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REVIEW

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The effects of felted foam in diabetic foot treatment: systematic review with meta-analysis*

Efeitos da espuma de feltro no tratamento do pé diabético: revisão sistemática com metanálise

Efectos de la espuma de fieltro en el tratamiento del pie diabético: revisión sistemática con metaanálisis

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ABSTRACT

Objective: To evaluate the effects of felted foam in the treatment of diabetic foot plantar ulcer. **Method:** Systematic review with meta-analysis. Research was conducted in Cochrane Library, PubMed, CINAHL, Science Direct, Web of Science, SCOPUS, IBECS and LILACS. Cochrane Collaboration Risk of Bias Tool was employed to evaluate risk of bias. The meta-analyses were calculated in the program Review Manager, while Grades of Recommendation, Assessment, Development and Evaluation was used for evaluating evidence quality. **Results:** Four clinical essays and two cohorts were included. Mean plantar pressure of individuals exposed to felt was reduced by 10.77 kilopascals (CI 95% -14.92, -6.62; p<0.001). **Conclusion:** Higher reduction of plantar pressure was observed to be associated with the use of felt. Development of new models of relief orthosis with felted foam for plantar pressure is recommended, along with more clinical research elucidating related outcomes.

DESCRIPTORS

Diabetic Foot; Foot Ulcer; Systematic Review; Meta-Analysis.

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INTRODUCTION

Approximately one million people with Diabetes Mellitus (DM) undergo amputation every year, accounting for a mean of three amputations per minute[1]. Foot insensitivity and deformation and limited joint mobility may result in abnormal mechanical loads, leading to chronic diabetic foot ulcers with impaired healing due to plantar pressure (PP)[2].

Adherence to an intervention for relieving PP is decisive for healing such ulcers. Aspects such as efficacy, higher user acceptance, lower costs for an unloading device and little interference in patients' routines may increase the possibility of achieving an appropriate pressure relief. Such characteristics have been reported with the use of felted foam[3-4].

However, studies diverge concerning this foam's effects. Some of them point that there is no statistical association between the foam's effects and lesion healing when compared to the conventional treatment with half-shoes[5-6]. Other studies identify that it presents effects on healing[7] and positive results in reducing plantar pressure[8-9], indicating the need for summarizing these results to establish the precise effects of felted foam.

A research conducted in the PROSPERO (International Prospective Register of Systematic Reviews) repository, Cochrane Library and PubMed Clinical Queries found three published systematic reviews[10-12] which only described this discharge device, but did not perform meta-analysis on the data to precisely identify the real effects of felted foam over diabetic foot ulcer treatment, leaving a research gap.

This study's objective was thus to evaluate the effect of felted foam on diabetic foot plantar ulcer treatment.

METHOD

Study type

This is a systematic review with meta-analysis of experimental and observational studies, based on recommendations from the Cochrane Collaboration[13]. This review's protocol is registered in PROSPERO with registration number CRD42017070352.

Data collection

The research question was elaborated under the PICOS strategy: Patient - patients with diabetic foot plantar ulcers; Intervention - felted foam; Comparison - other techniques for plantar pressure relief or no technique for plantar pressure relief; Outcomes - reduction in plantar pressure and reduction in healing time; and Study - Randomized Clinical Trials (RCT) and cohort studies. The following research question was thus formulated: "*What are the effects of felted foam on the treatment of diabetic foot plantar ulcer?*".

The sources for this research were Cochrane Library, PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Science Direct, Web of Science, SCOPUS, Spanish Bibliographic Index for Health Sciences (*Índice Bibliográfico Espanõl en Ciencias de la Salud* - IBECS), Latin-American Literature on Health Sciences (*Literatura Latino-Americana em Ciências da Saúde* - LILACS), Brazilian Network for Health Technology Evaluation (*Rede Brasileira de Avaliação de Tecnologias em Saúde* - REBRATS) and Nursing Database (*Base de Dados de Enfermagem* - BDENF).

For the inclusion of yet unpublished randomized clinical trials, research on Clinical Trials was performed. Also, references from selected studies were analyzed to identify the most relevant ones. Controlled descriptors from Medical Subject Headings (MeSH) were selected, along with non-controlled descriptors.

Hence, the search string used in PubMed was: *(((((((diabetic AND ulcer AND pressure plantar) OR (diabetes AND callus) OR (diabetic foot) OR (foot ulcer) OR (diabetic foot ulcer) OR (diabetic neuropathies) OR (diabetic feet) OR (feet, diabetic)))) AND ((felsted foam) OR (felt fitted) OR (foam melting) OR melting OR felt OR (foot ulcer treatment) AND (pressure relief) OR offloading OR (orthotic devices))))) AND (((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospectiv*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh]) OR (((((((("Epidemiologic Studies"[Mesh]) OR "Case-Control Studies"[Mesh]) OR "Retrospective Studies"[Mesh]) OR "Cohort Studies"[Mesh]) OR "Follow-Up Studies"[Mesh]) OR "Longitudinal Studies"[Mesh]) OR "Prospective Studies"[Mesh]) OR "Controlled Before-After Studies"[Mesh])))).* This string was adapted for each base or database in accordance with their specificities.

Searches were performed between May 13 and June 3, 2017. Two reviewers were engaged in searching and selecting papers in a paired manner. Endnote Web was initially used for tracking publications based on their title and abstract.

Eligibility criteria

The selection process abided by recommendations from PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[14].

Randomized clinical trials and observational studies in Portuguese, English or Spanish were included, with no restrictions regarding year of publication. Participants included people with type 1 or 2 diabetes and foot ulcers

with neuropathic etiology which used felted foam in the formats insole, either associated to another material or not, and adhesive felt adhered on foot or some kind of proper footwear.

After the articles were selected, study eligibility was confirmed by applying the previously defined criteria. Disagreements were solved in a consensus meeting between reviewers through consultation with a third reviewer. Kappa agreement index was used to evaluate agreement over publication inclusion and exclusion.

Data extraction

Identification data were extracted (authors, year of publication, country) and study design (follow-up, randomization, allocation, blinding, intention-to-treat analysis, selective publication, early interruption for benefit, participant selection and inclusion, controlling for confounding factors, and sponsorship by device manufacturers).

Participants' characteristics included age, gender, body mass index, diabetes duration, ulcer location and duration, lesion area when the study started, description of interventions for experimental and control groups, and the periodicity of change, as these were considered important for outcome evaluation.

The outcomes plantar pressure reduction (measured in kPa), healing time reduction (measured in days), and ulcer size reduction (measured in cm) were considered.

Risk of bias in individual studies

Cochrane Collaboration Risk of Bias Tool[13] was employed to classify the included studies' risk of bias, considering the following domains: random sequence generation; confidentiality maintenance for the allocation sequence; blinding of patients, investigator and outcome evaluators; incomplete outcome data; selective outcome reporting and early interruption for benefit. Risk of bias was thus classified as low, high, or unknown.

For observational studies, criteria recommended by GRADE (Grading of Recommendations Assessment, Development and Evaluation)[15] were employed: inadequate patient selection and inclusion; controlling for confounding factors; blinding of patients, investigators, and outcome evaluators; incomplete outcome data.

The main authors of these studies were emailed for requests of further information on the studies. Unanswered items were classified as "unknown risk of bias".

Data analysis and treatment

The meta-analyses were calculated with the program The Cochrane Collaboration's Review Manager 5® *(*RevMan 5*)* and their results were presented in *Forest Plot* graphs.

For meta-analyses calculation, fixed effects model was employed. The difference between means was used as an effect measure, calculating effect estimates for individual studies by the inverse of variance[16-17].

Heterogeneity was evaluated using the tests Cochran's Q, Chi-squared (X^2) and Inconsistence (I^2). An elevated Q value and $p<0.05$ support heterogeneity among studies. For X^2, a more conservative significance level, $p<0.10$, was chosen. For I^2, classification according to Higgins' scale was employed, accounting for: no heterogeneity for values close to 0%; low heterogeneity for values close to 25%; moderate heterogeneity for values close to 50%, and high heterogeneity for values close to 75%.

Heterogeneity was explored by calculating meta-analyses by sub-group, separating studies between those with appropriate methodological quality and low methodological quality.

Evaluation of reporting bias was conducted via funnel plot.

Quality of evidence

The GRADE system was adopted for evaluating evidence quality according to its four classification levels: high, moderate, low, and very low[18]. The final evidence profile was generated by the GRADEpro GDT (Guideline Development Tool) app, version 2015.

RESULTS

The process of compiling studies and eligibility is described in a flowchart (Figure 1). In this phase, Kappa agreement index was 0.857.

Four publications were excluded along this process for the following reasons: study type criterion was not met[19]; patients with healed neuropathic ulcers[20]; not all participants had diabetes[20-21] and felt was not used in the intervention[22]. Two publications were subsequently included after manual research in the references of the elected studies. The final sample for the systematic review comprised six publications.

Chart 1 presents the studies included in the systematic review. All authors denied being sponsored by companies. Four RCT[7,8-9,23] and two cohorts[5-6] were obtained.

Baseline participant characteristics revealed groups consisting of elderly, male, overweight or obese adults with long-lasting diabetes and ulcers in the hallux or forefoot regions, with varied duration and size.

Periodicity of intervention change was defined in four studies, since in both cross-over RCTs[8-9] the interventions were applied only to measure plantar pressure and not for the treatment of ulcers. In the other studies, the period for foam substitution ranged from three to seven days.

The evaluation of risk of bias was conducted through a study. For risk of bias evaluation of the individual studies, the criterion patient and researchers blinding was considered identical to the criterion outcome evaluator blinding, due to the fact that felted foam cannot be blinded to participants, so as not to impair the evaluation of the studies. Both cohorts were thus classified as unknown risk of bias according to these criteria, due to presenting insufficient information[5-6].

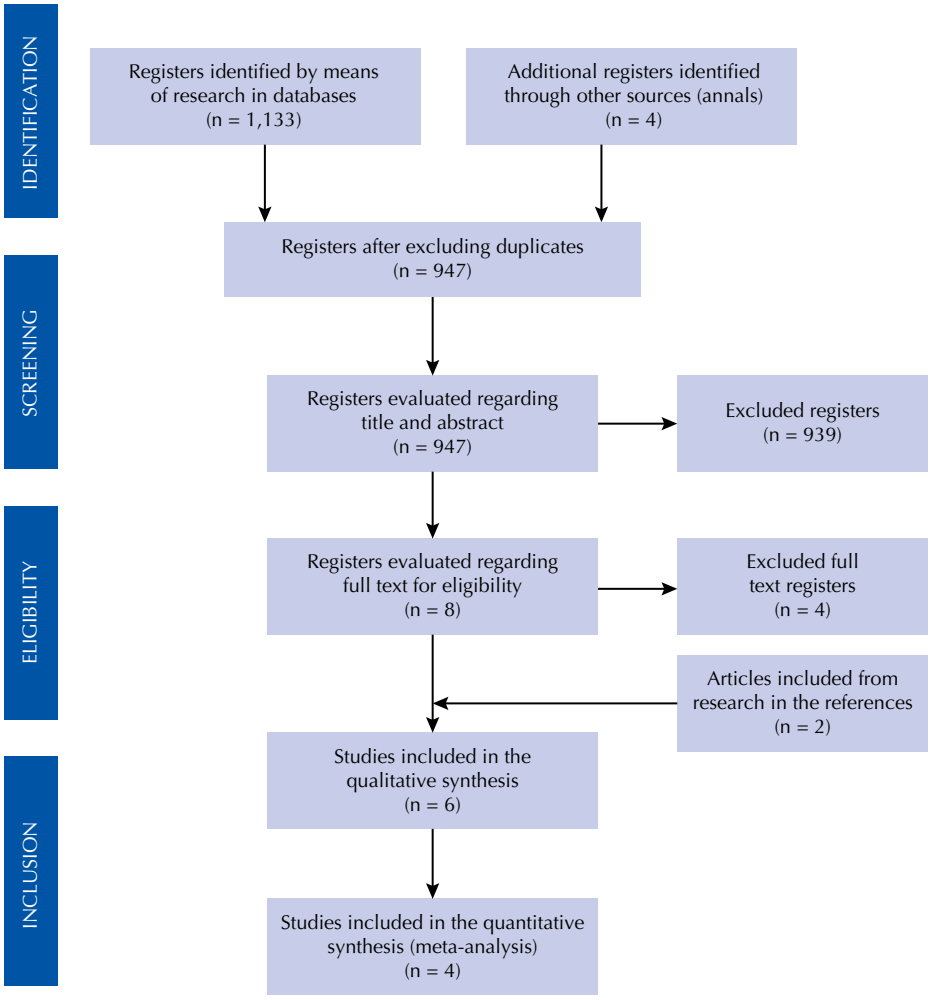

Figure 1 – Study selection flowchart based on a model presented in the PRISMA document[14].

Chart 1 – Characterization of the studies included in the systematic review – Crato, CE, Brazil, 2018.

Author/ year (Sample)	Inclusion (IC) and exclusion (EC) criteria	Intervention	Comparison /control	Evaluated outcomes	Baseline participant characteristics						Conclusion
					Age (years)	Gender M/F	BMI[1] (Kg/m²)	DM duration (years)	Location/ duration	Area (cm²)	
Fleischli et al., 1997[24] (n = 26)	IC: an active plantar NU[2]. EC: no reference.	Insoles made of felted foam plus polyethylene foam associated to a post-operative shoe.	CG4[1]: TCC[5] CG2: pressure relief orthosis DH®; CG3: orthopedic shoe Darco®; CG4: post-operative shoe Darco®.	Plantar pressure reduction.	Hallux 51.6 + 9.3 Forefoot 54.3 + 8.9	Hallux 15/4 Forefoot 1/6	Hallux 29.7 + 2.3 Forefoot 31.5 + 6.0	No reference	Hallux e metatarsus (forefoot). Duration: No reference	No reference	Felted foam was the fourth most effective modality for reducing plantar pressure.
Birke et al., 2002[6] (n=120)	IC: new non-surgical treatment NU. EC: post-operative wounds; recurrent non-plantar ulcers in midfoot or heel; osteomyelitis; ischemic wounds.	Felted foam adhered to modified post-operative shoe. Weekly change.	CG1: TCC CG2: modified surgical shoe CG3: modified walking splint; CG4: unspecified.	Reduced healing time; Number of healed ulcers.	IG: 57.5 +12 CG1: 47.3 + 9.1 CG2: 58.2+ 11.5 CG3: 56.5 + 9.6 CG4: 56.8 + 10.5	IG: 9/17 CG1: 7/6 CG2: 23/31 CG3: 14/4 CG4: 2/4	No reference	No reference	Hallux and metatarsus. Duration (days): GE: 149.2 + 153.6 CG1: 183.9 + 142.9 GC2: 67.9 + 99.7 CG3: 98.6 + 114.3 CG4: 150.7 + 168.7	IG: 1.17 + 0.84 CG1: 1.26 + 0.45 CG2: 0.84 + 0.45 CG3: 1.76 + 1.17 CG4: 1.6 + 0.35	There was no significant difference between the intervention and the groups regarding healing time; 81% of NUs healed in 12 weeks.

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Author/ year (Sample)	Inclusion (IC) and exclusion (EC) criteria	Intervention	Comparison /control	Evaluated outcomes	Baseline participant characteristics						Conclusion
					Age (years)	Gender M/F	BMI[1] (Kg/m²)	DM duration (years)	Location/ duration	Area (cm²)	
Zimny et al., 2002[5] (n=61)	IC: DM 1 or 2, with Wagner's grade 1 or 2 plantar NU. EC: OPAD[8], mediasclerosis or osteomyelitis.	Felted foam and rubber implanted in post-operational shoe.	Half shoe (Thanner®, Hoechstaedt, Germany).	Reduction in healing time and lesion area.	IG: 61.7 + 13.3 CG: 61.1 + 11.6	IG: 14/13 CG: 19/15	IG: 27.1 + 4.8 CG: 27.9 + 4.4	IG: 18.4 + 7.2 CG: 21.6 + 11.7	Refers neither location nor duration.	IG: 11.1 + 1.4 CG: 11.9 + 1.4	There was no difference in healing time and reduction in wound area among groups.
Zimny; Schatz; Pfohl, 2003[7] (n=54)	CI: DM 1 or 2, with plantar NU Wagner's grade 1 or 2. EC: OPAD, mediasclerosis or osteomyelitis.	Rubber foam and felted foam associated to post-operative shoe.	Half-shoe (Thanner®, Hoechstaedt, Germany).	Healing time reduction; lesion area reduction.	IG: 62.1 + 13.0 CG: 62.1 + 10.8	IG: 13/11 CG: 17/13	IG: 27.4 + 4.9 CG: 28.5 + 4.3	IG: 18.2 + 7.6 CG: 22.1 + 11.8	Metatarsus (forefoot). Duration: no reference.	IG: 10.2 + 4.5 CG: 11.3 + 5.1	Felted foam reduced plantar pressure as effectively as the shoe and contributed more to wound reparation.
Nubé et al., 2006[23] (n=32)	IC: DM 1 or 2; NU in hallux or metatarsus, Wagner's grade 1A or 1B. EC: impalpable pulsations or ABI <0.6; exudative ulcer with deep sinus.	Felted foam adhered to foot plus proper shoes for diabetic foot.	Felted foam adhered to a proper shoe for diabetic foot; Darco® shoe used in 65% of participants (8 in IG and 13 in CG).	Lesion area reduction. Comparison of healing rates for hallux and forefoot.	IG: 59 (50-70) CG: 56 (55-66)	IG: 14/1 CG: 12/5	No reference	IG: 14 (10-19) CG:12 (6-19)	Hallux e metatarsus (forefoot). Duration: IG: 14 (10-19) CG: 12 (6-19)	IG: 0.5 (0.2-1.3) CG: 0.5 (0.2-0.8)	Reduction of hallux or forefoot ulcer size were similar. There were few adverse events with felt (maceration and mycosis).
Raspovic; Waller; Wong, 2016[9] (n=15)	IC: >18 years; plantar NU[9] EC: not speaking basic English, not being able to roam for 10 steps; amputation under the knee; OPAD, exposed bone or infection.	New felted foam adhered to foot and associated to All Purpose Boot or post-operative shoe.	CG1: Felted foam worn after seven days of application; CG2: no felt.	Plantar pressure reduction.	55.8 + 10.7	14/1	31.7 + 2.9	11.8 +11.3	Hallux and metatarsus (forefoot), medium and heel. Duration: No reference	0.24 + 0.25	The new felt relieved 49% of plantar pressure in comparison to no felt. Worn felt relieved 32% in comparison to no felt.

[1]Body Mass Index; [2]neuropatic ulcer; [3]Comparison/control group; [4]Total contact casts; [5]Obstructive peripheral artery disease; [6]PEDIS-IWGDF Classification: perfusion grade 1; depth grade 1-2; infection grade 1 and sensation grade 2.

One of the cohorts had the criterion failure to control for confounding factors classified as high risk of bias, due to the study stating that specific bandages or topical agents used were not controlled and adherence to the use of adjuvants was not evaluated[6]. The other criteria were classified as low risk of bias.

Concerning the blinding of outcome evaluators, a study was classified as having unknown risk due to lack of information[23] and the others were classified as low risk, since they used accurate measurement instruments, reducing risk of bias.

The criterion incomplete outcome data was evaluated as high risk of bias in two studies: the first, due to 15% loss to follow-up of recruited participants[23]; the second, due to the exclusion of patients with suggestive peripheral arterial occlusive disease after randomization, with no specification of the group they belonged to[7]. The criterion selective reporting was evaluated as high risk of bias for two studies[7,23] due to unreported complications. The final classification for risk of bias was synthesized in Figure 2.

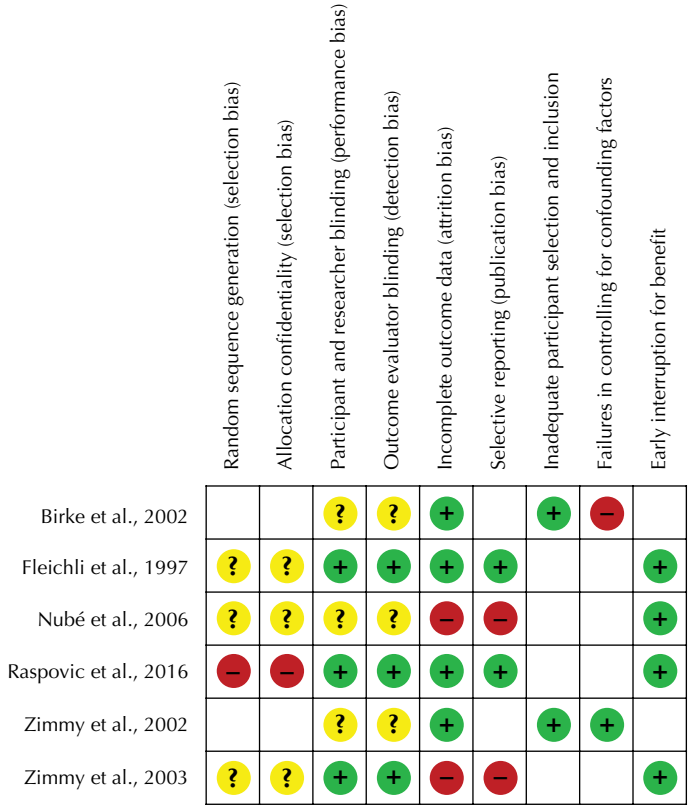

Figure 2 – Risk of bias summary for included studies.

Only four studies participated in the meta-analyses: two RCTs[8-9] and two cohorts[5-6]. The outcomes with sufficient and compatible data for meta-analytical calculations were plantar pressure reduction and healing time reduction.

Figure 3 represents the forest plot for the outcome reduction of plantar pressure. In this meta-analysis, both studies are repeated because they include more than one comparison. In the first study[8], comparison was established between felt and a post-operative shoe for ulcers located in the hallux, whereas the second comparison considered only ulcers located in the forefoot. In the second study[9], recently applied felt was compared to no felt, followed by a comparison between worn felt (seven days from application) and no felt.

Summarization of the effect on plantar pressure revealed a reduction of 10,77 kPa (kilo pascals) (CI95% -14.92, -6.62; p<0.001) in individuals using felted foam when compared to no felt or post-operative shoe. Moderate heterogeneity is observed between studies due to a difference in comparison groups, which was explored in sub-group analyses (Figure 3).

Meta-analysis was thus conducted considering studies with low risk of bias for one sub-group and studies with high risk of bias for another sub-group. No heterogeneity was observed for the groups, indicating its presence was due to risk of bias between studies. Also, the analysis shows that results for both the sub-group with high risk of bias and the one with low risk of bias favored felted foam regarding plantar pressure reduction, with an estimated effect of -6.57 kPa (CI95% -12.26, -0.88; p=0.02) for the subgroup with the highest risk of bias and -15.50 kPa (CI95% -21.55, -9.44; p<0.001) for the sub-group with the lowest risk of bias.

Summarization for the outcome healing time included two cohort studies. In the first[6], the healing shoe was taken as the comparator. This choice was made to avoid inconsistence between comparators, since the other cohort[5] also compared felt to a healing half-shoe.

Meta-analysis regarding healing time demonstrated it had a reduction of 3.71 days. However, it showed no statistical significance (CI95% -8.28, 0.85; p=0.11), also indicating no clinical heterogeneity.

From the studies comprising the meta-analysis, almost all the RCTs had results that favor the intervention. No study reported industrial sponsorship, reducing the possibility of conflicts of interest.

The funnel graphic analysis pointed no publication bias in the outcome reduction of plantar pressure, considering the symmetric distribution of studies in the tip of the pyramid. As for the outcome reduction in healing time, there were no sufficient data to issue a judgement on publication risk of bias, considering the small amount of studies included in this meta-analysis.

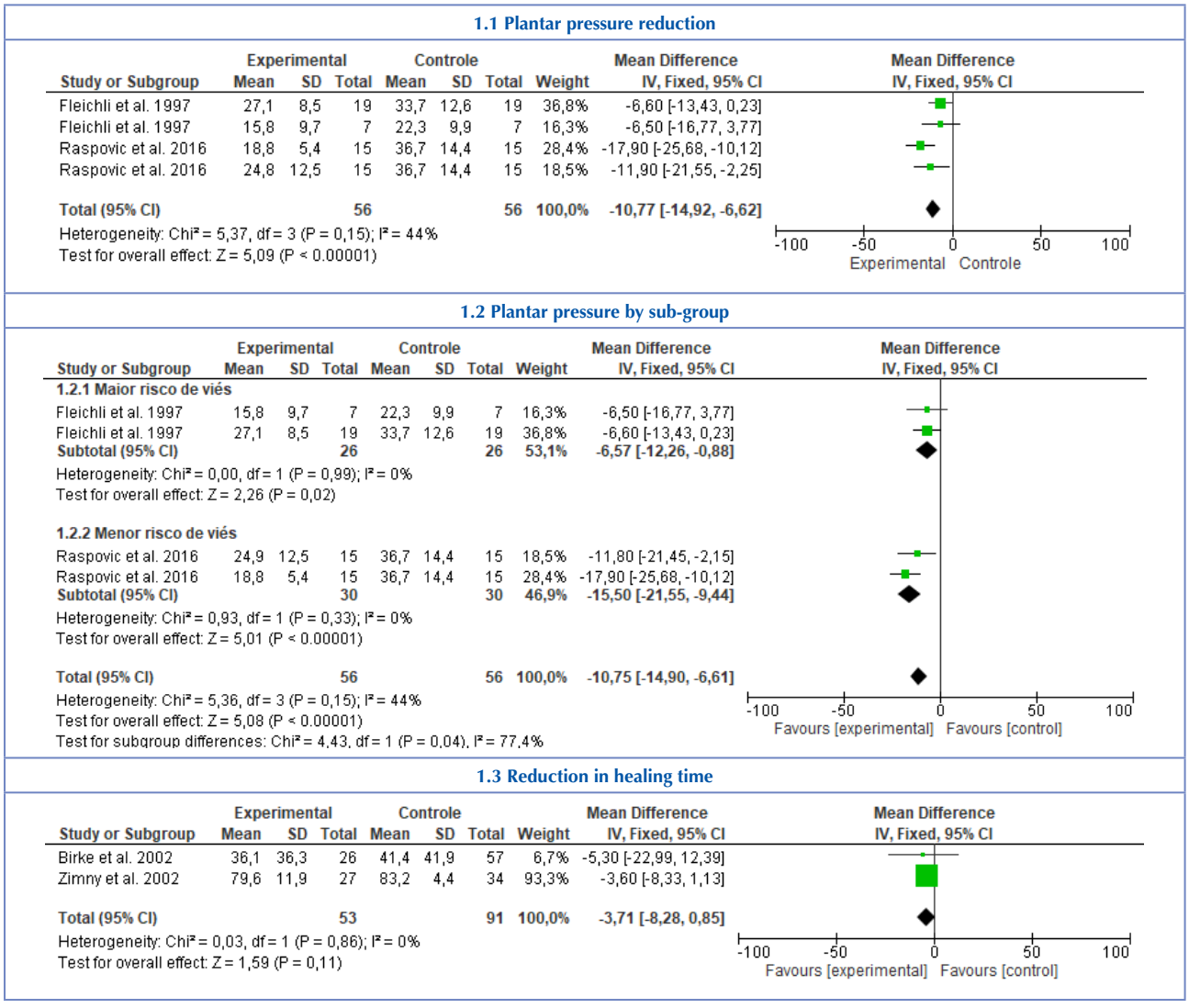

Figure 3 – Differences between means for felted foam effects versus comparators by analyzed outcome.

Chart 2 shows the evaluation of quality for the final evidence by GRADE. Penalty for the criterion inaccuracy, in both outcomes, is justified by broad summary confidence intervals associated to effect estimates based on a small number of events.

As shown in the chart containing the classification for quality of evidence, the estimated effect of felted foam on plantar pressure reduction of neuropathic diabetic foot ulcers was minus 10.77 kPa, supported by moderate-quality evidence. For the outcome reduction in healing time, the summarized effect estimate was minus 3.71 days, supported by evidence of particularly low quality.

Chart 2 – Classification of quality of evidence for felted foam efficiency in treating neuropathic diabetic foot ulcers – Crato, CE, Brazil, 2018.

EVALUATIONS						N OF PATIENTS		EFFECT	QUALITY OF EVIDENCE	RELATIVE IMPORTANCE OF OUTCOME
Number of studies	Study design	Risk of bias	Inconsistency	Indirect evidence	Inaccuracy	Felted foam	Other discharge techniques	Absolute (95% CI)		
Plantar pressure reduction (evaluated with the measurement of pressure reduction in kPa)										
4	Randomized clinical trials	Not severe	Not severe	Not severe	Severe[a]	56	56	DM: Minus 10.77 kPa (-14.92 to -6.62)	⊕⊕⊕◯ MODERATE	IMPORTANT
Healing time reduction (follow-up: mean of 11 weeks. Evaluated in days)										
2	Observational studies	Not severe	Not severe	Not severe	Severe[a]	53	91	DM: Minus 3.71 days (-8.28 to -0.85)	⊕◯◯◯ VERY LOW	IMPORTANT

CI: Confidence Interval; DM: Difference from the mean; a. Broad CI.

DISCUSSION

This review included six studies developed in the USA[6,8], Germany[5,7] and Australia[9,23] which presented promising results for felted foam regarding the outcome plantar pressure reduction in treating ulcers due to diabetic peripheral neuropathy.

The intervention was presented as an adhesive felt adhering to the foot, as well as felt as a fabricated insole of different breadths and in association with different materials such as rubber or polyethylene. Cointerventions, including coverages used for healing ulcers, were not controlled by employing the protocol in one study only[6].

Out of the six studies included in the systematic review, only four composed the meta-analysis[7-10]. Summarization of the effect of plantar pressure points the reduction of 10.77 kPa (CI95% -14.92, -6.62; p<0.001) in the mean pressure of participants using the felt. Plantar pressure relief is associated to the reduction of inflammatory components, reactivation, and acceleration of respiratory processes[4]. It reduces weight-related damage towards ulcer sinus when walking, which delays or inhibits healing[24].

An RCT showed that felted foam reduced mean plantar pressure to 48% in the forefoot and 34% in hallux[8]. Another study presented a mean of 49% plantar pressure discharge with new felt and 32% with worn felt after seven days of use, in comparison with no felt for plantar ulcers in the forefoot[9]. Reduction of plantar pressure was higher in the metatarsus region than in other pedal areas, suggesting a better performance for this material in the forefoot region[20].

Meta-analysis of plantar pressure reduction demonstrated moderate heterogeneity among studies, although baseline participant characteristics, such as age, gender, disease duration and ulcer location, were similar. Exploring heterogeneity for low and high risk of bias subgroups did not alter the effect estimates, confirming results in favor of this intervention.

As for the outcome healing time, a cohort conducted in the USA has shown that the proportion of healed ulcers was 81% among all followed-up participants, regardless of discharge methods. There was no significant difference in healing time with the use of felt when compared to total contact casts[6], similarly to RCT results in Australia[23].

On the other hand, in Germany, another cohort has shown that healing time was 79.6 days (CI95% 75.84) for the group treated with felt and 83.2 days (CI95% 77.90) for the group that received the half-shoe, suggesting that felt might not be as effective as conventional therapy with half-shoe after statistical analysis[5]. A similar result was presented in RCT, with a 75.2 days mean (CI95% 67.84) versus 85.2 days (IC95% 79.92), accounting for the best efficiency of felt in comparison with half-shoe (p=0.03)[7].

Meta-analysis of healing time showed no statistical association between exposure to the intervention and the effect. The confidence interval amplitude suggests inaccuracy regarding the estimated effect. The quality of this evidence was low, showing the need for further well-designed studies to understand the real effect of felt in lesion healing time.

The investigation of use of felt in wound area reduction was evidenced in two studies[5,7]. The first, which compared felt to a half-shoe for plantar pressure relief, indicates that lesion areas did not differ significantly between the groups (p=0.81 and p=0.13, respectively). As for the second, felt was shown to be more efficient in weekly reduction of wound radius than its comparator, obtaining reductions of 0.48 mm (CI95% 0.42; 0.56) in comparison to 0.39 mm (CI95% 0.35; 0.42) for the control group (p=0.005). It is possible that plantar pressure reduction achieved by felted foam may improve wound healing[5,7].

Similarly to mortality and amputation, complications were not sufficiently explored in most studies[7-9]. Only two studies reported bacterial infections, which did not compose a meta-analysis due to differences in design[6,10]. Also, the cohort reported fungus infection and perilesional maceration associated to the use of felt[23], which must be better investigated in future studies with duly controlled cointerventions.

Regarding the risk of publication bias, studies on the outcome plantar pressure reduction were published between 1997 and 2016, an interval of almost 20 years for the publication of "negative" or "little significant" results. This fact reinforces the absence of publication bias.

However, the lack of both positive and negative studies at the funnel's base was perceived, as well as the need for elaborating more well-designed clinical researches which contemplate other outcomes in the context of diabetic foot. Regarding the risk of publication bias for the outcome healing time reduction, the reduced number of studies shows the need for the publication of new studies that evaluate this outcome.

CONCLUSION

Felted foam granted the highest reduction of plantar pressure in the metatarsus region when compared to conventional methods for pressure relief. Efficacy estimates for felted foam in reducing plantar pressure are supported by moderate quality evidence. This material is recommended for the development of new orthosis models for discharging plantar ulcers, along with new clinical studies with higher methodological rigor.

RESUMO

Objetivo: Avaliar os efeitos da espuma de feltro no tratamento da úlcera plantar do pé diabético. **Método:** Revisão sistemática, com metanálise. As buscas foram realizadas na Cochrane Library, PubMed, CINAHL, Science Direct, Web of Science, SCOPUS, IBECS e LILACS. A *Cochrane Collaboration Risk of Bias Tool* foi utilizada para a avaliação do risco de viés. As metanálises foram calculadas pelo programa *Review Manager*, enquanto o *Grades of Recommendation, Assessment, Development and Evaluation* foi utilizado para a avaliação da qualidade da evidência. **Resultados:** Foram incluídos quatro ensaios clínicos e duas coortes. Houve a redução de 10,77 quilos pascais

(IC 95% -14,92, -6,62; p<0,001) na média de pressão plantar dos indivíduos expostos ao feltro. **Conclusão:** Evidenciou-se maior redução da pressão plantar com o uso do feltro. Recomenda-se o desenvolvimento de novos modelos de órteses de alívio de pressão plantar a partir da espuma de feltro, acompanhado de mais pesquisas clínicas que elucidem outros desfechos relacionados.

DESCRITORES
Pé Diabético; Úlcera do Pé; Revisão Sistemática; Metanálise.

RESUMEN
Objetivo: Evaluar los efectos de la espuma de fieltro en el tratamiento de la úlcera plantar del pie diabético. **Método:** Revisión sistemática con metaanálisis. Las búsquedas se realizaron en *Cochrane Library*, PubMed, CINAHL, *Science Direct*, *Web of Science*, SCOPUS, IBECS y LILACS. Se utilizó la herramienta *Cochrane Collaboration Risk of Bias Tool* para evaluar el riesgo de sesgo. Los metaanálisis fueron calculados por el programa *Review Manager*, mientras que para la evaluación de la calidad de las pruebas se utilizó *Grades of Recommendation*, *Assessment*, *Development and Evaluation*. **Resultados:** Se incluyeron cuatro ensayos clínicos y dos cohortes. Hubo una reducción de 10,77 kilopascales (95% IC -14,92, -6,62; p<0,001) en la presión plantar media de los individuos expuestos al fieltro. **Conclusión:** Hubo una mayor reducción de la presión plantar con el uso del fieltro. Se recomienda el desarrollo de nuevos modelos de ortesis de alivio de presión plantar a partir de espuma de fieltro, acompañado de nuevas investigaciones clínicas para dilucidar otros resultados conexos.

DESCRIPTORES
Pie Diabético; Úlcera del Pie; Revisión Sistemática; Metaanálisis.

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