LOWER LEG ULCER DIAGNOSIS
AND PRINCIPLES OF TREATMENT

INCLUDING RECOMMENDATIONS FOR COMPREHENSIVE ASSESSMENT AND REFERRAL PATHWAYS

WoundsAustralia

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8. Compression therapy

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After a database search for systematic reviews about the use of compression therapy for lower leg ulcers, 352 articles were retrieved, but only 15 met our inclusion criteria and were kept for detailed analysis. Most included systematic reviews report data from RCTs, followed by real-world studies or single-arm observational cohort studies. Some of the included studies focused on comparison of different types of compression systems comparing either with no compression or other compression types. The most common primary outcome was wound healing, and QoL and pain as a secondary outcome. Other systematic reviews focused on VLU recurrence, the association of compression with surgery, or physical activity. One included systematic review demonstrated the effect of modified compression therapy (MCT) with or without revascularisation on mixed ulcer healing. We decided to use the RAL classification in this chapter (Table 12).

Compression class	Pressure in kPa	Pressure in mmHg
I	2.4–2.8	18–21
II	3.1–4.3	23–32
III	4.5–6.1	34–46
IV	>6.5	>49

kPa: Kilopascal
mmHg: milimetres mercury

Table 12. Compression classes using the RAL classification

Compression compared to no compression

Two systematic reviews compared the effectiveness of several types of compression using complete healing time and complete VLU healing with no compression (151, 152). Shi and colleagues analysed 14 RCTs comparing some compression types – short-stretch bandage (SSB), 4-layer bandage (4LB) compression and Unna's boot – with no compression (151). As primary outcomes they investigated time-to-complete wound healing and complete healing. Pooling a hazard ratio from five studies, a shorter time to complete healing (2.17, 95% confidence interval (CI) 1.52 to 3.10; n=84) for patients wearing compression was found. The same systematic review reports in eight studies a better complete healing risk ratio (RR) (1.77, 95% CI 1.41 to 2.2; n=1120) as secondary outcomes pain and patients' QoL were investigated. A lower pooled mean difference (MD) for pain (–1.39, 95% CI –1.79 to –0.98; n=495) in patients wearing compression was shown in three studies. Two studies (n=426) showed an improvement in patients wearing compression for the disease-specific QoL in a follow-up from 12 weeks to 12 months using the total score of the Charing Cross Venous Ulcer Questionnaire (lower scores=better QoL) (MD=–6.87, 95% CI –13.10 to –0.64). Different types of compression were reported by O'Meara et al., including 48 RCTs including 4321 patients (153). One of the included smaller RCTs compared Unna's boot (compression) with simple bandages (no compression), resulting in complete healing at 12 months for patients wearing the Unna's boot (RR=2.30, 95% CI 1.29 to 4.10; P=0.005; n=36). Another RCT showed that SSB had a significant effect on complete healing compared to usual care (percentage of healed patients, 71% vs 25%; n=53). This systematic review also reported data from three trials assessing 4LB. One of them showed significantly more patients with complete healing at 3 months (RR=4.0, 95% CI 1.35 to 11.82; P=0.01; n=36).

Faster healing time was also reported in two other trials. One larger study used median weeks to healing (20 vs 43; P=0.03; n=233) and the other showed a p-value (P=0.006). Another systematic review focusing on QoL (153), demonstrated with eight studies that any VLU treatment (compression therapy, 4LB, 3-layer bandaging (3LB), SSB, advanced wound dressing, and superficial venous surgery) led to an improvement of QoL. Moreover, patients that had superficial venous surgery in addition to compression reported a significantly better QoL than patients with compression only.

Comparison between different compression systems

Comparing the efficacy of different compression bandage types, O'Meara and colleagues reported results from one study which showed that 4LB had better healing at 24 weeks than SSB (RR=0.74, 95% CI 0.59 to 0.92; n=245) and five others demonstrated faster healing for 4LB than for SSB (152). The median days to healing were estimated at 90 for 4LB and 99 days for SSB (hazard ratio=1.31, 95% CI 1.09 to 1.58). Three trials compared three-component systems containing an elastic component with the same system without elastic part. Two studies showed that elastic bandages healed significantly more ulcers at 3 to 4 months (RR=1.83, 95% CI 1.26 to 2.67), but another study observed no difference at 6 months (P=0.67). Four studies (n=317) showed that high-compression stockings are associated with better VLU healing outcomes than SSB at 2 to 4 months (RR=1.62, 95% CI 1.26 to 2.10). Similarly, another review pooled eight studies together and demonstrated that ulcer healing was better in the stockings group than SSB (pooled RR=1.33, 95% CI, 1.02–1.74) (156). This same review also demonstrated that there was a significantly lower median time to ulcer healing for 3LB (2.8 months) than for 4LB (3.7 months; P=0.04). Mauck and colleagues found 15 trials comparing long-stretch bandages (LSBs) and SSBs, but pooling the studies together (pooled RR=0.98; 95% CI 0.91–1.06), they saw no significant difference in healing outcomes (154).

Another review compared the efficacy of a 2-layer bandaging (2LB) compression system with other compression bandages, presenting five studies (155). At six months, a study demonstrated better ulcer healing for 2LBA compared to another 2LBB (odds ratio (OR)=1.57; 95% CI, 1.10–2.24; P=0.03) and to a 4LB (4LBA) (OR=1.93, 95% CI, 1.26–2.97, P=0.05). Real-world studies showed that 2LBA resulted in a significantly shorter healed time at 6 months (MD, months=–0.40, 95% CI, –0.74 to –0.06; P=0.02 (2LBs); MD=–0.50, 95% CI, –0.86 to –0.14; P=0.007 (for 4LBs). However, no significant difference between the groups was found. This result was maybe due to the presence of only newly diagnosed VLU in the real-world studies, but the presence of both old and new VLU in the study population, thus hard-to-heal VLU could have also been present. As a secondary outcome, 2LBA was also linked to a better health-related quality of life (HRQoL) (MD, months=0.02, 95% CI, 0.02 to 0.02; P<0.0001 (2LBs); MD, months=0.02, 95% CI, 0.01 to 0.03; P=0.003 (4LBs). Another review found a tendency for faster healing with 4LB compared with 2LB. However, the QoL would seem to be improved rather by 2LB than 4LB (156). Finally, Welsh investigated the impact of bandage systems containing both elastic and inelastic components, called mixed component systems (157). She found no significant difference in ulcer healing rates compared to alternative compression systems like 4LBs (P=0.3).

Effects of compression on VLU recurrence

VLU recurrence was investigated in two reviews (158, 159). One trial showed a significantly lower recurrence rate at 12 months in people that wore compression stockings (RR=0.43, 95% CI, 0.27–0.69; P=0.001). One study, investigating the lipodermatosclerosis area, observed a significantly lower area in the stocking group at 12 months (–33.1, 95% CI, –61.9–15.07) compared to without stocking (+11.9, 95% CI, –24.6 to 122.2; P=0.04). A trial also showed that treatment adherence reduced the risk of recurrence 6 times. Nelson et al. presented four

RCTs, and one trial demonstrated significant lower recurrence rates with compression than without at 6 months (RR=0.46, 95% CI 0.27 to 0.76) (158). One trial presented a better efficacy of high compression stockings than medium ones in recurrence at 3 years (RR=0.57, 95% CI 0.39 to 0.81). Nevertheless, medium pressure stockings (class II) showed better compliance than the high ones (class III).

Similarly, Dahm and colleagues reported results from studies investigating recurrence (160). One study showed a reduction in leg ulcer recurrence at 12 months for class II stockings (medium pressure) compared to class I (mild pressure) (RR 0.52; 95% CI 0.30 to 0.88). Another study compared class II and class III (medium to high pressure) stockings, but saw no significant difference on recurrence rates after 6 months (RR 0.64; 95% CI 0.20 to 2.03). Finally, a trial showed lower recurrence with class III stockings compared with no compression at 6 months (RR 0.46; 95% CI 0.27 to 0.76) and 12 (RR 0.43; 95% CI 0.27 to 0.69). Mauck and colleagues found one study showing that fewer ulcers recurred when wearing stockings (24/167) compared to 4LB (41/176) (HR 0.56; 95% CI 0.33–0.94; P=0.03) (154). The authors conclude that these results may be related to better compliance with lower compression.

Compression combined with physical activity

We found two reviews assessing the combination of physical activity with compression (161, 163). Jull and colleagues pooled a risk difference for any type of exercise from five RCTs (n=190) and found that there were 14 cases healed per 100 patients at 12 weeks (RD=14%, 95% CI, 1–27%; P=0.04) (164). Among these five trials, two studies assessed the effectiveness of progressive resistance exercise (different sets of heel raises), but did not find a significant result (RD=–6%; 95% CI, –32% to 21%; P=0.67, n=53). Two trials assessed prescribed physical activity with resistance exercise. One trial was conducted in a sport facility and the other had 30 minutes of walking three times per week as a physical activity. The exercises in facilities were calf raises, partial squats and 30 minutes of aerobic exercises three times per week and showed significantly more healed patients at 12 weeks. The pooled risk difference for both studies was significant even if the one not conducted in a facility did not present significant results alone (RD=27%; 95% CI, 9% to 45%; P=0.004). A trial also demonstrated that ankle exercises provided a significant median ulcer area change of 1.67cm^2. Concerning the review of Smith et al., they found six RCTs looking at the effect of exercise on VLU healing (161). Three studies together showed no significant results in doing a progressive resistance exercise program in addition to compression (RR=1.14, 95% CI 0.71 to 1.84; n=116 participants) and the same trials also showed no difference in QoL (MD=3 points better on 100 points scale with exercise, 95% CI –1.89 to 7.89; n=59 participants). They found one study showing that exercise may increase risk of adverse events (OR 1.32, 95% CI 0.95 to 1.85, one RCT; n=40).

Compression combined with endovenous interventions

One of the reviews looked at the combination of surgery with compression (163). De Carvalho and colleagues found four RCTs regarding this topic (163). After 24 weeks, two studies showed no significant difference of surgery in addition to compression (P=0.85; n=500). However, 428 patients who had their ulcers treated within the 24 weeks showed significant lower recurrence rates at 12 months when they had surgery in addition to compression (12% vs 28%; P<0.0001). These rates were still significant after 4 years (31% vs 56%; P<0.001). Another study (n=103) observed significant longer ulcer-free periods during the follow-up of the surgery group (62% vs 33% in the conservative group; P=0.02). This follow-up consisted of 36 months divided in intervals of 3 months.

Another review presented a RCT that showed a healing rate of 85.6% for early endovenous ablation of superficial venous reflux combined with compression and 76.3% (p=0.001) in the compression group with a deferred surgery (n=450) (164). The median ulcer-free time was 306 days for the early ablation group and 278 days for the deferred one (p=0.002). In addition,

more patients healed their ulcers with the early intervention (hazard ratio for healing, 1.38; 95% CI, 1.13 to 1.68; p=0.001).

Another study investigating USGFS showed that patients who had USGFS in addition to compression healed at a faster rate than those only treated with compression (9.7% vs 4.2%; p=0.001). A trial investigating recurrence rate showed that during a 4-year period, patients that had surgery and compression (31%) had less chance to have recurrence than those with compression only (56%; p<0.001). This change in recurrence rate was demonstrated through other studies shown by Elstone, where either surgery or USGFS showed better recurrence rate or longer ulcer-free time (164). Tollow and colleagues showed that patients who had had superficial venous surgery in addition to compression reported a significantly better QoL than patients with compression only (153).

Compression for mixed ulcers

We found one review investigating treatment for the mixed ulcers and arterial ulcers (MAVLU), i.e. VLUs with coexisting PAD, and presented the effect of the MCT with or without revascularisation depending on patients ABI (85). Lim and colleagues showed that MCT with a pressure between 20 and 30mmHg can promote healing in mixed ulcers when moderate arterial insufficiency is present (0.5 ≤ ABI ≤0.8), but if ABI is <0.5 (arterial ulcers), MCT can only be considered when acceptable ABI is achieved (87). They showed a study comparing healing rates of VLU and MAVLU with MCT. This trial presented similar healing rates between patients with MAVLU (60%; n=24) and VLU (65%; n=20). Lim and colleagues found several studies presenting similar healing rates between VLU and MAVLU when they are treated with MCT (87). Another study showed that 33 limbs with moderate peripheral arterial occlusive disease (PAOD) (ABI of 0.5–0.85) were treated with MCT at a compression of 30mmHg compared to 13 limbs with severe PAOD (ABI<0.5) that were treated with arterial revascularisation. After 36 weeks, it resulted in a healing of 64% (n=21) for patients treated with MCT who presented moderate arterial disease, and 23% (n=3) of patients with severe PAD healed.

Intermittent pneumatic compression (IPC)

IPC was the topic of one identified systematic review (165); nine RCT were included in this review assessing the impact of IPC on the healing of patients with VLU. In one trial (80 people), more ulcers healed with IPC than with dressings alone (62% vs 28%; p=0.002). Five trials compared IPC plus compression with compression alone. Two of these (97 people) found increased ulcer healing with IPC plus compression than with compression alone. The remaining three trials (122 people) found no evidence of a benefit for IPC plus compression compared with compression alone. Two trials (86 people) found no difference between IPC (without additional compression) and compression bandages alone. One trial (104 people) compared different ways of delivering IPC and found that rapid IPC healed more ulcers than slow IPC (86% vs 61%). The authors' conclusions were that IPC may increase healing when compared with no compression, but it is unclear whether it can be used instead of compression bandages. There is some limited evidence that IPC may improve healing when added to compression bandages.

Summary

The search for systematic reviews for the use of compression for lower leg wounds retrieved 352 articles, but only 15 were kept for detailed analysis. The included reviews mainly reported data from RCTs and focused on the effectiveness of different compression types for VLUs compared to no compression or other compression types. ***Most reviews demonstrated that compression therapy improves complete healing time and complete healing of VLUs compared to no compression. Additionally, any VLU treatments (including compression therapy) lead to an improvement of QoL, and patients who had superficial venous surgery in addition to compression reported significantly better QoL than patients with compression only.*** Furthermore, some studies showed that high-compression stockings and 3LB were associated with better VLU healing outcomes than SSBs.

The available evidence from systematic reviews supports the use of compression therapy for the treatment of VLUs, with high-compression stockings and 4LB showing better outcomes than SSBs. However, more studies are needed to determine the optimal compression type, duration, and frequency of use for leg wounds. In addition, most studies use complete healing as their primary outcome. A clear definition of healing was lacking. Future research should also focus on understanding the mechanisms behind compression therapy and its cost-effectiveness, as well as exploring patient perspectives and strategies to improve adherence to treatment regimens. ***Overall, compression therapy should be used, if there are no contraindications, from the first visit for the management of lower leg ulcers.***

In evidence other than systematic reviews and clinical practice it has been shown that along with the outlined compression bandages and stockings, also adjustable compression wrap devices using hook and look fasteners can be used. They also present an opportunity for improving treatment outcomes, supporting patient independence and self-management in the use of compression therapy. However, further research is necessary to optimize their effectiveness and ensure their widespread adoption in clinical practice.

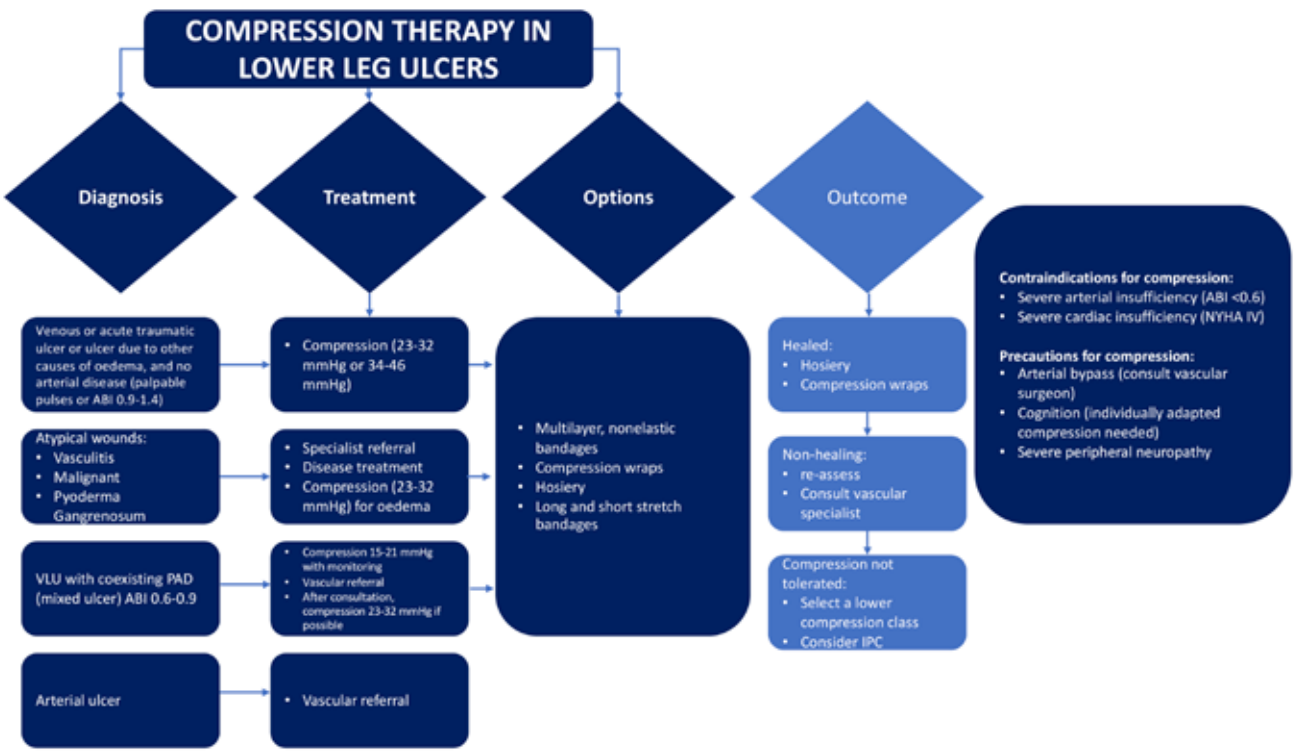

Figure 32. Compression therapy in lower leg ulcers

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