

Pubmed search:

(((((((((Negative Pressure Wound Therapy) OR Negative-Pressure Wound Therapies) OR Vacuum Assisted Closure) OR Vacuum-Assisted Closure) OR Topical Negative Pressure Therapy) OR Negative Pressure Dressings) OR VAC) OR NPWT)) AND (((Foot, Diabetic) OR Diabetic Feet) OR Feet, Diabetic) OR Foot Ulcer, Diabetic)

Reasons for final exclusion 27 studies

Did not describe diabetic wounds on the foot only (n=4):

1. Mody G N, Nirmal I A, Duraisamy S, Perakath B. A blinded, prospective, randomized controlled trial of topical negative pressure wound closure in India. Ostomy/wound Management 2008 Dec; 54(12):36-46. PMID:19104122
2. Riaz M U, Khan M U R, Akbar A. Comparison of vacuum assisted closure versus normal saline dressing in healing diabetic wounds. Pakistan Journal of Medical & Health Sciences 2010; 4(4):661-665.
3. HU K X, Zhang H W, Zhou F, YAO G, SHI J P, CHENG Z. Observation on the therapeutic effects of negative-pressure wound therapy on the treatment of complicated and refractory wounds. Chinese journal of burns 2009 Aug; 25(4):249-252.
4. Farah R, Gantus M, Kogan L. Vacuum-assisted therapy for various wound types including diabetic foot ulcer. Harefuah 2011 Mar; 150(3):222-226. PMID:21574351

They were review articles (n=7):

1. Zhang J, Hu Z C, Chen D, Guo D, Zhu J Y, Tang B. Effectiveness and safety of negative-pressure wound therapy for diabetic foot ulcers: a meta-analysis. Plastic

- & Reconstructive Surgery 2014 Jul; 134(1): 141-151. doi: [10.1097/PRS.0000000000000275](https://doi.org/10.1097/PRS.0000000000000275) PMID: 24622569
2. Dumville J C, Hinchliffe R J, Cullum N, Game F, Stubbs N, Sweeting M, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database of Systematic Reviews 2013 Oct; 10(10): 1201-1206. doi: [10.1002/14651858](https://doi.org/10.1002/14651858) PMID: 24132761
 3. Guffanti A. Negative pressure wound therapy in the treatment of diabetic foot ulcers: a systematic review of the literature. Journal of Wound Ostomy & Continence Nurs. 2014 May-Jun; 41(3):233-237. doi:10.1097/WON.0000000000000021 PMID:24805174
 4. Peinemann F, Sauerland S. Negative-pressure wound therapy systematic review of randomized controlled trials. Deutsches Ärzteblatt International 2011 Jun; 108(22): 381-389. doi: 10.3238/arztebl.2011.0381 PMID: 21712971
 5. Noble-Bell G, Forbes A. A systematic review of the effectiveness of negative pressure wound therapy in the management of diabetes foot ulcers. International Wound Journal 2008 Jun; 5(2):233-42. doi:10.1111/j.1742-481X.2008.00430.x PMID:18494629
 6. CADTH. Negative Pressure Wound Therapy for Managing Diabetic Foot Ulcers: A Review of the Clinical Effectiveness, Cost-effectiveness, and Guidelines [M]. Canadian Agency for Drugs and Technologies in Health, 2014.
 7. Schintler M V, Prandl E C. Vacuum-assisted closure – what is evidence based? European Surgery 2008 Feb 40(1):11-18. doi: 10.1007/s10353-008-0381-5

Not a RCT(n=10)

1. Vassallo I M, Formosa C. Comparing calcium alginate dressings to vacuum-assisted closure: a clinical trial. *Wounds A Compendium of Clinical Research & Practice* 2015Jul; 27(7): 180-190. PMID: 26192736
2. Ulusal A E, Sahin M S, Ulusal B, Cakmak G, Tuncay C. Negative pressure wound therapy in patients with diabetic foot. *Acta Orthop Traumatol Turc* 2011, 45(4):254-260. doi: 10.3944/AOTT.2011.2283. PMID:21908965
3. Lone A M, Zaroo M I, Laway B A, Pala N A, Bashir S A, Rasool A. Vacuum-assisted closure versus conventional dressings in the management of diabetic foot ulcers: a prospective case-control study. *Diabetic Foot & Ankle* 2014 Apr; 5: 1-5. doi: [10.3402/dfa.v5.23345](https://doi.org/10.3402/dfa.v5.23345) PMID: 24765245
4. Nather A, Hong N Y, Lin W K, Sakharam J A. Effectiveness of bridge V.A.C. dressings in the treatment of diabetic foot ulcers. *Diabetic Foot & Ankle*, 2011 Mar, 2:1-7. doi: [10.3402/dfa.v2i0.5893](https://doi.org/10.3402/dfa.v2i0.5893)
5. Apelqvist J, Armstrong D G, Lavery L A, Boulton A J. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. *Am J Surg* 2008 Jun; 195(6):782-788. doi:10.1016/j.amjsurg.2007.06.023 PMID:18355797
6. Driver V R, Blume P A. Evaluation of wound care and health-care use costs in patients with diabetic foot ulcers treated with negative pressure wound therapy versus advanced moist wound therapy. *Journal of the American Podiatric Medical*

Association 2014 Mar 104(2):147-153. doi:10.7547/0003-0538-104.2.147
PMID:24725034

7. Lavery L A, Barnes S A, Keith M S, Seaman JW Jr, Armstrong D G. Prediction of healing for postoperative diabetic foot wounds based on early wound area progression. Diabetes Care 2008 Jan; 31(1):26-29. doi:10.2337/dc07-1300
PMID:17934156
8. Lavery L A, Boulton A J, Niezgoda J A, Sheehan P. A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care. International Wound Journal 2007 Jun; 4(2):103-113.
doi:10.1111/j.1742-481X.2007.00317.x PMID:17651226
9. Whitehead S J, Forestbendien V L, Richard J L, Halimi S, Van G H, Trueman P. Economic evaluation of vacuum assisted closure® therapy for the treatment of diabetic foot ulcers in France. International Wound Journal 2011 Feb; 8(8):22-32.
doi: [10.1111/j.1742-481X.2010.00739.x](https://doi.org/10.1111/j.1742-481X.2010.00739.x) PMID: 20875048
10. Flack S, Apelqvist J, Keith M, Trueman P, Williams D. An economic evaluation of VAC therapy compared with wound dressings in the treatment of diabetic foot ulcers. Journal of Wound Care 2008 Feb; 17(2):71-78. doi:
[10.12968/jowc.2008.17.2.28181](https://doi.org/10.12968/jowc.2008.17.2.28181) PMID: 18389832

Did not meet inclusion criteria (n=4)

1. Armstrong D G, Lavery L A, Boulton A J. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity? International Wound Journal 2007 Mar; 4(1):79-86.

doi:[10.1111/j.1742-481X.2006.00270.x](https://doi.org/10.1111/j.1742-481X.2006.00270.x) PMID:17425550

2. Akbari A, Moodi H, Ghiasi F, Sagheb H M, Rashidi H. Effects of vacuum-compression therapy on healing of diabetic foot ulcers: randomized controlled trial. *Journal of Rehabilitation Research & Development* 2007, 44(5):631-636. PMID:17943674
3. Armstrong D G, Marston W A, Reyzelman A M, Kirsner R S. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. *Wound Repair and Regeneration* 2012 May-Jun; 20(3):332–341. doi:[10.1111/j.1524-475X.2012.00780.x](https://doi.org/10.1111/j.1524-475X.2012.00780.x) PMID:22564228
4. Morbi A H, Shearman C P. Topical Negative Pressure Therapy for Diabetic Foot Ulcers: Where Is the Evidence? *International Journal of Lower Extremity Wounds* 2016 Mar; 15(1):96. doi:[10.1177/1534734615595564](https://doi.org/10.1177/1534734615595564) PMID:26933117

Merely a study protocol (n=1)

1. Seidel D, Mathes T, Lefering R, Storck M, Lawall H, Neugebauer E A. Negative pressure wound therapy versus standard wound care in chronic diabetic foot wounds: study protocol for a randomized controlled trial. *Trials* 2014; 15(1):4876-4880. doi:[10.1186/1745-6215-15-334](https://doi.org/10.1186/1745-6215-15-334) PMID:25158846

Merely a case report (n=1)

1. Khanbhai M, Fosah R, Oddy M J, Richards T. Disposable NPWT device to

facilitate early patient discharge following complex DFU. Journal of Wound Care

2012 Apr; 21(4):180,182. doi:10.12968/jowc.2012.21.4.180 PMID:22584676

The_risk_of_bias_in_the_included_studies

Armstrong 2005

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was accomplished by using www.randomizer.org to generate 15 blocks of 10 random numbers each."
Allocation concealment (selection bias)	Low risk	"Numbers were systematically assigned to each treatment group, and sealed envelopes containing opaque, black paper labelled with assigned treatment and patient ID number were sequentially numbered and provided to each site. The black paper was added to ensure that the contents of the envelope were not visible to participants and patients. It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in the lower limb."
Blinding of participants and personnel (performance bias)	Unclear risk	"Wound dimensions and surface area were determined in a blinded fashion by computerized planimetry using University of Texas Health Science Center at San Antonio ImageTool (Version 3.0) software." assessment of healing seems to have had a blinded method.
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Low risk	No evidence of incomplete outcome data
Other bias	Low risk	No evidence of other bias

Blume 2008

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was accomplished by generating blocks of numbers through http://www.randomizer.org ."
Allocation concealment (selection bias)	Low risk	"Numbers were assigned to a treatment group and sealed in opaque envelopes containing black paper labelled with treatment and patient ID. Envelopes were sequentially numbered before clinical trial site distribution. At patient randomisation, treatment was assigned on the basis of the next sequentially labelled envelope." It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one
Blinding of participants and personnel (performance bias)	Unclear risk	"Blinded photographic evaluation was conducted." seems to have had a blinded method.
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	It is not clear whether participants who were discontinued for reasons other than death were also censored from the
Other bias	Low risk	No evidence of other bias

Karatepe 2011

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation of the patients was arranged by the free use web based system (http://www.tufts.edu/~gdall/PLAN.HTM)"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one group compared to the other. As a result of this we classed the risk of bias for this domain as unclear
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Other bias	Low risk	No evidence of other bias

Eginton 2003

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	unclear risk	"Patients were randomized to receive either moist gauze dressings or VAC treatments for 2 weeks"
Allocation concealment (selection bias)	Unclear risk	"Patients were randomized to receive either moist gauze dressings or VAC treatments for 2 weeks"
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one "Wound dimensions and surface area were determined in a blinded fashion by computerized planimetry using University of Texas Health Science Center at San Antonio Image tool." seems to have had a blinded
Blinding of outcome assessment (detection bias)	Unclear risk	"4 were unable to complete the protocol. One patient did not return for follow-up visits, and another was unable to return because insurance coverage was denied. One patient was treated at another institution with hyperbaric oxygen therapy and was disqualified from further participation in this study. One patient was a clinical failure of VAC therapy."
Incomplete outcome data (attrition bias)	Low risk	No evidence of other bias
Other bias	Low risk	

Sun 2007

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	High risk	Even numbers were treated with the VAC first, followed by the moist dressings, while patients receiving odd numbers were reverse
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one group compared to the other. As a result of this we classed the risk of bias for this domain as unclear
Blinding of outcome assessment (detection bias)	Unclear risk	Wounds of DFU were photographed digitally following initial debridement, on the moment when changing the therapy and at the end of study for data analysis. Wound length, width, depth, surface area and volume were determined by nonmedical staff using VeV MD software seems to have had a blinded method
Incomplete outcome data (attrition bias)	Low risk	All of 38 patients were involved in the result analysis
Other bias	Low risk	No evidence of other bias

Sepúlveda 2009

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The random sequence was elaborated using a computer programme."
Allocation concealment (selection bias)	Low risk	"Closed envelopes were created with an arbitrary identification number and inside the previously determined treatment assignment was found, which was hidden until the end of the study."
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one "The photography was crosshatched and analyzed square by square to determine the fraction of granulated tissue in each square. The total percentage of granulation of the wound came from the average of all of the fractions of all of the squares of the image. An independent group of the research team masked from the assigned treatment, conducted the evaluation of the percentage of granulation."we classed the risk of bias for this domain as low
Blinding of outcome assessment (detection bias)	Low risk	"During the follow-up period, 23 subjects (96%) reached a rate of granulation around 90%. Only 1 case from group B did not reach 90% granulation and the complete closure time of the wound was considered"
Incomplete outcome data (attrition bias)	Low risk	
Other bias	Low risk	No evidence of other bias

Vaidhya 2015

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Sixty patients were randomized into either the experimental NPWT group or conventional dressing group (control)."
Allocation concealment (selection bias)	Unclear risk	"Sixty patients were randomized into either the experimental NPWT group or conventional dressing group (control)." It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one
Blinding of participants and personnel (performance bias)	Unclear risk	
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	"NPWT failed in three patients in whom the therapy discontinued. While conventional therapy failed in seven patients. Failure considered when there was no improvement after 2 week, worsening of condition or development of complication. In NPWT group, two patients showed no response and one patient developed worsening of condition. In conventional dressing group, four patients showed no improvement and three patients developed worsening of wound."
Other bias	Low risk	No evidence of other bias

Nain 2011

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomly divided into two groups - study group and control group."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Other bias	High risk	Reporting that Wound discharge Granulation tissue et al

Ravari 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"23 participants with diabetic foot ulcers were enrolled for moist dressing (13 patients) and vacuum-assisted closure (VAC) (10 patients) randomly (by simple randomisation method according to the date of admission."
Allocation concealment (selection bias)	High risk	"23 participants with diabetic foot ulcers were enrolled for moist dressing (13 patients) and vacuum-assisted closure (VAC) (10 patients) randomly (by simple randomisation method according to the date of admission."
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one
Blinding of outcome assessment (detection bias)	Unclear risk	"Depth of ulcers was measured by means of vernier caliper in the biggest vertical diameter of the ulcers and improvement of ulcer defined according to the Wagner scale." As a result of this we classed the risk of bias for
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Other bias	Low risk	No evidence of other bias

Sajid 2015

Bias	Authors' judgement	support for judgement
Random sequence generation (selection bias)	Low risk	"Random allocation based on computer generated table of random numbers."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one "Wound was assessed digitally every week for 2 weeks. Wound dimension and surface area were determined using University of Texas Health Centre at San Antonio (UTHCSA) image tool version 3.0."assessment of healing seems to have had a blinded component
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Other bias	Low risk	No evidence of other bias

Mccallon 2000

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Coin method
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	It is understandably not possible to blind participants and patients to whether or not they receive NPWT. However, given this, it is important that any decision-making that might be affected by performance bias is recognised and blinding is introduced where possible. We note that unblinded health professionals were able to make decisions about closure surgery that could then have resulted in more wounds being closed (and classed as healed) or amputated in one "Wound was assessed digitally every week for 2 weeks. Wound dimension and surface area were determined using University of Texas Health Centre at San Antonio (UTHCSA) image tool version 3.0."assessment of healing seems to have had a blinded component
Blinding of outcome assessment (detection bias)	Unclear risk	
Incomplete outcome data (attrition bias)	Low risk	No evidence of incomplete outcome data
Other bias	Low risk	No evidence of other bias