Review report of MTG20: Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers

This medical technology guidance was published in November 2014.

All medical technology guidance is usually reviewed 3 years after publication, unless NICE become aware of significant new information before the expected review date.

This review report summarises new evidence and information that has become available since this medical technology guidance was published, and that has been identified as relevant for the purposes of this report. This report will be used to inform NICE's decision on whether this guidance will be updated, amended, remain unchanged (static list) or withdrawn.

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Date completed: 12 February 2021

Acknowledgements

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1. Original objective of guidance

To assess the clinical and cost effectiveness of Parafricta Bootees and Undergarments for reducing skin breakdown in people with frail skin or at risk of pressure ulcers.

2. Current guidance recommendations

NICE MTG20 (NICE, 2014) makes the following recommendations:

1.1 Parafricta Bootees and Undergarments show potential to reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. However, more evidence for their effectiveness in clinical practice is needed to support the case for routine adoption of Parafricta Bootees and Undergarments in the NHS.

1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of using Parafricta Bootees and Undergarments. This should take the form of comparative research against standard care, preferably carried out in a hospital. The research should include development of criteria to recognise people who would most benefit from the technology in both hospitals and community care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will update this guidance if and when substantive new evidence becomes available.

3. Methods of review

Update searches were conducted by information specialists at NICE on 13th November 2020 and were based on the original EAC searches for this guidance. Details are provided in appendix D. Search results provided to the EAC were imported into Endnote and duplicate records were removed. References provided by clinical experts were cross-checked against the Endnote library.

One researcher reviewed all records identified by the searches as well as any additional ones noted by the clinical experts. 19 were selected as being relevant for full review. A second researcher reviewed the 19 selected publications to confirm relevance and 3 were included; these 3 publications pertained to 2 studies.

Searches were also conducted for ongoing and/or unpublished trials in ClinicalTrials.gov, ISRCTN and WHO International Clinical Trial Registry Platform (ICTRP).

4. New evidence

4.1. Changes in technology

The packaging no longer indicates that walking is a contraindication. Correspondence with the manufacturer confirmed this removal, and the advice provided to the EAC is that patients may transfer from bed to chair and vice versa while wearing the bootees. The manufacturer has not stated whether walking is advisable and in the randomised control trial initiated by Cedar, the perceived risk of patients walking in the bootees by Directors of Nursing was a significant obstacle to patient recruitment. However the ethics committee accepted that the study design was adequately safe.

4.2. Changes in care pathways

Some relevant recommendations have been published since the original MTG20 guidance as highlighted in the literature or by the clinical experts. NICE Clinical Guideline CG179 was published soon after the original report and recommends in point 1.1.15 to discuss with the patient (and family/carers if appropriate) the use of heel pressure offloading strategies in those patients at risk of developing heel pressure ulcers. The clinical guideline (CG179) recommends research into pressure redistributive devices (which includes those designed to reduce friction and shearing forces) due to the limited evidence available at that point; it also highlights that most of the evidence has been funded by industry. One clinical expert highlighted the Surface, Skin Inspection, Keep Moving, Infection and Nutrition (SSKIN) care bundle. There is no official reference document for this bundle but McCoulough (2016) provides an overview of it; the SSKIN bundle encourages the use of pressure relieving equipment. The International Skin Tear Advisory Panel (Beeckman, 2020; Table 3 in reference) details ‘best practice recommendation for holistic strategies to promote and maintain skin integrity’. These include a risk reduction programme with a checklist discussing the use of protective clothing as well as recommendations on avoiding friction and shearing forces (though highlighting it in the context of manual handling).

It should be noted that Parafricta products are not designed to reduce pressure but to reduce friction and associated shear.

4.3. Results from the MTEP research commissioning workstream

The randomised controlled trial reported by Cleves et al. (unpublished; NCT04023981) was commissioned by NICE as a result of the research recommendations made in the original NICE review of Parafricta bootees and undergarments, and aimed to compare in hospitalised and non-ambulant patients with a Waterlow risk score of ≥20, whether Parafricta bootees, added to standard care (SC), prevent heel pressure ulcers (HPUs) compared to SC alone.[redacted]

[redacted]The investigators performed clinical examination of patients' heels at the bedside on Day 0, Day 3 and Day 14, to ensure gold standard assessment of skin integrity.

[redacted]A study report has been made available to NICE

[redacted]

4.4. New studies

Gleeson (2015) is a non-comparative study and discusses the results of using the slip on Parafricta bootees over a 2-year period at Whiston Hospital, St Helens and Knowsley Teaching Hospitals NHS Trust, with further years of the evaluation reported in Gleeson (2016). The bootees were introduced into the hospital in 2012 and more were purchased in 2013. The author states that the occurrence of grade 2 heel pressure ulcers has dropped every year in the 2011-2013 period; the study was based on patient admission data (see Appendix C for details on patient and bootee numbers). Moreover, the author highlights that while the incidence of all grade 2 pressure ulcers has dropped in this period, the ratio of grade 2 pressure ulcers on the heels to grade 2 pressure ulcers on other sites has also fallen. No hypothesis testing has been carried out on the data. The author concludes that while the overall fall in

incidence of grade 2 pressure ulcers can be attributed to a general change in care practice implemented over this time and increased awareness of the issue of pressure ulcers, the steeper decline in grade 2 heel pressure ulcer incidence is likely linked to the use of Parafricta bootees. The author notes that the Trust uses stricter standards for recording pressure ulcer incidents than is mandated by the NHS Safety Thermometer. In relation to resources use, the author states that tracked bootees at the Trust have been through at least six wash cycles and found to be completely reusable, and also commented on the implied cost-saving aspect of the intervention, but suggested that an audit would need to be conducted to make the evidence on this conclusive. The article was supported by the company APA Parafricta Ltd, who provided comments on the manuscript. The author is also described as the inventor of the bootees in a press article (Weston 2016) that is also referenced on the APA Parafricta Ltd. Website (Parafricta n.d.), which presents a risk of bias.

Gleeson (2016) reports results from a further 2 years of the pressure reduction initiative reported in Gleeson 2015. The initiative involved the introduction of the bootees in 2012, introduction of education in 2013 and a new assessment tool in 2014, with 2011 acting as the baseline and 2015 as the year of full implementation; the study was based on patient admission data (see Appendix C for details on patient and bootee numbers). While the 2015 report discusses the incidence of grade 2 pressure ulcers, the 2016 report discusses the incidence of pressure ulcers from all categories, while noting a lack of grade 3 and 4 pressure ulcers and using the same figures for pressure ulcer incidence for the years 2011, 2012 and 2013 as the 2015 report. The author highlights a decrease of heel pressure ulcer incidents, which held true for all study years except 2014, when the incidence was the same as in 2013. Compared to the 2015 publication there is no mention of the ratio of heel ulcers to all other ulcers for any year. This ratio would have been higher in 2014 compared to 2013, with the 2015 figure being similar to the 2013 figure (see EAC calculation in Appendix C). The paper presents data, using the 2012 mean costs of grade 2 pressure ulcer healing, showing a reduction in heel pressure ulcer care costs despite the purchase of Parafricta bootees. Of note is the fact that the highest savings were achieved in 2013. The company APA Parafricta Ltd provided assistance in the production of this manuscript.

Schofield (2018) is a cross-sectional study, which reports a 2-week intervention in three care settings (residential care home, acute stroke unit and a community intermediate care hospital) for existing heel pressure damage with no separate control group. Out of an initial recruitment of 30 patients, 15 patients completed the evaluation. The patients wore the booties constantly while in bed or in a chair, but the booties were removed for heel

assessment, hygiene purposes or when patients mobilised for rehabilitation purposes. The patients were not independently mobile and the mean age was 86 years (range 79 to 98 years); the study sample was 11 females and 4 males. Ultrasound assessment of pedal pulses revealed that two patients had monophasic irregular pulse waves and the rest had recorded biphasic pulses with signs of venous insufficiency. The author reports that patients rated the performance of the bootees highly (fourteen patients scored it 4/4 and one patient scored it 3/4). The report lists the average and peak pressures on the heels in the different care settings and during different activities (such as sitting or lying in bed) with standard care and with the bootees, but no hypothesis testing statistics have been carried out and there is no mention of the protocol used during these measurements (e.g. when were the standard care measurements taken with respect to the intervention measurements). The author states in a footnote to a pressure data entry that the '[c]hange in pressure is attributed to micro-movement of the heels'. The publication of this article was supported by the company APA Parafricta Ltd.

4.5. Adverse events

There were no entries related to Parafricta products on the FDA's MAUDE website or the MHRA's 'Alerts and recalls for drugs and medical devices' website, as checked on the 27th January 2021.

4.6. Ongoing trials

The only unpublished trial identified by the search is NCT04023981, which has been reported in section 4.4 as Cleves et al. (unpublished).

4.7. Changes in cost case

The price of the product on the NHS Drug Tariff has changed from £35.14 to £35.50.

4.8. Other relevant information

A poster presented by Cunningham at the 2018 Tissue Viability Society Conference, discusses a pressure ulcer change package implemented in Northampton General Hospital Trust, but only the abstract has been retrieved. It mentions an educational programme supported by the company APA Parafricta Ltd and a trial of low friction bootees (though it does not specify if these were Parafricta products). The abstract mentions a reduction of heel pressure ulcers, but no data is available for appraisal.

Gefen (2017) is a non-systematic review of heel pressure ulcers. It provides no new evidence. The author declared being a scientific advisor to APA Parafricta Ltd and other companies in the pressure ulcer prevention field.

The company has submitted an economic analysis based on the data obtained by Gleeson (2015, 2016) indicated a potential cost saving in annual

treatment and hotel costs ranging £61.2 million - £97.6 million, including 136300 – 194300 bed days saved. The figures are based on calculations using data from the years 2016/2017 to 2019/2020.

The company has provided a draft manuscript (Glover et al., unpublished) further outlining the cost saving potential of Parafricta bootees.

5. Conclusion

No new high-quality evidence has been published that evaluates the use of Parafricta bootees or undergarments as compared to standard care. The only randomised controlled trial of Parafricta bootees is NCT04023981 (Cleves et al., unpublished), but the trial failed to recruit the necessary number of participants to draw any meaningful conclusions

. All other studies were not designed as randomised trials. In conclusion, the new evidence does not fulfil the research recommendations outlined in the original MTG20 guidance.

Appendix A – Relevant guidance

Supplied by the NICE gIS team

NICE guidance – published

- Leg ulcer infection: antimicrobial prescribing (2020) NICE guideline NG152
- Diabetic foot problems: prevention and management (2015, last updated 2019) NICE guideline 19
- Multiple sclerosis in adults: management (2014, last updated 2019) NICE guideline 186

- Pressure ulcers: prevention and management (2014) NICE guideline CG179
- SEM Scanner 200 for preventing pressure ulcers (2020) NICE medical technologies guidance 51
- 3C Patch System for treating diabetic foot ulcers (2020) NICE medical technologies guidance 230
- Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers (2019) NICE medical technologies guidance 40
- Chronic wounds: advanced wound dressings and antimicrobial dressings (2016) NICE evidence summary 2
- Multiple sclerosis (2016) NICE quality standard 108
- Pressure ulcers (2015) NICE quality standard 89
- The Debrisoft monofilament debridement pad for use in acute or chronic wounds (2014) NICE medical technologies guidance 17

NICE guidance – in development

Multiple sclerosis in adults: management NICE guideline. Publication expected July 2022

Allantoin for untreated epidermolysis bullosa (Topic selection ID number 8304) NICE technology appraisal guidance. Status: A-List - STS

Oleogel-S10 for treating epidermolysis bullosa (Topic selection ID number ID9875) NICE technology appraisal guidance. Status: A-list - STS

Guidance from other professional bodies

MHRA (2018) Pressure ulcers: safeguarding adults protocol

MHRA (2015, last updated 2018) Pressure ulcers: applying All Our Health

Appendix B – Costing report (if available)

Parafricta bootee and undergarment prices

Price in MTG20 as per NHS Drug Tariff	Current Price as per NHS Drug Tariff
£35.14	£35.50

Potential cost savings for NHS England resulting from the adoption of St Helens and Knowsley heel pressure ulcer risk protocol in acute hospitals and the community setting, as calculated by APA Parafricta Ltd. (based on data from St Helens and Knowsley Trust).

	2019/20	2018/19	2017/18	2016/17
% below NHS England level of St Helens incidence/100,000 admissions	80%	83%	76%	72%
Potential annual treatment & hotel cost savings	£97.3m	£89.1m	£97.6m	£61.2m
Potential annual bed day savings*	194,300	176,000	154,600	136,300

* The monetary saving resulting from these saved bed days is included in the 'Potential annual treatment & hotel cost savings' row.

Appendix C – Details of studies and ongoing trials

Study	Design	Population	Interventions	Comparator	Outcomes	Results
Gleeson (2015, 2016)	Product evaluation	Whiston Hospital (St Helens and Knowsley Teaching Hospitals NHS Trust) Number of patient admissions 2011: 212668 2012: 224252 2013: 220381 2014: 221905 2015: 220596 Number of Parafricta bootees in circulation 2011: 0 2012: 832 2013: 1024 2014: not stated 2015: not stated Note: the number of admissions or bootees does not correspond to the number of patients at risk of pressure ulcers.	A new care pathway consisting of Parafricta bootees, education and an assessment tool	Data from 2011 - the year before Parafricta bootees were introduced	Incidence of avoidable pressure ulcers Incidence of avoidable heel pressure ulcers Ratio of heel pressure ulcers to those on other sites (it is unclear if the above outcomes refer to only grade 2 or also other grades of pressure ulcers) Cost savings attributed to the new care pathway	H - heel pressure ulcer cases A - all pressure ulcer cases R – ratio of heel pressure ulcers to non-heal pressure ulcers [H/(A-H)] as reported in the 2015 publication for years 2011, 2012 and 2013 and as calculated for the years 2014 and 2015 by the EAC from data reported in the 2016 publication £ - reported cost saving compared to 2011 Gleeson 2016 reported no incidence of grade 3 or 4 heel pressure ulcers 2011 H: 50 A: 125 R: 0.67 £: 0 2012 H: 34 A: 117 R: 0.41 £: 53,371.52 2013 H: 11 A: 56 R: 0.24 £: 196,116.12 2014 H: 11 A: 39 R: 0.39 £: 158,748.44

						2015 H: 8 A: 41 R: 0.24 £: 149,912.00
Schofield (2018)	Product evaluation	15 not independently mobile patients, 79-98 years old (mean 86), 11 females and 4 males. 7 in residential care home setting, 4 in a community hospital setting, 4 in an acute hospital stroke ward setting. The patients care varied by types of mattress, 'current heel prevention', mobility and heel appearance.	Parafricta bootees	'Current heel prevention' it is unclear if this is a before/after measurement on the same patients or not.	A) Patient performance rating of the product. B) Appearance of skin at end of treatment C) Patient, carer, health professional view on Parafricta. D) Pressure on heels.	A) 14 patients scored it 4/4 and one patient as 3/4 B) 'All non-blanching and blanching erythema fully resolved to normal intact skin after 3–4 days 1 DTI [deep tissue injury] had resolved after 7 days 2 blistered DTIs had reduced in size, reabsorbed dry and intact' C) 'All responses were that they would like bootees to be continued as a treatment due to ease of use, comfort factor and positive results Patient compliance was not an issue' D) The data below pertains to six combinations of settings and care provided in the following format: average (peak) pressure in standard care; average (peak) pressure in low-friction bootees; all in mmHg. Note that sometimes the standard care group has a

						peak pressure given for a specific heel, but the intervention group does not, and that sometimes several time measurements are given for the intervention but not for standard care. 1) 45 (124) | 27 (79) 2) 28 (104) | 23 (65) 3) 63 (195) | immediate 44 (122) after 10 min 39 (83) 4) 21 (51) | 15 (36) 5) 42 (214) | 34 (99) 6) 24 (78) | immediate 29 (49) after 10 min 21 (35)
Cleves et al. (unpublished)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Appendix D – Literature search strategy

Search results

Searches conducted by NICE gIS, RIS and text files supplied to EAC for import to reference library.

Databases*	Date searched	No retrieved	Version/files	Records imported by EAC to reference library with automatic de-duplication
MEDLINE (Ovid)	13/11/2020	28	1946 to November 12, 2020	28
MEDLINE In-Process (Ovid)	13/11/2020	2	1946 to November 12, 2020	2
MEDLINE ePub ahead of print (Ovid)	13/11/2020	9	November 12, 2020	9
EMBASE (Ovid)	13/11/2020	48 + 14 conference abstracts	1974 to 2020 November 12	48 + 14
CDSR (Wiley)	13/11/2020	2	Issue 11 of 12, November 2020	1
CENTRAL (Wiley)	13/11/2020	2	Issue 11 of 12, November 2020	2
**Database of Abstracts of Reviews of Effects – DARE (CRD)	13/11/2020	1	-	1
HTA database (CRD)	13/11/2020	1	-	1
**NHS EED (CRD	13/11/2020	0	-	N/A
Econlit (Ovid - for economic searches)	13/11/2020	1	1886 to November 05, 2020	1
			Total	107
			Total after manual de-duplication	78

Search strategies

Database: MEDLINE
Strategy used: Database: Ovid MEDLINE(R) <1946 to November 12, 2020> Search Strategy: ---------- 1 Parafricta*.tw. (3) 2 exp Skin ulcer/ (45483) 3 Pressure Ulcer/ (12399) 4 Skin/ and Ulcer/ (209) 5 ((skin or pressure or decubital) adj4 (ulcer* or sore* or blister*)).tw. (17397) 6 (bed sore* or bedsore*).tw. (621) 7 decubitus.tw. (4570) 8 ((frail* or fragil* or delicate*) adj4 skin).tw. (1058) 9 exp epidermolysis bullosa/ (5035) 10 (epidermolys* adj4 bullosa*).tw. (4869) 11 ("butterfly child*" or "cotton wool bab*" or "crystal skin child*").tw. (2) 12 or/2-11 (61998) 13 Protective Clothing/ (5958) 14 (protective adj4 (clothes or clothing)).tw. (1618) 15 Shoes/ (6331) 16 (boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*).tw. (30939) 17 Textiles/ (5007) 18 (fabric or fabrics or textile*).tw. (13395) 19 or/13-18 (53156) 20 friction/ (3964) 21 friction.tw. (9078) 22 (skin adj4 (breakdown or damag*)).tw. (6697) 23 (shear or scar*).tw. (181537) 24 or/20-23 (197426) 25 12 and 19 and 24 (92) 26 1 or 25 (92) 27 animals/ not humans/ (4722437) 28 26 not 27 (92) 29 limit 28 to english language (87) 30 limit 29 to ed=20140401-20201130 (28)

Database: MEDLINE in Process
Strategy used:

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <1946 to November 12, 2020>
Search Strategy:
---
1 Parafricta*.tw. (0)
2 exp Skin ulcer/ (0)
3 Pressure Ulcer/ (0)
4 Skin/ and Ulcer/ (0)
5 ((skin or pressure or decubital) adj4 (ulcer* or sore* or blister*)).tw. (2059)
6 (bed sore* or bedsore*).tw. (89)
7 decubitus.tw. (506)
8 ((frail* or fragil* or delicate*) adj4 skin).tw. (130)
9 exp epidermolysis bullosa/ (0)
10 (epidermolys* adj4 bullosa*).tw. (402)
11 ("butterfly child*" or "cotton wool bab*" or "crystal skin child*").tw. (1)
12 or/2-11 (3025)
13 Protective Clothing/ (0)
14 (protective adj4 (clothes or clothing)).tw. (177)
15 Shoes/ (0)
16 (boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*).tw. (5820)
17 Textiles/ (0)
18 (fabric or fabrics or textile*).tw. (4558)
19 or/13-18 (10353)
20 friction/ (0)
21 friction.tw. (6594)
22 (skin adj4 (breakdown or damag*)).tw. (820)
23 (shear or scar*).tw. (43183)
24 or/20-23 (49739)
25 12 and 19 and 24 (2)
26 1 or 25 (2)
27 animals/ not humans/ (1)
28 26 not 27 (2)
29 limit 28 to english language (2)

Database: MEDLINE ePubs

Strategy used:

Database: Ovid MEDLINE(R) Epub Ahead of Print <November 12, 2020>
Search Strategy:
---
1 Parafricta*.tw. (0)
2 exp Skin ulcer/ (0)
3 Pressure Ulcer/ (0)

4 Skin/ and Ulcer/ (0)
5 ((skin or pressure or decubital) adj4 (ulcer* or sore* or blister*)).tw. (367)
6 (bed sore* or bedsore*).tw. (7)
7 decubitus.tw. (67)
8 ((frail* or fragil* or delicate*) adj4 skin).tw. (28)
9 exp epidermolysis bullosa/ (0)
10 (epidermolys* adj4 bullosa*).tw. (82)
11 ("butterfly child*" or "cotton wool bab*" or "crystal skin child*").tw. (0)
12 or/2-11 (511)
13 Protective Clothing/ (0)
14 (protective adj4 (clothes or clothing)).tw. (26)
15 Shoes/ (0)
16 (boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*).tw. (956)
17 Textiles/ (0)
18 (fabric or fabrics or textile*).tw. (332)
19 or/13-18 (1300)
20 friction/ (0)
21 friction.tw. (276)
22 (skin adj4 (breakdown or damag*)).tw. (152)
23 (shear or scar*).tw. (5137)
24 or/20-23 (5521)
25 12 and 19 and 24 (9)
26 1 or 25 (9)
27 animals/ not humans/ (0)
28 26 not 27 (9)
29 limit 28 to english language (9)

Database: Embase

Strategy used:

Database: Embase <1974 to 2020 November 12>
Search Strategy:
---
1 Parafricta*.tw,dv,dm. (7)
2 exp Skin ulcer/ (72765)
3 Skin/ and Ulcer/ (2009)
4 Decubitus/ (21230)
5 ((skin or pressure or decubital) adj4 (ulcer* or sore* or blister*)).tw. (26958)
6 (bed sore* or bedsore*).tw. (1043)
7 decubitus.tw. (7329)
8 ((frail* or fragil* or delicate) adj4 skin).tw. (1820)
9 exp epidermolysis bullosa/ (7961)
10 (epidermolys* adj4 bullosa*).tw. (6872)

11 ("butterfly child*" or "cotton wool bab*" or "crystal skin child*").tw. (5)
12 or/2-11 (97382)
13 Protective Clothing/ (10858)
14 (protective adj4 (clothes or clothing)).tw. (2197)
15 Shoe/ (9678)
16 (boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*).tw. (50077)
17 Textile/ (5916)
18 (fabric or fabrics or textile*).tw. (22018)
19 or/13-18 (84650)
20 friction/ (10040)
21 friction.tw. (16293)
22 (skin adj4 (breakdown or damag*)).tw. (10786)
23 Shear stress/ (29321)
24 (shear or scar*).tw. (296504)
25 or/20-24 (330546)
26 12 and 19 and 25 (164)
27 1 or 26 (167)
28 nonhuman/ not human/ (4740676)
29 27 not 28 (167)
30 limit 29 to english language (153)
31 limit 30 to dc=20140401-20201130 (62)
32 limit 31 to (conference abstract or conference paper or "conference review") (14)
33 31 not 32 (48)

Database: Cochrane

Strategy used:

Search Name: MTG20 Parafricta_2020 review
Date Run: 13/11/2020 09:04:34
Comment:

ID	Search	Hits
#1	(Parafricta*):ti,ab,kw	1
#2	MeSH descriptor: [Skin Ulcer] explode all trees	2866
#3	MeSH descriptor: [Pressure Ulcer] this term only	745
#4	MeSH descriptor: [Skin] this term only	3989
#5	MeSH descriptor: [Ulcer] this term only	1351
#6	#4 and #5	4
#7	(((skin or pressure or decubital) near/4 (ulcer* or sore* or blister*))):ti,ab,kw	3040
#8	((bed sore* or bedsore*)):ti,ab,kw	244
#9	(decubitus):ti,ab,kw	1286
#10	(((frail* or fragil* or delicate*) near/4 skin)):ti,ab,kw	44
#11	MeSH descriptor: [Epidermolysis Bullosa] explode all trees	53

#12 ((epidermolys* near/4 bullosa*)):ti,ab,kw 135
#13 ((butterfly NEXT child* or cotton NEXT wool NEXT bab* or crystal NEXT skin NEXT child*)):ti,ab,kw 2
#14 #2 or #3 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 5937
#15 MeSH descriptor: [Protective Clothing] this term only 244
#16 ((protective near/4 (clothes or clothing))):ti,ab,kw 457
#17 MeSH descriptor: [Shoes] this term only 401
#18 ((boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*)):ti,ab,kw 4717
#19 MeSH descriptor: [Textiles] this term only 60
#20 ((fabric or fabrics or textile*)):ti,ab,kw 499
#21 #15 or #16 or #17 or #18 or #19 or #20 5547
#22 MeSH descriptor: [Friction] this term only 52
#23 (friction):ti,ab,kw 536
#24 ((skin near/4 (breakdown or damag*))):ti,ab,kw 714
#25 ((shear or scar*)):ti,ab,kw 12889
#26 #22 or #23 or #24 or #25 14026
#27 #14 and #21 and #26 16
#28 #1 or #27 with Cochrane Library publication date Between Apr 2014 and Nov 2020 13
#29 "conference":pt or (clinicaltrials or trialsearch):so 512719
#30 #28 not #29 4

Database: CRD

Strategy used:

Line	Search	Hits	
☐	1	(parafricta*)	1
☐	2	MeSH DESCRIPTOR skin ulcer EXPLODE ALL TREES	437
☐	3	MeSH DESCRIPTOR Pressure Ulcer	169
☐	4	MeSH DESCRIPTOR Skin	84
☐	5	MeSH DESCRIPTOR Ulcer	24
☐	6	#4 AND #5	0
☐	7	(skin or pressure or decubital) AND (ulcer* or sore* or blister*)	495
☐	8	(bed sore* or bedsore*)	7
☐	9	(decubitus)	20

☐	10	(frail* or fragil* or delicate*) AND (skin)	7
☐	11	MeSH DESCRIPTOR epidermolysis bullosa EXPLODE ALL TREES	5
☐	12	(epidermolys* and bullosa*)	8
☐	13	("butterfly child*" or "cotton wool bab*" or "crystal skin child*")	0
☐	14	#2 OR #3 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	684
☐	15	MeSH DESCRIPTOR Protective Clothing	25
☐	16	(protective) AND (clothes or clothing)	34
☐	17	MeSH DESCRIPTOR Shoes	34
☐	18	((boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*))	2191
☐	19	MeSH DESCRIPTOR Textiles	3
☐	20	((fabric or fabrics or textile*))	15
☐	21	#15 OR #16 OR #17 OR #18 OR #19 OR #20	2237
☐	22	#14 AND #21	73
☐	23	MeSH DESCRIPTOR friction	2
☐	24	(friction)	88
☐	25	(skin) AND (breakdown or damag*)	112
☐	26	(shear or scar*)	590
☐	27	#23 OR #24 OR #25 OR #26	774
☐	28	#21 AND #27	52
☐	29	#1 OR #28	52

Note: Only 2 results found since 2014. 1 DARE record and 1 HTA record

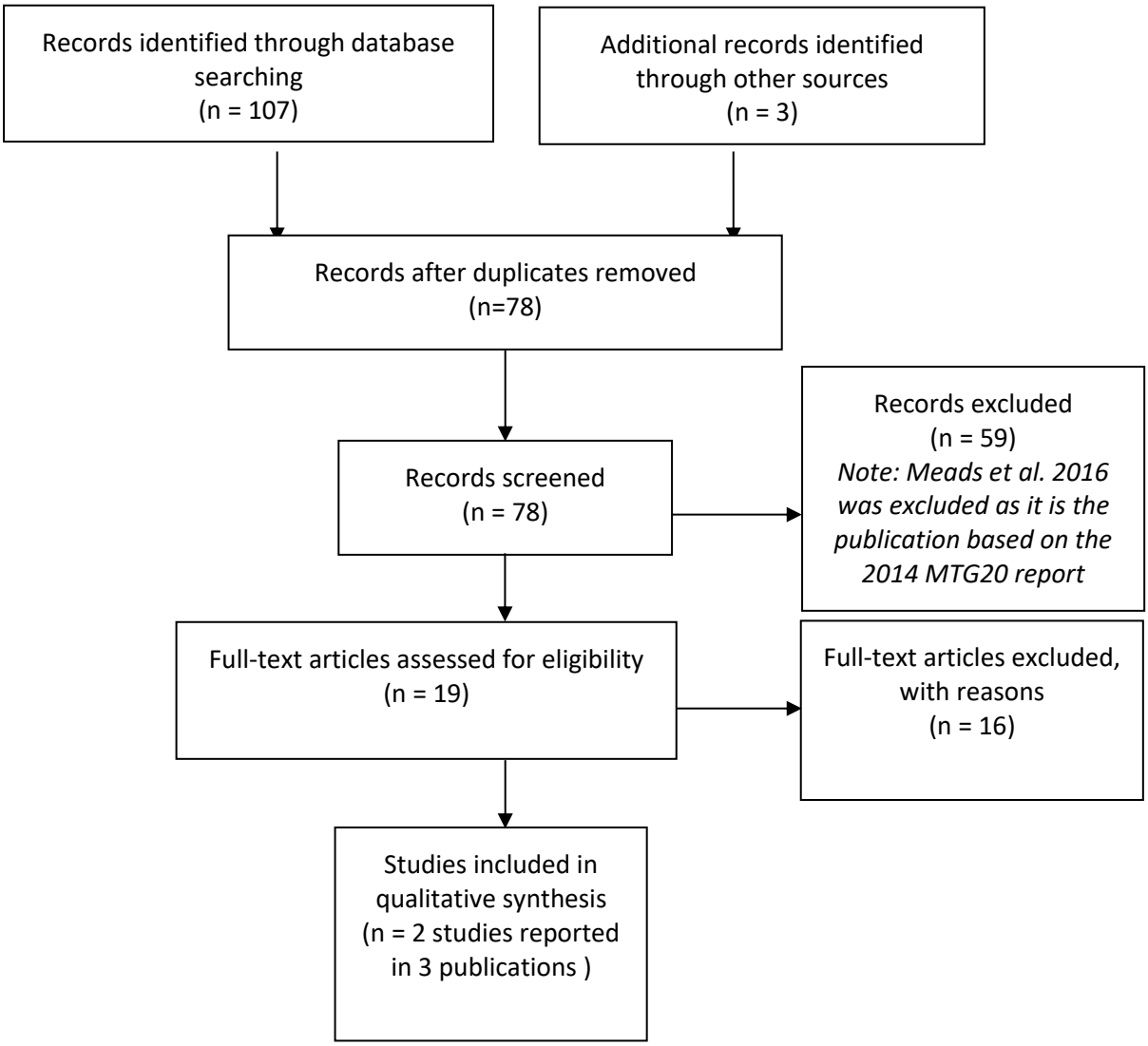
Database: Econlit

Strategy used:

Database: Econlit <1886 to November 05, 2020>
Search Strategy:
---
1 Parafricta*.tw. (1)

2 [exp Skin ulcer/] (0)
3 [Pressure Ulcer/] (0)
4 [Skin/ and Ulcer/] (0)
5 ((skin or pressure or decubital) adj4 (ulcer* or sore* or blister*)).tw. (20)
6 (bed sore* or bedsore*).tw. (2)
7 decubitus.tw. (0)
8 ((frail* or fragil* or delicate*) adj4 skin).tw. (0)
9 [exp epidermolysis bullosa/] (0)
10 (epidermolys* adj4 bullosa*).tw. (1)
11 ("butterfly child*" or "cotton wool bab*" or "crystal skin child*").tw. (0)
12 or/2-11 (23)
13 [Protective Clothing/] (0)
14 (protective adj4 (clothes or clothing)).tw. (2)
15 [Shoes/] (0)
16 (boot* or shoe* or footwear or undergarment* or briefs or boxers or "boxer shorts" or garment* or underwear* or under-wear* or knicker* or pants*).tw. (6338)
17 [Textiles/] (0)
18 (fabric or fabrics or textile*).tw. (3516)
19 or/13-18 (9590)
20 [friction/] (0)
21 friction.tw. (1194)
22 (skin adj4 (breakdown or damag*)).tw. (4)
23 (shear or scar*).tw. (7965)
24 or/20-23 (9149)
25 12 and 19 and 24 (1)
26 1 or 25 (1)
27 [animals/ not humans/] (0)
28 26 not 27 (1)

Study selection



List of excluded articles from the full-text assessment stage. Note that first two entries are mentioned in section 4.8.

First Author	Year	Title	Comment
Gefen	2017	Why is the heel particularly vulnerable to pressure ulcers?	Review (not systematic)
Cunningham	2018	Reducing the incidence of heel pressure ulcers; pressure ulcer change package project	Conference abstract
Petcu	2016	Analysis of the effectiveness of an orthotic solution for the diabetic foot	Conference abstract; no mention of Parafricta
Morey	2010	Applied biomechanics: Footwear industry	Conference abstract; no mention of Parafricta
Minshall	2014	Characteristics and health care resource utilization of type 2 diabetes mellitus (T2DM) patients using therapeutic footwear	Conference abstract; no mention of Parafricta
Crisologo	2019	Conservative Offloading	No mention of Parafricta
van Netten	2018	Diabetic Foot Australia guideline on footwear for people with diabetes	No mention of Parafricta
Fletcher	2016	Does friction play a role in the occurrence of pressure ulcers?	No mention of Parafricta
Khan	2012	Podiatry assessment for epidermolysis bullosa	No mention of Parafricta
Janisse	2015	Pedorthic management of the diabetic foot	No mention of Parafricta
Lavery	2015	Randomised clinical trial to compare total contact casts, healing sandals and a shear-reducing removable boot to heal diabetic foot ulcers	No mention of Parafricta
Cychosz	2016	Preventive and therapeutic strategies for diabetic foot ulcers	Expert opinion; no mention of Parafricta
Larionov	2017	Treatment of lymphedema in case of complications	Conference abstract; no mention of Parafricta
Bardhan	2018	Epidermolysis bullosa and gait analysis: One big step toward improving quality of life	Conference abstract; no mention of Parafricta
Reinar	2019	Interventions for ulceration and other skin changes caused by nerve damage in leprosy	No mention of Parafricta
Viswanathan	2020	Foot care practices among Diabetologists in India: A descriptive study by the Diabetic Foot Research India	No mention of Parafricta

Appendix E – References

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5. Gefen, A., 2017. Why is the heel particularly vulnerable to pressure ulcers?. British Journal of Nursing, 26(Sup20), pp.S62-S74.

6. Gleeson, D., 2015. Pressure-ulcer reduction using low-friction fabric bootees. British Journal of Nursing, 24(Sup6), pp.S26-S29.

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8. [redacted]

9. McCoulough, S., 2016. Implementing an adapted SSKIN bundle and visual aid in the community setting. Wounds UK, 12(1).

10. NCT04023981. Parafricta Bootees vs UK Standard Care to Prevent Heel Pressure Ulcers. https://clinicaltrials.gov/ct2/show/results/NCT04023981 Accessed 12/02/2021 01

11. NHS Digital. Hospital Episode Statistics 2016-20. NHS Digital. 2020. Available at: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics

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13. Schofield, A., 2018. Mitigating the damaging effects of tissue distortions by using a low-friction heel protector. British Journal of Nursing, 27(Sup12), pp.S27-S34.

14. Smith G, Ingram A., 2010. Clinical and cost effectiveness evaluation of low friction and shear garments. Journal of wound care, 19(12):535-542

15. Weston, P. 2016. Nurse's bootee brainwave saves the NHS £200,000. Liverpool Echo (10th December) https://www.liverpoolecho.co.uk/news/liverpool-news/nurses-bootee-brainwave-saves-nhs-12300869