maximum and minimum diameter of the median and the radial nerve and the brachial artery were measured on three axial planes in the T2 weighted sequences: the plane of the compression by the HemaClear™, 4 cm proximal and 4 cm distal to that point. Since the radial nerve divides in several fascicles at the spiral groove, the maximum diameter could not be measured at this point. The cross sectional area of the nerves was calculated assuming that the shape of the nerve resembles an ellipse.

### **Statistical analysis**

For statistical analysis we used the SPSS 16.0 software package (SPSS, Chicago, Ill., United States). Mean values and standard error of the mean are given unless otherwise indicated for continuous variables. Discrete data are presented as counts and percentages. To





**Figure 2** Red arrow indicates brachial artery, yellow arrow indicates median nerve. A-F: MRI imaging; A-C: Baseline imaging proximal, sulcus and distal humeral arm; D-F: Compression with the broad tourniquet proximal, sulcus and distal humeral arm; G-L: MRI imaging; G-I: Baseline imaging proximal, sulcus and distal humeral arm; J-L: Compression with the narrow tourniquet proximal, sulcus and distal humeral arm. MRI: Magnetic resonance imaging.

**Table 1** Mean values of median nerve in mm without compression (NORM), with the HemaClear device (HEM) and with a pneumatic tourniquet (PNEU)

	PROX	SULC	DIST
MIN <sup>1</sup>			
NORM	0.287	0.25	0.254
HEM	0.281	0.234	0.244
PNEU	0.275	0.253	0.285
MAX <sup>1</sup>			
NORM	0.396	0.403	0.376
HEM	0.384	0.415	0.381
PNEU	0.389	0.386	0.368

<sup>1</sup>All results are mean values in mm.

compare the two study groups we used a dependent sample student's *t*-test. A two-tailed *P* value less than 0.05 was considered statistically significant. Statistics was performed by GE, a biomedical statistician.

## RESULTS

Fourteen subjects, nine males and five females with complete data participated in the present study. As a result we were able to acquire data from 14 placements of each device. For the HemaClear™, we used six Pink and eight Yellow devices. In the A group we used the same device in all patients, adapted to the circumference of the upper arm.

### MRI measurements

Levels for compression of the median and radial nerve were almost similar in both groups (Figure 2A and B, Table 1). The brachial artery was compressed in all individuals by both tourniquets as a sign of adequate vessel compression. In one patient the compression of the HemaClear™ was 2 cm proximal of the beginning of the spiral groove, in all other volunteers the radial nerve was passing the spiral groove at the point of

compression.

We could not detect a significant difference concerning the diameters or of the calculated area of the nerves between no compression, compression by HemaClear™ and the standard pneumatic tourniquet.

### Pain

VAS and FPS levels were evaluated at baseline, immediately after removal of the tourniquet device, and 30 min post removal. VAS and FPS levels at baseline were 0 in all volunteers. In group A, VAS was  $5.4 \pm 2.2$  compared to results of group B,  $2.9 \pm 2.5$ , showing a significant difference ( $P = 0.028$ ). FPS levels in group A were  $2.6 \pm 0.9$  compared to levels in group B  $1.6 \pm 1$ , showing a significant difference ( $P = 0.039$ ). VAS and FPS levels, post removal, were 1 and 1 in only two volunteers, both male and occurring after Day 1 with the HemaClear™ device.

Only two out of 14 volunteers described independent the pneumatic tourniquet as more painful. One volunteer was male, one female, both experienced the HemaClear™ device on Day 2. The reasons, given by the study subjects, why the HemaClear™ device was more painful were as following: the roll on process was described as uncomfortable, but the main pain was caused by the placement (silicon ring) at the upper arm, which was felt as a pulsing or throbbing sensation.

### Nerve impairment

Levels (manual force grade) for both nerves were identical within the same group, but there was a slight difference between group A  $4.5 \pm 1.4$  and group B  $4.3 \pm 1.1$  ( $P = 0.098$ ).

### Application

Placement of the silicon ring device was more practicable, because of the simple roll up whereas for the broad pneumatic tourniquet, placement of the bating, LOP/RTP detection, and finally inflating was mandatory.

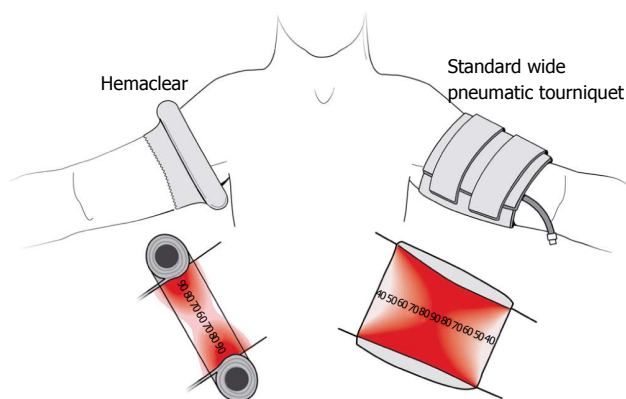


Figure 3 Detailed illustration of the different models of pressure application (reprinted with permission).

No other data than mentioned are available.

## DISCUSSION

The primary aim of the present study was to investigate the differences between HemaClear™ blood free device and standard pneumatic tourniquet, concerning possible nerve damage in healthy volunteers. We also investigated the pain scale during compression with both devices.

Our first hypothesis that a narrow silicone ring causes more nerve compression compared to a wide tourniquet was disproved. Our second hypothesis that a narrow silicone ring causes more pain compared to a wide tourniquet was approved.

The most gravid article concerning this topic, by Noordin *et al.*<sup>[14]</sup>, defaming the use of a HemaClear™ similar device, caused some controversial response. The substituted opinion by McEwen and his study group is in sharp contrast to findings of other various trials, and may be influenced by commercial interests<sup>[1,2,4,13-16]</sup>.

A study of female baboons suggests that the damage to the nerve fibers is a direct result of the applied pressure, and not a consequence of secondary ischemia<sup>[17]</sup>. The same paper also showed that the pressure gradient was higher at the edges rather than in the middle of the tourniquet, a finding that also supports the idea of a narrow tourniquet<sup>[17]</sup>. Another trial concluded that a wider cuff would not be intrinsically safer than a regular cuff, a result that is contrary to Crenshaw's findings<sup>[18]</sup>.

The relationship between tourniquet cuff width and the pressure that, last on the surface and the layers underneath it, is the core point in the current discussion. The fundamental difference is the technique, attaining the pressure and as a direct consequence fulfill the goal of exsanguination. In a narrow cuff the pressure is substantially diminished towards the middle of the limb, with a drop of 45%-55%, leading to a small gradients at the cuff's end and a short length of vessels and nerves under compression<sup>[18]</sup>. In contrast, in a wider cuff the nerves and vessels are exposed to

a relatively high compression stress, because the high pressure is transmitted across the limb at the same level as in the cuff and leads to high shear forces at the edges<sup>[18]</sup>. The wide tourniquet applies the pressure over a wide surface, resulting in shear forces at both edges, squeezing the nerve at two points in an unnatural way, and not as suggested by many users over the whole length of the tourniquet<sup>[18]</sup>.

Behind the HemaClear™ device, is a different model of pressure application, which is at the beginning confusing and controversial discussed in the literature<sup>[14]</sup> (Figure 3).

Contrary to Noordin's suggestions, narrow tourniquets can look back on a broad use in surgical settings in civilian hospitals and their safe use should not be reduced to military indications only<sup>[1,3,19]</sup>. Depending on the placement of the cuff, the occurrence of nerve related injuries has been experienced by 21%-28% of surgeons<sup>[5]</sup>. An experimental study in 20 healthy volunteers concluded that wider cuffs result in more severe changes in the nerve<sup>[3]</sup>.

The experience of a novel elastic tourniquet in 43 pediatric patients was published, concluding that it is safe and valuable in clinical practice<sup>[1]</sup>. Another trial reports, that application of a silicon ring device is practical, provides bloodless field for a certain time, and does not increase the complication rate related with the pressure applied to underlying tissues, but is not appropriate for long surgical procedures<sup>[20]</sup>.

### Limitations of the study

First is the small number of volunteers ( $n = 16$ ), due to the fact of limited financial and logistical feasibility. The limited number of tourniquet time is accidental by the local ethics commission, due to their concerns of pain and soft tissue damage. For ethical reasons, we were not allowed to use anesthesia. The time interval of 20 min of compression in this study can not be compared to a clinical setting with compression times over 60 min and longer. We also have to admit that we did not investigated the possible influence of secondary ischemic factors on our reported results.

### Limitations of both devices

The HemaClear™ occupies only 2 cm on the limb after application and enables a wider limb surface compared to regular pneumatic tourniquets. But there are also disadvantages like the constant pressure, performed by the silicon ring, which cannot be changed during surgery. The use in open or dislocated fractures has to be seen limited because of the roll up mechanism and in limbs with applied external fixation devices it cannot be used.

In contrast to those findings, the broad pneumatic tourniquet can be used in open and dislocated fractures because of its different application technique. Inflation and deflation during surgery are possible and enable longer surgical procedures, because reperfusion is possible after 2 h. Despite the mentioned advantages,

the main disadvantages are the large surface the tourniquet occupies on the limb, the additional console to operate the tourniquet and to detect LOP and RTP.

To the best of our knowledge we are the first to have visualized nerve compression with MRI using two different devices of surgical tourniquets *in vivo* in healthy human volunteers. Application of both devices resulted in a similar degree of vascular- and nerve compression. There were no indirect MR imaging signs of nerve compression (change in nerve cross sectional area, increased T2-weighted signal intensity) noted. No patient related complications were observed.

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## COMMENTS

### Background

Nerve injury is a serious potential complication associated with clinical use of tourniquets in surgery. Several studies related to tourniquet use have investigated various complications, the most frequent one being nerve palsy. In the current literature, the impact of the width of a tourniquet and as a consequence the pressure expansion, is discussed controversial.

### Research frontiers

The invention by McEwen in 1981, a modern microcomputer-based tourniquet system can be seen as a modified version of this basic idea of Cushing. Following a different approach, OHK Medical Devices Inc. launched an elastic rubber ring with a stockinet and gained common approval.

### Innovations and breakthroughs

Based on these results, no differences between narrow and wide tourniquets were identified.

### Applications

Silicon ring tourniquets can be regarded as safe for short time application.

### Terminology

HemaClear™ consists of a silicon ring wrapped in a stockinet sleeve and pull straps.

### Peer-review

The authors describe a valuable study which is well conducted and gives important clinical conclusions which may influence surgical and ethical conduct of interested surgical specialties.

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## Surgical interventions for anterior shoulder instability in rugby players: A systematic review

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literature on surgical treatment interventions for elite rugby players with anterior shoulder instability.

**METHODS:** We conducted a systematic review according to the PRISMA guidelines. A literature search was performed in PubMed, EMBASE and Google Scholar using the following search terms: "rugby" and "shoulder" in combination with "instability" or "dislocation". All articles published from inception of the included data sources to January 1<sup>st</sup> 2014 that evaluated surgical treatment of elite rugby players with anterior shoulder instability were examined.

**RESULTS:** Only five studies were found that met the eligibility criteria. A total of 379 shoulders in 376 elite rugby union and league players were included. All the studies were retrospective cohort or case series studies. The mean Coleman Methodological Score for the 5 studies was 47.4 (poor). Owing to heterogeneity amongst the studies, quantitative synthesis was not possible, however a detailed qualitative synthesis is reported. The overall recurrence rate of instability after surgery was 8.7%, and the mean return to competitive play, where reported, was 13 mo.

**CONCLUSION:** Arthroscopic stabilization has been performed successfully in acute anterior instability and there is a preference for open Latarjet-type procedures when instability is associated with osseous defects.

**Key words:** Shoulder; Instability; Dislocation; Rugby; Latarjet

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**Core tip:** Arthroscopic stabilization can be performed successfully for acute anterior instability and an open Latarjet procedure is preferred where there is instability associated with an osseous defect. Interestingly, within the latter group a large proportion of patients do not return to competitive play following their surgery. The

### Abstract

**AIM:** To systematically evaluate the evidence-based



evidence base in this field is based on a limited number of studies which lack methodological rigor. As shoulder instability represents a serious musculoskeletal injury within competitive level rugby, there is a need for well-designed trials or sports medicine registries, to better inform orthopaedic surgeons on the management of this cohort of patients.

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## INTRODUCTION

The glenohumeral joint is the most mobile joint in the human body owing to its relative lack of osseous constraint<sup>[1]</sup>. The incidence of shoulder dislocation in the general population is estimated at between 23.9 and 56.3 per 100000 person-years<sup>[2,3]</sup>. The incidence of instability is double this number in athletes<sup>[4]</sup>. The largest and most current descriptive epidemiological study in young athletes found that the probability of at least one shoulder instability event per year is 2.8%<sup>[5]</sup>. Although shoulder instability in professional rugby union accounts for 0.03 injuries per 1000 player-hours, only anterior cruciate ligament injuries cause more days of absence from competitive play<sup>[6]</sup>.

Existing literature on anterior shoulder instability supports primary repair in young and active patients owing to a lower risk of recurrent instability compared to conservative treatment<sup>[7]</sup>. More recent research demonstrates superiority of open repair over arthroscopic repair in younger male patients in relation to recurrence of instability<sup>[8]</sup>. Comparative analysis of popularized techniques such as Bristow-Latarjet and Bankart repairs has shown improved clinical outcomes in the former procedure irrespective of the presence of an osseous lesion<sup>[9]</sup>.

Research with a focus on treatment interventions in collision athletes most commonly describes sports such as judo, American football, wrestling and soccer<sup>[10,11]</sup>. The mechanisms of shoulder instability in elite rugby players have been described as "try scoring" with a hyperflexed outstretched arm, "tackling" with extension and adduction of the arm, and "direct impact" when there is a compressive force applied to an adducted, internally rotated arm<sup>[12]</sup>. Although similarities in mechanisms of injury exist with American football<sup>[13]</sup>, the collision forces acting on the shoulder are likely to be different owing to protective equipment worn by football players which are thought to contribute to a significant risk reduction of shoulder injuries when compared to rugby<sup>[14]</sup>. With the exception of Australian Rules football, the biomechanics of shoulder instability injuries in rugby players is therefore probably distinctive from other collision sports

and there is clinical value in research on treatment interventions that specifically focuses on this group of athletes. This study aims to systematically evaluate the evidence-based literature on surgical treatment interventions for elite rugby players with acute and recurrent anterior shoulder instability.

## MATERIALS AND METHODS

### Review protocol

This study was performed in accordance with the guidelines from the preferred reporting items for systematic reviews and meta-analyses (PRISMA)<sup>[15]</sup>.

### Search strategy and information sources

A literature search was performed in PubMed, EMBASE and Google Scholar using the following search terms: "rugby" and "shoulder" in combination with "instability" or "dislocation". The time horizon for search was performed from inception of the databases to January 1<sup>st</sup> 2014. The last date the search was performed was the 1<sup>st</sup> July 2014. A summary of the search strategy is shown in Figure 1.

### Inclusion and exclusion criteria

Studies that described a surgical treatment intervention for elite rugby players with anterior shoulder instability were included. Elite rugby players were defined as professional or semi-professionals who participated in both rugby league or rugby union. Studies that described surgical treatment interventions in collision athletes in which there was a sub-group of elite rugby players with their own clinical outcomes specifically reported were also included. Only studies with a minimum follow up of 12 mo were included. Clinical and biomechanical studies were deemed eligible for evaluation. Case reports, expert opinion and personal observations were excluded.

### Data extraction

Two investigators (Sabharwal S and Patel NK) independently extracted the following data using a standardized spreadsheet: study title, authorship, year of publication, level of evidence according to the Oxford Centre for Evidence Based Medicine<sup>[16]</sup>, country of origin of research, number of players, type of anterior instability (acute/recurrent), descriptions and frequency of osseous lesions, mean age of surgery, mean time to surgery from injury, surgical stabilization technique, post-operative rehabilitation description, number of players that returned to competition at the same level, mean time for return to full training, mean time for return to competitive match, post-operative evaluation tools and summary, incidence of recurrence of instability, post-operative complications and mean follow up. Patients with acute instability were defined as those who received treatment after a first episode of dislocation. Discrepancies between data extracted by the two investigators were reviewed and corrected. Where there was disagreement on data



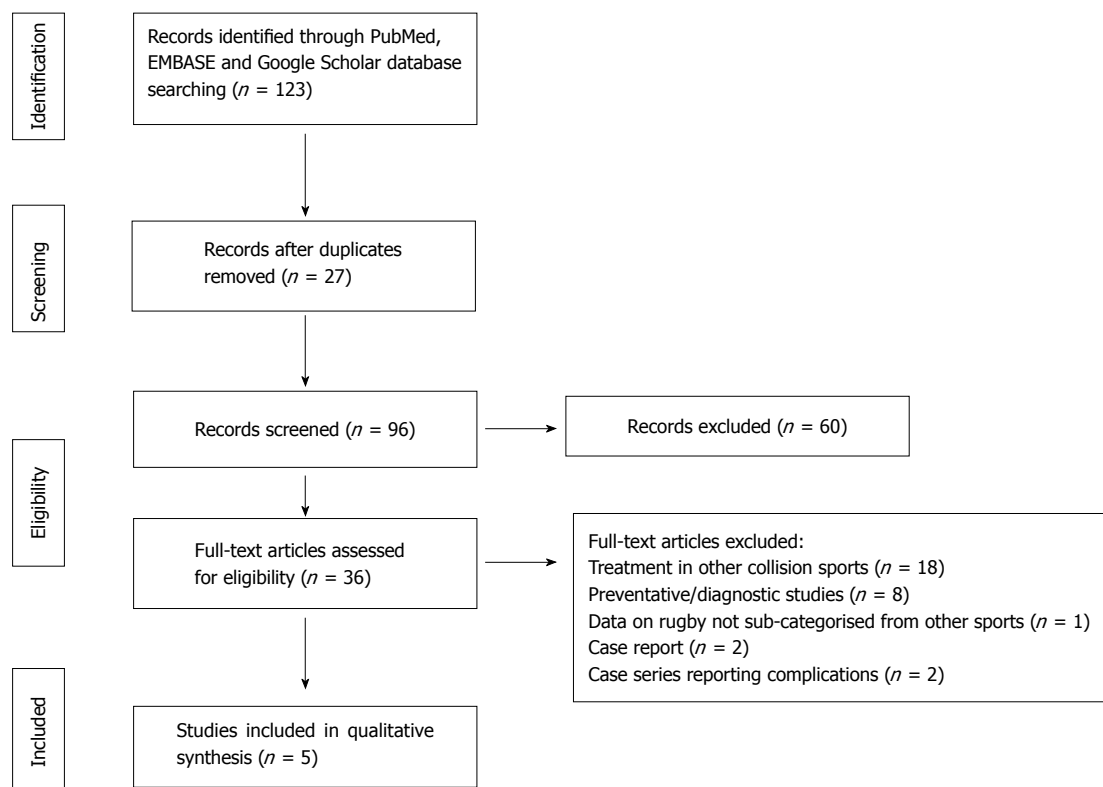


Figure 1 PRISMA flowchart showing search strategy for this study.

extracted, consensus was reached after discussion with a senior author (PR).

### Quality assessment and risk of bias of individual studies

Study quality was assessed using a modified Coleman Methodology Score (CMS). The CMS is a quality assessment tool that was initially used to grade methodology in patellar tendinopathy studies<sup>[17]</sup>. It has subsequently been adapted to a wide variety of musculoskeletal research<sup>[18,19]</sup> and more recently has been used in evaluating methodology of shoulder instability studies<sup>[20]</sup>. There are 10 criteria that are evaluated giving a total score from 0 to 100 points. A study that scores 100 represents clinical research that largely avoids chance, biases and confounding factors. Studies can be categorized as excellent (85-100), good (70-84), fair (50-69) and poor (< 50)<sup>[20]</sup>. Two investigators (SS and NKP) independently scored the included studies using the modified CMS (Table 1).

### Statistical analysis

Descriptive statistics were produced and data were analyzed in SPSS 21.0 (SPSS Inc, Chicago, IL). Inter-rater reliability for the modified CMS was assessed with a Pearson's R coefficient. An average of the two investigators' scores for each study was presented in the results.

## RESULTS

In total only five studies were found that met the eligibility criteria of this systematic review (Table 2).

Bonnevalle *et al.*<sup>[21]</sup> reported on 31 rugby players with recurrent shoulder instability and their data formed part of a subsequent study by Fabre *et al.*<sup>[22]</sup> that examined outcomes in 49 contact athletes<sup>[21,22]</sup>. To ensure the same patient group was not included twice, the latter group's article was excluded from our analysis. All the studies were retrospective cohort or case series studies (Level of Evidence IV). A total of 368 shoulders in 365 elite rugby union and rugby league players were included. Overall, the mean age at surgery was 23.2 years, with a range from 16 to 35 years (Table 3). The mean duration of follow up was 72 mo, with a range of 17 mo to 237 mo (Table 4). Return to competitive play was reported in 230 out of 269 patients (85.5%) at a mean time of 13 mo, with a range of 2 to 24 mo. Recurrence of instability occurred in 32 of the 368 cases (8.7%).

A complete sub-group comparison of all pathology and treatment related recurrence rates was not possible because of lack of specific descriptions within some of the studies. However, where reported recurrent instability after surgery occurred in only 1 out of 41 (2.4%) reported cases of acute instability and 16 out of 231 (6.9%) cases of chronic or recurrent shoulder instability. Furthermore, recurrence of instability after arthroscopic surgery was reported in only 2 out of 39 (5.1%) cases compared to reported recurrences in 14 out of 84 (16.7%) cases after an open surgical technique was performed. Recurrence after soft tissue surgical techniques were adopted occurred in 7 out of 133 (5.2%) cases and recurrence after a Latarjet procedure was performed occurred in 14 out of 77

**Table 1 Modified Coleman Methodology Scoring system used to assess methodological quality of the studies included in this review**

Only one score to be given for each of 7 sections		
Study size	< 20	0
	20-50	4
	51-100	7
	> 100	10
Mean follow up	< 12 mo	0
	12-36 mo	4
	37-60 mo	7
	> 61 mo	10
Surgical or conservative approach	Different approach used and outcome no reported separately	0
	Different approaches used and outcome reported separately	7
	Single approach used	10
Type of study	Retrospective cohort	0
	Prospective cohort	10
	Randomised controlled trial	15
Description of indications/ diagnosis	Described without % specified	0
	Described with % specified	5
Description of surgical or conservative technique	Inadequate (not stated, unclear)	0
	Fair (technique only stated)	5
	Adequate (technique stated, details of surgical or conservative procedure given)	10
Description of postoperative rehabilitation	Described	5
	Not described	0
Scores may be given for each option in each of the 3 sections if applicable		
Outcome criteria	Outcome measures clearly defined	2
	Timing of outcome assessment clearly stated	2
	Use of outcome criteria that has reported reliability	3
	General health measure included	3
Procedure of assessing outcomes	Participants recruited	5
	Investigator independent of surgeon	4
	Written assessment	3
	Completion of assessment by patients themselves with minimal investigator assistance	3
Description of subject selection	Selection criteria reported and unbiased	5
	Recruitment rate reported > 90%	5
	≤ 90%	0

**Table 2 Summary table on each study's demographics**

Ref.	Journal	Level of evidence	Country	No. of players (shoulders)	Type of instability	Osseous lesion(s)
Neyton <i>et al</i> <sup>[23]</sup>	<i>Journal of shoulder and elbow surgery</i>	IV	France	34 (37)	Recurrent, anterior	Bony Bankart 18/37, Hills-Sachs 25/37
Bonnevalle <i>et al</i> <sup>[21]</sup>	<i>Rev Chir Orthop Reparatrice Appar Mot</i>	IV	France	31	Recurrent, anterior	None
Larrain <i>et al</i> <sup>[26]</sup>	<i>Arthroscopy</i>	IV	Argentina	198	Acute anterior instability (40), recurrent anterior instability (158)	Large bony defect: Bony Bankart 16/198, Hills-Sachs 2/198, Combined 9/198 Small bony defect: Bony Bankart < 25% 36/198, Hills Sachs < 1/4 172/198 1/6 Bony bankart
Goldberg <i>et al</i> <sup>[24]</sup>	<i>British Journal of Sports Medicine</i>	IV	Australia	6	Acute anterior instability (1/6), chronic recurrent (5/6), all patients had rotator cuff tears	
Burkhart <i>et al</i> <sup>[25]</sup>	<i>Arthroscopy</i>	IV	United States/ South Africa	96	Anterior instability acute and recurrent	8/96 Bony Bankart and Hill-Sachs

(18.2%) cases. It was observed that where open procedures were performed instead of arthroscopic procedures, or a Latarjet procedure in preference of soft tissue stabilization, the patients groups were more likely to have osseous defects.

#### Soft tissue lesions and bone defects

Descriptions of soft tissue and bone defects were found to be incomplete in a majority of the studies<sup>[21,23-25]</sup>.

Soft tissue Bankart lesions were reported in three studies<sup>[21,24,26]</sup> in which they were identified in 208 (88.5%) out of 235 shoulders. The presence of a bony Bankart and Hills-Sachs lesion was described in two studies that evaluated a total of 235 shoulders<sup>[23,26]</sup>. Cumulatively, they reported 79 (33.6%) bony Bankarts and 199 (84.7%) Hills-Sachs lesions. One study examined instability in conjunction with rotator cuff injury and reported a supraspinatus tear in all 6

**Table 3** Summary table on mean age of rugby players, time to surgery, surgical procedure, return to match play and post-operative rehabilitation

Ref.	Mean age of player at surgery Years (range)	Mean time to surgery Months (range)	Type of stabilization	Post-operative treatment	No. of players that returned to competition after surgery	Mean return to competitive match
Neyton <i>et al</i> <sup>[23]</sup>	23.4 (17-33)	40 (3-163)	Latarjet-Patte procedure (Anterior instability)	Sling for 15 d with passive exercises and no limitation on external rotation. Return to rugby advised at 3 mo	22/34	7 mo (3-24)
Bonnevialle <i>et al</i> <sup>[21]</sup>	21 (16-34)	4.44 (2-20)	Open Bankart capsular repair	Immobilisation Velpeau bandage for 2-3 wk. No formal physiotherapy	30/31	4.6 mo (2-8)
Larrain <i>et al</i> <sup>[26]</sup>	22 (16-35)	For acute (all within 3 wk, Recurrent not specified)	Arthroscopic acute (39/40) Mini open acute (conversion from arthroscopic 1/40) Arthroscopic recurrent (121/158) Open recurrent (Latarjet 37/158)	Not stated	Acute 40/40  Recurrent 133/158	Acute: 5.3 mo (4-7)  Recurrent: 7.5 mo (5.5-9)
Goldberg <i>et al</i> <sup>[24]</sup>	26.5 (23-29)	Not stated: Mean time between presentation and operation 5.9 d (2-15)	2 Stage Open RC suture repair and approximately 9 wk later open capsular repair/osseous bankart repair	After RC repair: sling immobilisation for 6 wk with passive ROM exercise at 3 d. At 6 wk active exercise programme. After Stabilisation: 6 wk immobilisation then passive ROM exercises and light weights after 4 mo	5/6 players (1 player retired because of other injuries)	9 mo
Burkhart <i>et al</i> <sup>[25]</sup>	Not specified for rugby players	Not specified for rugby players	Arthroscopic capsular ± open capsular shift or Latarjet for when osseous lesion present	3 wk immobilisation in a sling, forward flexion at 3 wk, ER at 6 wk, Strengthening at 8 wk	Not stated	Not stated

ROM: Range of motion.

**Table 4** Summary table on patient outcomes, recurrence of instability, complications and study quality

Ref.	Post-operative evaluation tools	Recurrence of instability	Complications	Mean follow up months (range)	Mean Coleman Methodology Score
Neyton <i>et al</i> <sup>[23]</sup>	Radiographic, Walsh-Duplay score (mean 86), Rowe score (mean 93), VAS score (mean 1.6)	0/37	3/37 (1 glenoid fracture, 1 post op haematoma, 1 pseudoarthrosis of bone block)	144 (68-237)	58
Bonnevialle <i>et al</i> <sup>[21]</sup>	Mean external rotation decreased 6.2 degrees, Rowe (excellent for 86%), Walsh-Duplay (excellent for 80%), patient satisfaction (88%), Samilson radiographic degeneration in 32%	6/31	None stated	82 (60-120)	48
Larrain <i>et al</i> <sup>[26]</sup>	Acute: Rowe 33/40 excellent, 4/40 good, 2/40 poor Recurrent: Rowe 105/158 excellent, 6/158 good, 10/158 poor	Arthroscopic acute (2/40) Recurrent (10/158)	1/198 (radial paraesthesia)	68.4 (39.6-99.6)	55
Goldberg <i>et al</i> <sup>[24]</sup>	ROM normal except external rotation 70% and internal rotation 60% compared to contra-lateral side	0/6	None	34.3 (12-50)	42.5
Burkhart <i>et al</i> <sup>[25]</sup>	Not stated	Non osseous lesion (6/87 re-dislocated), osseous (8/9 re-dislocated)	Not specified	Not stated	35

ROM: Range of motion.

patients included in their case series<sup>[24]</sup>.**Outcome measures**

A number of different outcome measures were reported in the included studies (Table 4). The most commonly adopted was the Rowe score for shoulder instability that was used in 3 (60%) of the 5 studies. The Walch-

Duplay Score was reported in 2 studies. There were two studies that did not adopt any patient reported outcome measures<sup>[24,25]</sup>.

**Acute anterior instability**

The surgical management of acute anterior instability was described in 3 studies<sup>[24-26]</sup>. Interpretation of the

results of two of these studies is challenging because Burkhart *et al*<sup>[25]</sup> did not clearly differentiate their population of rugby players with acute instability from those with recurrence. However, this study did state that of the 87 rugby players that underwent an arthroscopic capsular repair, there were 6 (6.9%) that had a recurrent episode of instability and amongst the 9 players that had an open capsular shift or Latarjet procedure, there were 8 (88.9%) that had recurrent instability. Goldberg *et al*<sup>[24]</sup> described a two-stage procedure for management of rotator cuff injury associated with acute anterior instability in 6 players. None of the players were reported to have gone on to re-dislocate their shoulder. Only Larrain *et al*<sup>[26]</sup> clearly described the surgical management of acute anterior instability in rugby players in the absence of other significant shoulder pathology. There were 40 patients that underwent acute arthroscopic repair within 3 wk of the patient's first dislocation. A modification of the suture anchor technique described by Synder and Strafford was performed by the surgeons in this study<sup>[26]</sup>. One of the cases was converted to a mini-open procedure intra-operatively for a humeral avulsion of the glenohumeral ligament (HAGL) reinsertion. Post-operative rehabilitation was not described, however all 40 rugby players returned to competitive play 7 mo after their surgery. Within this group of players 2 (5%) had a recurrent dislocation whilst playing rugby within 2 years of surgery.

### Recurrent anterior instability

Surgical intervention for recurrent anterior instability was described in 4 of the studies<sup>[21,23,25,26]</sup>. Burkhart *et al*<sup>[25]</sup> reported on the combined results of both acute and recurrent anterior instability. Neyton *et al*<sup>[23]</sup> performed a Latarjet-Patte procedure on 37 shoulders in 34 rugby union players. A bony lesion on the glenoid was present in 27 (73%) cases, of which 18 (48.6%) were reported to be glenoid fractures. Only 22 (64.7%) players returned to play competitive rugby and the mean time of return to match fitness was 7 mo (range 3-24). The authors reported that only 1 of the 12 players stopped competitive rugby because of a problem related to his shoulder. This patient had apprehension to contact. The remaining 11 patients were reported to have retired from competitive rugby because of reasons independent from their operated shoulder. None of the patients had a recurrence of their instability at a mean follow up of 144 mo (range 68-237).

Bonnevalle *et al*<sup>[21]</sup> performed an open Bankart repair for recurrent instability in 31 rugby players. The authors reported that none of the players had a major bony Bankart or Hills-Sachs lesion. Thirty (96.8%) of the players returned to competitive match play at a mean time of 4.6 mo (range 2-8). There were 6 (19.4%) cases of recurrence of dislocation whilst playing rugby that occurred on average 3.8 years (range 0.5-6) years after surgery.

Larrain *et al*<sup>[26]</sup> reported on the management of 158 shoulders in rugby players with recurrent anterior instability<sup>[26]</sup>. Players were managed with a modified Latarjet procedure, or an arthroscopic suture anchor technique that they also used for their patients with acute anterior instability. A specific exclusion criteria for arthroscopic reconstruction in their study included; bone loss > 25% on the glenoid, a Hills-Sachs lesion comprising greater than one quarter of articular head, capsular laxity with poor quality tissue and the presence of a HAGL. Of the 121 arthroscopic cases for recurrent anterior instability, there were 10 (8.3%) recurrences of instability which fared slightly worse than the 2 (5%) cases of recurrence in their acute anterior instability cohort. There were no cases of recurrent instability in the group of patients that underwent a modified Latarjet procedure. One hundred thirty-three (84.2%) of the 158 players with recurrent anterior instability returned to competitive match play at a mean time of 7.5 mo (range 5.5-9). The authors did not provide data on how this differed between open and arthroscopic surgery.

### Complications

Complications were reported in only 4 of the studies<sup>[23,24,26]</sup> (Table 4). There was an overall complication rate of 1.7% (5 out of 290 patients). In Neyton *et al*<sup>[23]</sup>'s study, 3 patients had a fracture of the bone block observed on radiographs taken 3 mo postoperatively and one of these patients required revision surgery. Larrain *et al*<sup>[26]</sup> had one case of radial nerve paraesthesia which resolved after 9 mo.

### Quality assessment

A comparison of each CMS domain scores between the two raters using a Pearson's correlation was 0.966, indicative of strong inter-rater reliability. The mean CMS score for the 5 studies included in this systematic review was 47.4 (range 35-58) (Table 4). None of the studies had "excellent" (85-100) or "good" (70-84) CMS scores. Two studies had a "fair" CMS score (55-69) and 3 had a "poor" CMS score (< 55).

## DISCUSSION

This systematic review has found that there is a dearth of published evidence that evaluates surgical interventions for shoulder instability in the elite rugby player. The few studies that exist are based on retrospective cohort or case series, and on average their methodological quality is poor. Considerable heterogeneity between the 6 studies means that inference of overall outcomes, instability recurrence rates and complications rates has limitations.

Larrain *et al*<sup>[26]</sup> produced the most comprehensive analysis on treatment of acute anterior shoulder instability. Amongst the 40 rugby players that underwent arthroscopic capsular repair there were only 2 (5%) episodes of recurrent instability. These results compare



favorably to a cited recurrence rate of 11% in the general population<sup>[27]</sup> and 14.3% in young athletes<sup>[28]</sup> treated with arthroscopic stabilization repairs for acute anterior instability. Interestingly, Larraine *et al*<sup>[26]</sup> found that amongst the 121 patients who underwent arthroscopic stabilization for recurrent instability the results were slightly poorer as 10 (8.3%) players sustained a subsequent dislocation. Higher rates of dislocation are reported after arthroscopic surgery for patients with recurrent instability in other collision sports. Mazzoca *et al*<sup>[10]</sup> reported on a case series of 13 collision athletes (American football) who underwent arthroscopic stabilization for recurrent anterior shoulder instability and 2 (15%) experienced a recurrent dislocation. Larrain *et al*<sup>[26]</sup> described specific criteria for patients undergoing arthroscopic surgery, and therefore it is unlikely that underlying osseous pathology contributed to a higher risk of dislocation in the group with recurrent instability. Existing evidence indicates that there is no difference in recurrence among patients undergoing arthroscopic stabilization after primary dislocation compared with those who have surgery after multiple recurrent episodes<sup>[29]</sup>. This research is based on general population studies and this limits its applicability to collision athletes or rugby players. Repeated traumatic dislocations in rugby may attenuate anterior soft tissue structures in the shoulder and make delayed arthroscopic surgery more difficult. Furthermore it is possible that there is more disruption to sporting activities from recurrent instability and apprehension that occurs in players treated conservatively after their first dislocation. Such factors lend credence to the hypothesis that early arthroscopic stabilization in rugby players may result in better clinical outcomes and earlier return to competitive play. Future research within this domain should test this hypothesis from a clinical viewpoint as well examine the financial impact on both player and club.

Open anterior stabilization surgery is recommended in young male patients and has been demonstrated to be more favorable than arthroscopic surgery in collision athletes based on a lower incidence of recurrence of instability<sup>[8,30]</sup>. With the exception of a single mini open procedure performed for a HAGL by Larrain *et al*<sup>[26]</sup>, only Bonneville *et al*<sup>[21]</sup> performed open capsular repair on their patients with anterior instability. Their study reported that 19.4% of rugby players had a subsequent dislocation. This is more than twice the recurrence rate Larrain *et al*<sup>[26]</sup> presented in their cohort of rugby players treated with arthroscopic capsular repair and considerably higher than the results of an American study that reported a recurrence rate of 3% for open capsular repair in American football players with recurrent anterior instability<sup>[31]</sup>. Heterogeneity between the studies in our review and the limitations of their methodological quality underline the need for rugby specific studies to reliably inform clinicians whether a significant difference in outcome exists between open and arthroscopic anterior shoulder stabilization.

Two of the three studies that described a Latarjet type procedure for anterior shoulder instability stated it was performed for specific indications related to bone loss on the glenoid. Although Burkhart *et al*<sup>[25]</sup> reported 8 recurrent dislocations out of their 9 patients, there were no subsequent episodes of instability in the 64 shoulders operated on in the other 2 studies<sup>[23,26]</sup>. Despite the apparent success of restoring shoulder stability, both these studies reported that a large number of players were not able to return to a competitive level. Bony stabilization for anterior shoulder instability is often considered the gold-standard treatment especially in cases where there are osseous defects, however they are associated with a 30% complication rate<sup>[32]</sup>. More evidence is needed to establish whether it offers any benefit over capsular repair when osseous defects are not present, and specifically whether it can achieve stability in rugby players and allow them to return to their previous sporting level.

Over the last decade there has been a significant increase in publication of Level I and II evidence in sports medicine and orthopaedic surgery<sup>[33,34]</sup>. As a result of the potential of serious injury and disability, the management of head and neck injury has been the focus of much of the current clinical research that is ongoing in rugby<sup>[35-37]</sup>. Research evaluating shoulder instability in rugby players may be lacking because of the perception that the disability that follows such an injury is not common or severe enough to warrant the effort and financial cost of research. Epidemiological research in English professional rugby union has shown that on average, shoulder instability is the second most severe musculoskeletal injury after ACL rupture in terms of absence from competitive play, and results in a mean time of 22.4 wk of absence from training or match play<sup>[6]</sup>. Furthermore, many of the studies identified in this review have demonstrated that a concerning proportion of players are unable to return to their previous level of sport and are forced to retire soon after surgery. Professional rugby has been transformed over the last 20 years and the revenue of the Rugby Football Union in the 2012/2013 financial year was £153.5 million<sup>[38]</sup>. Responsible professional bodies have financial and ethical interests in supporting research related to the prevention and management of injuries sustained by their athletes. This is often seen in football, for example, where the Fédération Internationale de Football Association funds clinical research in football players<sup>[39]</sup>.

Prospective randomized trials comparing interventions such as arthroscopic versus open capsular repair in rugby players would be the gold-standard model for future research, however the creation of professional rugby association health databases, similar to the National Basketball Association epidemiological database in the United States<sup>[40]</sup>, would also provide important retrospective data on outcomes of treatment. Furthermore biomechanical laboratory and computer simulation studies that are tailored to the forces exerted

on a rugby player's shoulder<sup>[41]</sup> and compare stability and function after different surgical procedures would also offer important information on optimal management.

### Limitations

The main weakness in this study relates to a lack of existing research within this field which has limited our ability to draw conclusions on the benefit of different treatment interventions. The 5 studies we identified were heterogeneous in patient selection, pathologies and measurement of outcome measures. Despite this, we adopted recognized methodology to systematically reviewing the evidence in this field<sup>[15]</sup> and this has allowed us to summarize successful management techniques as well as recurrence rates of instability cited by different studies.

### Conclusion

Existing research that evaluates surgical treatment interventions for shoulder instability in elite rugby players is limited. Arthroscopic stabilization has been performed successfully in acute anterior instability and there is a preference for an open Latarjet procedure when instability is associated with osseous defects, however the current evidence base consists of a small number of studies with poor methodological quality. Clinicians are likely to continue to inform their practice using research that is based on other collision sports or general population studies. This paper underlines aspects of treatment that future clinical and basic science research should be directed towards in order to improve management of one of the most severe musculoskeletal injuries in elite rugby players.

## COMMENTS

### Background

Anterior shoulder instability is one of the most severe musculoskeletal injuries in elite-level rugby in terms of days of competitive play lost. The biomechanics of this injury are distinct from other contact sports and therefore research with a focus on rugby players may have more clinical applicability.

### Research frontiers

To the best of our knowledge, no systematic review evaluating treatment options for anterior shoulder instability in rugby players has been published. The aim of this study was to systematically review all published studies that investigated surgical management for anterior shoulder instability in elite rugby players.

### Innovations and breakthroughs

Arthroscopic stabilization for acute anterior instability has been performed successfully in a few clinical studies. A Latarjet-type procedure is performed preferentially when there is an osseous defect associated with the instability, however a large proportion of rugby players with such injuries do not return to competitive level sports.

### Applications

Although this study can inform clinicians on proven surgical techniques such as arthroscopic stabilization in the case of acute anterior instability, or Latarjet-type procedures where there is an osseous defect, the results also provide realistic rehabilitation timeframes and return to match play information based on the current evidence base. Importantly, the limitations in currently available evidence, underlines aspects of treatment that future clinical and basic science research should be directed towards in order to improve management of one of the most severe musculoskeletal injuries in elite rugby players.

### Terminology

A Bankart lesion is an injury of the anterior-inferior glenoid labrum that occurs due to an anterior shoulder dislocation. It predisposes the shoulder to further episodes of anterior instability. A bony Bankart is a fracture of the anterior-inferior glenoid rim that may accompany this injury. A Latarjet procedure is a surgical procedure often used to treat a bony Bankart lesion, in which a section of the coracoid process and its attached tendons are transferred to the anterior aspect of the glenoid to prevent ongoing anterior instability.

### Peer-review

This manuscript is well organized and written.

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