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ORIGINAL RESEARCH

Pain Relief and Protection of Corns, Calluses and Bunions Using COMPEED® Foot Care Hydrocolloid Plasters: A Prospective Non-Interventional Study in Primary Care/Community Pharmacies

Jérôme Zakka Bajjani[1], Pascale Auzou[1], Hubert Paniez[1], Maria Katsogiannou[2], Véronique Chapalain[2], Carole Pierre[2], Sandra Wiederkehr[2], Rémi Gauchoux[2], Matthieu Gauthier[3], Cécile Artus-Arduise[1]

[1]Laboratoire HRA Pharma, A Perrigo company, Chatillon, France; [2]ICTA PM, Fontaine les Dijon, France; [3]Totum Pharmaciens, Paris, France

Correspondence: Jérôme Zakka Bajjani, Laboratoire HRA Pharma, A Perrigo company, Chatillon, France, Email jerome.zakka-bajjani@perrigo.com

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Purpose: Pathologic hyperkeratosis due to skin thickness increase includes corn, callous, and bunion. These conditions can cause important pain and discomfort. Treatment relies on eliminating the cause of friction and/or rubbing. Moreover, hydrocolloid occlusive dressings rehydrate hard skin, leading to maceration, facilitating removal of dead skin. Our goal was to further confirm real-life clinical performance and benefits of COMPEED® Foot Care plasters in providing pain/discomfort relief, protection and cushioning of corns, calluses and bunions.

Patients and Methods: This was a non-interventional, longitudinal, multi-center investigation, conducted from July 2021 until February 2022, during which participants were enrolled in 36 community pharmacies in France. Eligible participants were ≥18 years old at enrolment, presented painful corn, callous and/or bunion on at least one foot, accepted to buy from the participating pharmacist at least one box of targeted COMPEED® Foot Care plasters, to be used according to their instructions for use.

Results: Overall, 417 participants gave their consent to participate in the study, and analysis was performed on 391 participants: 199 with corn, 106 with callous, 87 with bunion, whose median age was, respectively, 55.0, 59.0 and 55.0 years old (overall ranging 20.0 to 94.0 years old). Among participants with either of the 3 conditions, 21.7–37.9% reported instant pain/discomfort relief upon plaster application and an increasing number of participants with corns, calluses or bunions reported pain/discomfort elimination over the 21-days follow-up period. Significant increases in pressure relief and cushioning were also observed during follow-up in all 3 conditions. Median duration of plasters was 3 days. At study end, 66.0% of participants with calluses and up to 73.0% with corns reported their condition was removed.

Conclusion: This investigation demonstrated and confirmed COMPEED® Foot Care plasters clinical benefits in pain/discomfort and pressure relief, cushioning against rubbing/friction of corns, calluses and bunions, and adhesion to skin, in the general population.

Keywords: hydrocolloid plasters, foot corn, foot callus, bunion, cushioning, pain/discomfort relief

Introduction

Prolonged compression and/or friction of the skin results in skin thickness increase (called hyperkeratosis) at these sites of excessive mechanical stress. Hyperkeratosis is a normal protective response of the skin, which becomes pathological when it grows large and becomes a source of symptoms.[1] Intrinsic factors such as genetic anatomical predisposition creating spinal or foot deformities (eg, flat feet), as well as systemic diseases (eg, gout, rheumatoid arthritis) contribute to hyperkeratosis.[2,3] Several extrinsic factors, including restrictive or worn-down footwear, bare feet, wrong training methods or overtraining, may also be involved in hyperkeratosis. Pathologic hyperkeratosis includes corn, callus, and bunion.[2] All 3 conditions can cause such pain and discomfort that is sufficiently severe to affect shoe choice or

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compromise participant's daily activities.[4] Indeed, it has been shown among a large number of patients that corns (among other non-fungal foot diseases) induce pain in 35.5% of patients, discomfort in walking in 46.9%, limitations in daily activities in 22.7% and embarrassment in 27.1% of patients.[5] Consistent with previous research, a recent descriptive study on 10 participants confirmed the negative impact of painful hallux valgus on health related qualify of life, including pain, reduced function, distress, and challenges with footwear.[6]

Corns are circumscribed sharply demarcated areas of hyperkeratotic plaque over the bony prominences of feet and toes.[1] They have a visible translucent central core which presses deeply into the dermis, causing pain and sometimes inflammation. This central core distinguishes the corn from the callus. Calluses are broad-based, diffuse areas of hyperkeratosis of relatively even thickness. They are less circumscribed than corns, usually larger, do not have a central core, and may or may not be painful.[7] Corns and calluses prevalence is 26%.[8] Bunions develop over the first metatarsophalangeal (MTP) joint as a result of a hallux valgus abduction contracture, which is a lateral deviation of the first toe.[9] It is the most common forefoot problem in adults.[10] Over time, and if not treated, the foot deformity progresses, causing internal subluxation with articular deterioration, and there may be callus formation on the bunion. It can interfere with daily activities and affects the quality of life of many people. Hallux valgus prevalence may reach 23% in adults from 18 to 65 years and up to 74% in older adults.[10] The pain associated with a bunion is caused by pressure and frictional force exerted on the skin, soft tissue, and bursa at the medial prominence of the first MTP joint.

Treatment of corns/calluses conditions and of bunion symptoms relies on elimination of the cause of friction and/or rubbing. This may include conservative measures, such as the use of pad cushions or well-fitting shoes. Moisturizing creams may help soften the skin.[11] Nevertheless, if nothing is done to eliminate the origin of friction or rubbing, the skin could become thicker and more painful over time and in the case of corn and calluses, they may return despite moisturizing treatments. The initial treatment of bunions is primarily conservative providing short-term symptomatic pain relief for mild-to-moderate forms, addressing the participant's footwear. Surgery may be considered if pain persists or progresses in case of partial or complete failure of conservative measures.[12]

Occlusive dressings control skin surface moisture and enhance the re-epithelialization rate compared to dry conditions.[13] In addition, and of particular relevance to corn, callus, and bunion, hydrocolloid occlusive dressing rehydrates the hard skin, leading to maceration, which facilitates the removal of dead skin.

This study was part of a group of three clinical investigations on COMPEED® hydrocolloid plasters.[14,15] The goal of this study was to further confirm in real-life settings the clinical performances and benefits of COMPEED® Foot Care plasters in providing pain/discomfort relief, protection and cushion against rubbings/frictions of corns, calluses and bunions.

Materials and Methods

Study Design and Participants

This was a non-interventional, longitudinal, multi-center investigation, conducted from July 2021 until February 2022, during which participants were enrolled in 36 community pharmacies in France.

Eligible participants were aged 18 years old or more at enrolment, presented with painful corn, callus and/or bunion on at least one foot, accepted to buy in the participating pharmacy at least one box of targeted COMPEED® Foot Care plasters, to be used according to their instruction for use. Participants understood the full nature and purpose of the study, were willing to give an oral consent and were willing to complete the French questionnaire booklet and bring it back to the pharmacy. Finally, they had to be covered by healthcare insurance. Those excluded from the investigation were participants presenting with a contraindication/hypersensitivity/allergy to any component of any plaster, receiving or planning to receive any other treatment for corn, callus and/or bunion, including consultation by a podiatrist for corn/callus removal during the study participation. The expected participant's study duration was up to 24 days upon inclusion or complete corn/callus removal (whichever came first), knowing that the first plaster application could take place within 3 days after inclusion. This 24-days study period was also applicable to participants with bunions since this is a condition that cannot be removed (unlike corn and callus). The end of the study was defined as the date of completion of the last expected ePRO questionnaire.

Investigational Product

The COMPEED® Foot Care plasters considered in this clinical investigation are all medical devices, intended to be used to protect and cushion the concerned area from external rubbing, to relieve pain from corns, calluses and bunions on feet and to provide continuous moisturization. They are non-invasive and non-sterile dressings composed of a semi-permeable membrane (polyurethane film) allowing the skin/wound to breathe and protecting it from external contaminants such as dirt and bacteria; a hydrocolloid adhesive, adhering to skin and providing wound micro-environment moisturizing capabilities. Five hydrocolloid plasters of the COMPEED® Foot Care range were used during the investigation: COMPEED® Foot Care Corn (herein referred to as Corn), COMPEED® Foot Care Corn between toes (Corn between toes), COMPEED® Foot Care Moisturizing Corn (Moisturizing Corn), COMPEED® Foot Care (Callous), COMPEED® Foot Care Bunion (Bunion).

Ethical Aspects

The protocol and verbal informed consent procedure were reviewed and approved by the French Ethics Committee (EC) Sud-Méditerranée 3, on June 30th, 2021, prior to inclusion of participants. This clinical investigation was conducted in compliance with the latest version of the Declaration of Helsinki (October 2013), the international standard EN ISO 14155:2020 ("Clinical Investigation of medical devices for human subjects – Good Clinical Practice"), Regulation (EU) 2017/745 of 5 April 2017, MEDDEV 2.12/2 Post market clinical follow-up studies, for France, French Public Health Code. Before any inclusion, the participating pharmacist provided patients with the information/non-opposition note as well as an oral explanation before their decision to participate or abstain from participation, in order to inform patients of the purpose of processing of the collected data, the nature of data transmitted, the recipients of data and of their right of access, rectification, limitation, restriction of processing or to object to processing as well as their right to refuse the transmission of their data. Oral consent was obtained by all participants before the start of any study-related procedure and date of oral consent was recorded in the dedicated electronic Case Report Form (eCRF).

Study Procedures

Upon participant enrolment, participating pharmacists verified the eligibility criteria and confirmed participant's condition (corn including severe/recurrent corn, callus, bunion), chose the foot (feet) to be considered for the study, according to the most appropriate plaster type bought by the participant and collected baseline study data (including socio-demographics, basic clinical characteristics) of interest through a dedicated eCRF. Then, the pharmacist asked the participant to evaluate his/her current level of pain/discomfort with regard to their condition(s) using an 11-points (0–10) Numeric Rating Scale (NRS) and provided the participant with the dedicated paper-based questionnaire according to their condition to be completed over the study follow-up period. Study follow-up data were reported directly by enrolled participants on a dedicated paper questionnaire at D0' (day of 1st plaster application), D2 (day 2 after 1st plaster application), D8 (day 8 after 1st plaster application) and Dlast (end of study, either maximum 20 days after 1st plaster application occurring up to 3 days after inclusion or complete removal of corn/callus as assessed by the participant) and upon plaster change anytime during the study period. At the end of the study period, participants gave their pharmacists their completed questionnaire.

Primary Outcome

Pain/Discomfort Relief

Instant pain/discomfort relief at D0' ie upon first plaster application after putting on shoes, with respect to Baseline (D0). An instant pain/discomfort relief was defined by a decrease of at least 1 point in the 11-points NRS used to rate the pain/discomfort between 2 time points, D0 and D0' (0: "no pain/discomfort at all" and 10: "worst possible pain/discomfort"). Pain/discomfort was rated at each time point (D0, D0', D2, D8 and Dlast) using the same NRS as the primary endpoint. Pain/discomfort relief and/or pain elimination (Pain elimination being defined as a score of 0 on the NRS over the study follow-up period) with respect to Baseline at DX (Day X), was defined as a decrease in the NRS between D0 and DX.

Secondary Outcomes

Pressure Relief

The plaster's capacity to provide pressure relief was assessed at each time point (D0', D2, D8, Dlast) by a 7-point Likert scale ranging from 1 to 7 (1: "no relief" and 7: "full relief").

Duration

The duration of the first plaster was calculated in days from D0' until the first plaster change. The mean duration of the first plaster was calculated as the sum of the durations divided by the number of participants.

Softening After Plaster Change

The plaster's capacity to provide corn/callus softening was assessed at each plaster change by participants with corns and calluses, by a 7-point Likert scale ranging 1 to 7 (1: "no softening" and 7: "complete softening").

Healing State/Removal

The healing/removal of corn and callus was assessed at each plaster's change and described as: Not healed-removed at all/Partially healed-removed/Fully healed-completely removed.

Cushioning

The overall plaster cushioning capacity was assessed at Dlast by a 7-point Likert scale ranging from 1 to 7 (1: "no cushioning at all" and 7: "excellent cushioning").

Adhesion

The overall plaster adhesion capacity was assessed at Dlast by a 7-point Likert scale ranging from 1 to 7 (1: "no adhesion" and 7: "excellent adhesion").

Global Perception/Satisfaction

The plaster global impression on improvement and satisfaction were assessed at the end of the study (Dlast). Participant's global perception on improvement of condition was rated using a 7-point Likert scale (1: "very much worse" and 7: "very much better"); participant's overall satisfaction using a 7-point Likert scale (1: "very unsatisfied" and 7: "very satisfied"); participant's likeliness to recommend COMPEED® Foot Care plaster to family/friends assessed using a 5-point Likert scale (1: "certainly not" and 5: "absolutely") and participant's willingness to use the plaster again (yes and no).

Medical Device Vigilance

The Medical Device Vigilance corresponds to the collection of all adverse device effects (ADE) related to each COMPEED® Foot Care hydrocolloid plaster.

Statistical Analysis

Six analysis populations were defined:

- Consented set consisted of all participants who gave their consent.
- Enrolled sets:
  - Enrolled pharmacist set consisted of all selected pharmacists having accepted to participate in the study.
  - Enrolled participant set consisted of all participants presenting the condition of interest enrolled by the pharmacist, with condition filled in the eCRF and having sent back a questionnaire. There was one enrolled set of participants per condition (corn, callus and bunion). The enrolled participant set was used to describe the disposition of participants.
- Participating set composed of all pharmacists having recruited at least one participant presenting the condition of interest. This set described the disposition of pharmacists.
- Safety set consisted of all participants having used at least once COMPEED® Foot Care plaster. There was one safety set of participants per condition (corn, callus, and bunion). The safety set was used to describe ADEs with

COMPEED® Foot Care plasters. It was assumed that participants who did not send back a questionnaire have not used the plasters within the context of the study.

- Reference set consisted of all enrolled participants having used the study COMPEED® Foot Care plaster according to the instructions for use, regardless of the duration use, and having sent back a questionnaire where the primary endpoint could be calculated. There was one reference set of participants per condition (corn, callus, and bunion). The reference set was used for the analysis of the primary and secondary outcomes (pain/discomfort relief and pressure relief).
- Principal Analysis set consisted of all participants having used a study COMPEED® Foot Care plaster, having fully completed the questions about pain/discomfort and having no major deviation from protocol. There was one principal analysis set of participants per condition (corn, callus, and bunion). This set was used only for the sensitivity analysis of the primary outcome.

Statistical analyses were performed separately for each condition at the end of the study. All statistical analyses were performed using Statistical Analysis Systems (SAS®) release 9.4. The Agresti-Coull 95% confidence intervals (CI) were provided for discrete variables and the Wald 95% CI for continuous variables. The statistical significance of the evolution with respect to baseline of each parameter measured at baseline and in evolution, evaluated by the participant, was appreciated by using a statistical test for paired data (Mac Nemar test, paired *t*-test or signed-rank test of Wilcoxon, as adapted and applicable). Descriptive analysis of the level of pain/discomfort as evaluated by the participant using the NRS was performed at Baseline (D0) and at D0'. Moreover, the absolute and relative changes from baseline at D0' in the pain/discomfort were described. The percentage of participants experiencing instant pain/discomfort relief at D0' with respect to baseline (ie, absolute change from baseline (NRS at D0 – NRS at D0') > 0) was computed and the corresponding 95% CI displayed. Moreover, a paired *t*-test or its non-parametric equivalent was used to confirm that the mean change from baseline at D0' was statistically significantly >0. All secondary analyses were descriptive analyses. The statistical significance level of the various two-sided tests performed was 5.0%.

Results

Participant's Disposition and Baseline Characteristics

From July 7th, 2021, to January 29th, 2022, a total of 124 pharmacists were initiated, of whom a total of 36 (29.0%) enrolled at least one participant. Overall, 417 participants gave their oral consent to participate in the study: 208 participants with corn, 113 participants with callus and 93 participants with bunion; one participant presented with corn and bunion and participated in both conditions but was counted once in the total sample size per set (Figure 1). Three participants who consented (0.7%) were considered as screen failures as their condition at baseline was not reported and they did not send back their questionnaire. They were excluded from the Enrolled set, finally composed of 414 participants (208 participants with corn; 113 participants with callus; 93 participants with bunion). Of these participants, 21 (5.1%) had no available post-baseline data, and it was assumed that participants who did not send back a questionnaire have not used the plasters within the context of the study; they were thus excluded from the Safety set (199 participants with corn; 107 participants with callus; 87 participants with bunion). Among these 393 participants, 1 participant provided at least one key post-baseline data but had unknown condition and 1 participant had missing level of pain at D0', so the primary endpoint could not be calculated. These 2 participants were excluded from the Reference set. Among the 391 participants (including the participant with both corn and bunion) in the Reference set, there were 199 participants with corn, 106 participants with callus; 87 participants with bunion. Among these participants, 42 were excluded for major protocol deviations: level of pain/discomfort at D0 equal to 0 (n_{all} = 4), non-respect of the time-window for D0' (n_{all} = 24), pain/discomfort not assessed at each time (n_{all} = 13) or level of pain at D0 missing and level of pain at D0' missing (n_{all} = 1); resulting in 349 participants in the Principal Analysis set (Figure 1).

Median age of participants with corn (co), callus (ca) or bunion (bu) was, respectively, 55.0, 59.0 and 55.0 years old (overall ranging 20.0 to 94.0 years old) (Table 1). Over 60.0% of participants in the 3 conditions were women. Most participants either had normal weight (n_{co}=84; 42.2%, n_{ca}=32; 30.2%, n_{bu}=42; 48.3%) or were overweight (n_{co}=83; 41.7%,

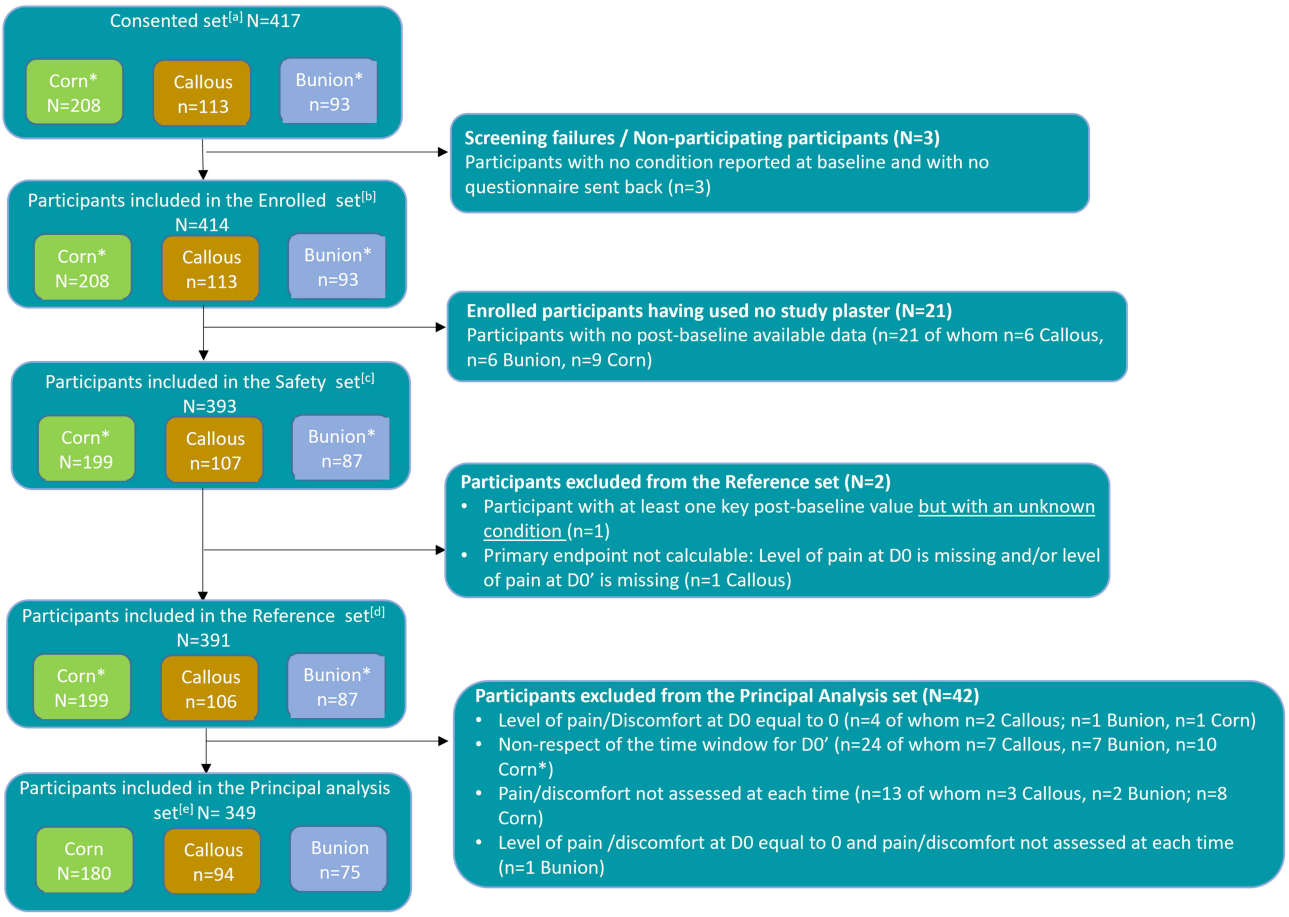

Figure 1 Study Flow chart. Flow chart of participants enrolled and included in the analysis sets of the study. *One participant was enrolled for both corn and bunion conditions but was only considered once in each concerned set. **[a]** Consented set: All participants who gave their consent. **[b]** Enrolled set: All consented participants presenting the condition of interest enrolled by the pharmacist, with condition filled in the eCRF and having sent back a questionnaire. **[c]** Safety set: All enrolled participants having applied at least one COMPEED® Foot Care Plaster. **[d]** Reference set: All enrolled participants having applied a COMPEED® Foot Care Plaster according to the instructions for use, regardless of the duration use, and having sent back a questionnaire where the primary endpoint can be calculated. **[e]** Principal Analysis set: All enrolled participants having applied a COMPEED® Foot Care Plaster, having fully completed the pain/discomfort assessment part of the questionnaire and having no major deviation from protocol.

n_{ca}=52; 49.1%, n_{bu}=38; 43.7%), with comparable proportions among the 3 conditions. Proportions of participants performing different types of physical activities were comparable among participants with corn, callus, or bunion (Table 1): over 50.0% of all participants performed walking/hiking. Most participants with corn performed a physical activity less than 1 time/week (n_{co}=100; 50.3%); most participants with callus were physically active either never (n_{ca}=29; 27.4%) or less than 1 time/month (n_{ca}=29; 27.4%); most participants with bunion performed a physical activity less than 1 time/month (n_{bu}=34; 39.0%) or 1 time/week (n_{bu}=24; 27.6%). Over 55.0% of participants in all 3 conditions did not have sensitive foot skin, as per their own evaluation; over 37.0% wore street shoes and over 26.0% wore casual footwear. Over 65.0% of participants in all 3 conditions were non-smokers (Table 1). Finally, more than 73% of participants within the Reference set with corn, callus or bunion had normal feet (as opposed to flat or hollow foot).

Primary Outcome – Pain/Discomfort Relief

Pain/discomfort relief was evaluated by participants instantly after first plaster application (D0') and overall, over the follow-up period. Participants attributed a score on their experienced pain/discomfort using an NRS ranging from 0 to 10. Results are presented below for each condition separately.

Table 1 Participants' Baseline Characteristics

		Corn (N=199)[a]	Callus (N=106)	Bunion (N=87)[a]
Age (years)	Median	55.0	59.0	55.0
	Min; Max	20; 91	22; 92	18; 94
Gender	Female	130 (65.3%)	64 (60.4%)	58 (66.7%)
	Male	69 (34.7%)	42 (39.6%)	29 (33.3%)
BMI categories (Kg/m²)	< 18.5 Underweight	11 (5.5%)	2 (1.9%)	4 (4.6%)
	[18.5–25] Normal weight	84 (42.2%)	32 (30.2%)	42 (48.3%)
	[25–30] Overweight	83 (41.7%)	52 (49.1%)	38 (43.7%)
	≥ 30 Obese	21 (10.6%)	20 (18.9%)	3 (3.4%)
Physical activities	Walking/Hiking	113 (56.8%)	62 (58.5%)	44 (50.6%)
	Dancing	17 (8.5%)	3 (2.8%)	4 (4.6%)
	Running	26 (13.1%)	8 (7.5%)	13 (14.9%)
	Swimming	11 (5.5%)	7 (6.6%)	6 (6.9%)
	Other	51 (25.6%)	40 (37.7%)	28 (32.2%)
Level of activity	Never	28 (14.1%)	29 (27.4%)	17 (19.5%)
	Less than 1 time/month	50 (25.1%)	29 (27.4%)	17 (19.5%)
	2–3 times/month	22 (11.1%)	10 (9.4%)	13 (14.9%)
	1 time/week	59 (29.6%)	19 (17.9%)	24 (27.6%)
	2–3 times/week	36 (18.1%)	13 (12.3%)	12 (13.8%)
	> 3 times/week	4 (2.0%)	6 (5.7%)	4 (4.6%)
Sensitive foot skin*	Yes	62 (31.2%)	34 (32.1%)	39 (44.8%)
	No	137 (68.8%)	72 (67.9%)	48 (55.2%)
Everyday footwear habits	Running/Hiking shoes	18 (9.0%)	14 (13.2%)	12 (13.8%)
	High heels	14 (7.0%)	5 (4.7%)	7 (8.0%)
	Street shoes	74 (37.2%)	47 (44.3%)	39 (44.8%)
	Casual footwear	82 (41.2%)	31 (29.2%)	23 (26.4%)
	Boots	2 (1.0%)	2 (1.9%)	0 (0.0%)
	Slippers	6 (3.0%)	3 (2.8%)	4 (4.6%)
	Orthopaedic shoes	3 (1.5%)	4 (3.8%)	2 (2.3%)
Smoking status	Non-smoker	145 (72.9%)	69 (65.1%)	63 (72.4%)
	Previous smoker	28 (14.1%)	15 (14.2%)	12 (13.8%)
	Current smoker	26 (13.1%)	22 (20.8%)	12 (13.8%)
Type of foot	Flat foot (Fallen arch)	29 (14.6%)	18 (17.0%)	13 (15.5%)
	Normal foot	149 (74.9%)	83 (78.3%)	62 (73.8%)
	Hollow foot (High arch)	21 (10.6%)	5 (4.7%)	9 (10.3%)

Notes: Data are presented as median or n (%). [a]One participant was enrolled for both corn and bunion conditions but was only considered once in the Reference set (N=391). *as per participant's own evaluation.

Corn Condition

Among the 199 participants with corns, 39 participants (21.7%) having applied Corn/Corn between toes and 7 participants (36.8%) having applied Moisturizing Corn, reported instant pain/discomfort relief at D0' (Figure 2a). It is to note that at baseline (D0) levels of pain/discomfort in participants with corn were markedly low. Mean ± SD level of pain/discomfort reported by participants having applied Corn/Corn between toes was 5.51 ± 2.03 at D0 and statistically significantly decreased to 5.24 ± 2.14 at the first plaster application (D0') (p=0.0267). Participants having applied Moisturizing Corn plasters reported mean ± SD levels of pain/discomfort at D0 and D0' of 5.74 ± 2.28 vs 5.89 ± 1.76, respectively; a non-statistically significant difference (p=0.8082).

A sensitivity analysis of instant pain/discomfort was performed for participants having used a study plaster (Corn or Corn between toes or Moisturizing Corn plaster), having fully completed the questions about pain/discomfort and having no major deviation from protocol. The percentage of participants within the principal analysis set who reported instant pain relief/discomfort at D0' was 19.9% for those who applied Corn/Corn between toes plasters (n=32) and 36.8% for those who applied Moisturizing Corn plasters (n=7).

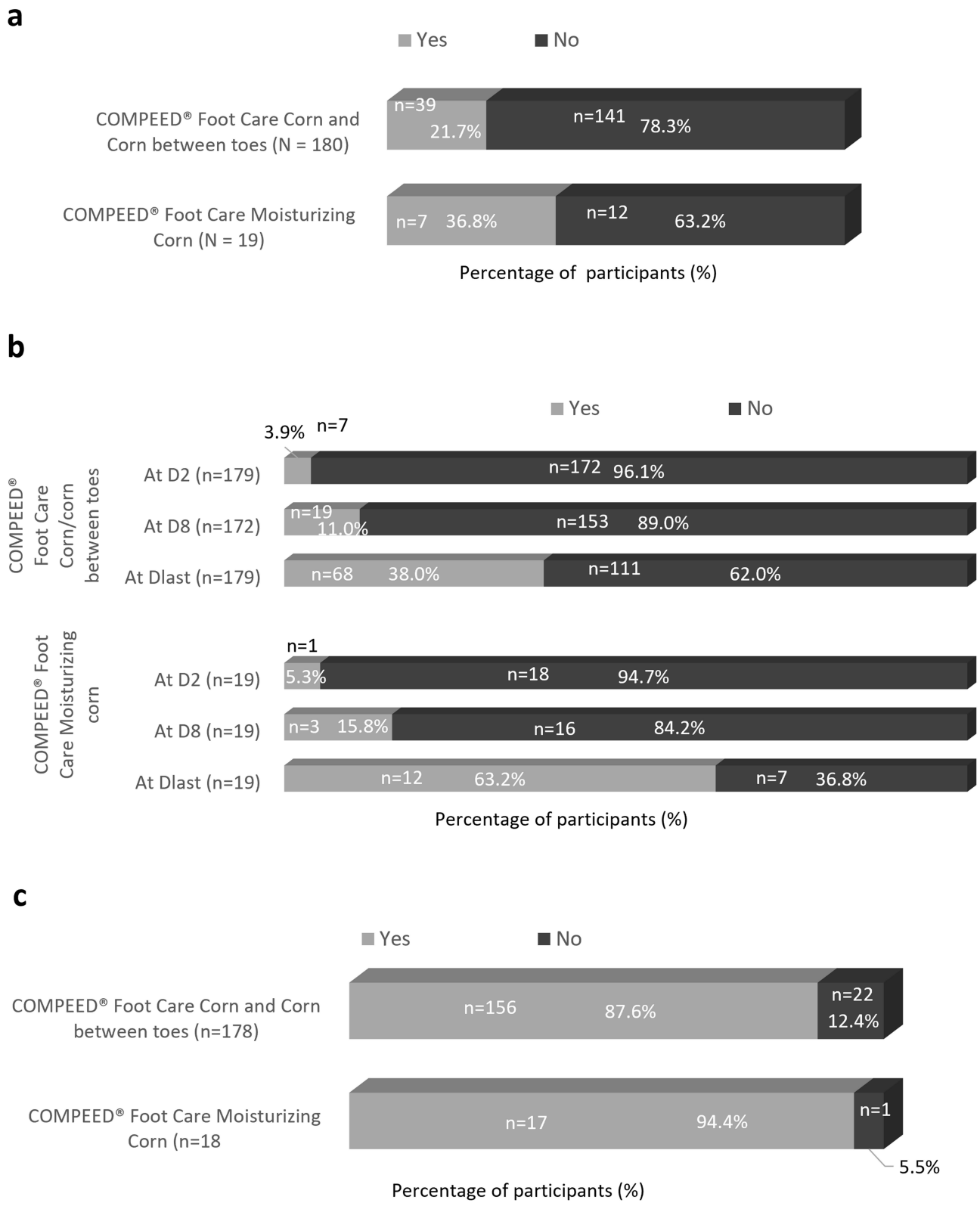

Figure 2 Pain/discomfort relief for corn condition. (**a**) Instant pain/discomfort relief was defined as a decrease of at least 1 point in the NRS between D0 and D0'. Percentage of participants reporting instant pain/discomfort relief after first plaster application (at D0'). (**b**) Percentage of participants reporting pain/discomfort elimination at D2, D8 and Dlast. Pain elimination was defined as a score of 0 over the study follow-up. (Corn/Corn between toes plasters: 1 missing value at D2, 8 missing values at D8 and 1 missing value at Dlast). (**c**) Percentage of participants reporting "good overall pain/discomfort relief" (if the overall level of pain/discomfort relief was rated as "good" + "very good" + "complete" relief); 2 missing values in Corn/Corn between toes and 1 missing value in Moisturizing Corn.

Participants were also asked to evaluate pain elimination (defined as a score of 0 over the study follow-up) over time and to give their global perception at Dlast of plaster's effectiveness on pain/discomfort relief. Among participants who applied Corn/Corn between toes plasters, 7 participants (3.9%) reported pain/discomfort elimination at D2, 19 (11.0%) at D8 and 68 participants (38.0%) at Dlast (Figure 2b). An increasing number of participants who applied Moisturizing Corn plasters reported pain/discomfort elimination from D2 to Dlast (n=1; 5.3% to n=3; 15.8% to n=12; 63.2%) (Figure 2b). Finally, participants with corns were asked to assess their global perception at Dlast of plaster's effectiveness on pain/discomfort relief. Among participants who applied Corn/Corn between toes and Moisturizing Corn plasters, respectively, 156 (87.6%) and 17 (94.4%) assessed the plaster's ability to relieve pain/discomfort, as at least "good" (Figure 2c).

Callus Condition

Among the 106 participants with calluses, 30 participants (28.3%) reported instant pain/discomfort relief at D0' (Figure 3a). Mean ± SD level of pain/discomfort reported by participants having applied Callous plasters, was 5.33 ± 1.97 at baseline (D0) and 4.99 ± 2.37 at first plaster application (D0'); no statistically significant difference was observed between the levels of pain/discomfort at D0 and D0'.

A sensitivity analysis of instant pain/discomfort was performed for participants having used a Callous plaster, having fully completed the questions about pain/discomfort and having no major deviation from protocol. Mean ± SD levels of pain/discomfort reported by these participants were comparable to the reference set at D0 and D0'; no statistically significant difference in the level of pain/discomfort was observed. Among participants within the principal analysis set, 27 participants (28.7%) reported instant pain relief/discomfort at D0' vs 67 participants (71.3%) who reported no instant pain/discomfort relief.

Participants were also asked to assess pain/discomfort elimination over time, at D2, D8 and Dlast; 7 participants (6.6%) reported pain/discomfort elimination at D2, 15 (14.4%) at D8 and 41 participants (39.0%) at Dlast (Figure 3b). Finally, participants who applied Callous plasters were asked to assess their global perception of plaster's effectiveness on pain/discomfort relief at Dlast; 95 (90.5%) assessed the plaster's ability to relieve pain/discomfort, as at least "good" (Figure 3c).

Bunion Condition

Among the 87 participants with bunions, 33 participants (37.9%) reported instant pain/discomfort relief at D0' (Figure 4a). Mean ± SD level of pain/discomfort reported by participants having applied Bunion plasters, was 5.62 ± 2.25 at baseline (D0) and statistically significantly decreased to 5.01 ± 2.45 at first plaster application (D0').

A sensitivity analysis of instant pain/discomfort was performed for participants having used a Bunion plaster, having fully completed the questions about pain/discomfort and having no major deviation from protocol. Mean ± SD levels of pain/discomfort reported by these participants were statistically significantly different at D0 and D0'. Among participants within the principal analysis set, 28 participants (36.8%) reported instant pain relief/discomfort at D0' vs 48 participants (63.2%) who reported no instant pain/discomfort relief.

Participants were also asked to assess pain/discomfort elimination over time, at D2, D8 and Dlast; 6 participants (6.9%) reported pain/discomfort elimination at D2, 9 (10.7%) at D8 and 17 participants (19.5%) at Dlast (Figure 4b). Finally, participants who applied Bunion plasters were asked to assess their global perception of plaster's effectiveness on pain/discomfort relief; 68 participants (79.1%) assessed the plaster's ability to relieve pain/discomfort, as at least "good" (Figure 4c).

Secondary Outcomes

Pressure Relief

The plaster's capacity to provide pressure relief was assessed at each time point (D0', D2, D8, Dlast) by a 7-point Likert scale ranging from 1 to 7 (1: "no relief" and 7: "full relief"). Participants in all 3 conditions, assessed pressure relief after the first plaster application (D0'), at D2, at D8, at Dlast. Mean ± SD level of pressure relief reported at D0' by participants who applied Corn/Corn between toes was 4.28 ± 1.35, and it significantly progressively increased from D2 (4.55 ± 1.31), to D8 (5.20 ± 1.16) to Dlast (5.93 ± 1.05) (Table 2). Mean ± SD levels of pressure relief reported by participants who applied Moisturizing Corn plasters also significantly progressively increased over time (from 3.53 ± 1.50 at D0' to 4.00 ± 1.56 at D2 to 5.00 ± 1.41 at D8 to 6.53 ± 0.77 at Dlast) (Table 2). Mean ± SD level of pressure relief

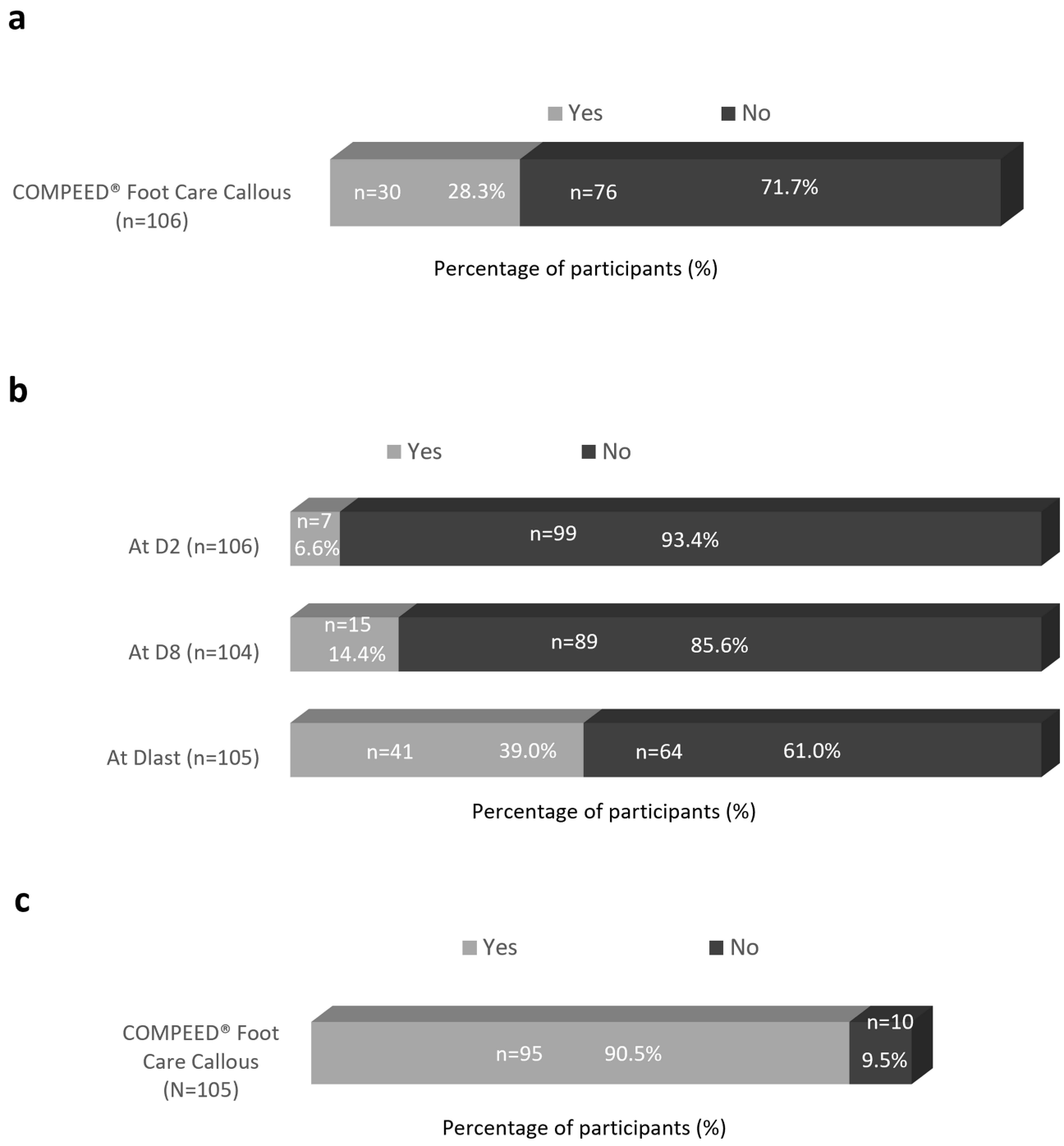

Figure 3 Pain/discomfort relief for callus condition. (**a**) Instant pain/discomfort relief was defined as a decrease of at least 1 point in the NRS between D0 and D0'. Percentage of participants reporting instant pain/discomfort relief after first plaster application (at D0'). (**b**) Percentage of participants reporting pain/discomfort elimination at D2, D8 (2 missing values) and Dlast (1 missing value). Pain elimination was defined as a score of 0 over the study follow-up. (**c**) Percentage of participants reporting "good overall pain/discomfort relief" (if the overall level of pain/discomfort relief was rated as "good" + "very good" + "complete" relief) (1 missing value).

reported at D0' by participants with callus was 4.30 ± 1.38, and it significantly progressively increased from D2 (4.60 ± 1.31), to D8 (5.34 ± 1.08) to Dlast (5.87 ± 1.16) (Table 2). Mean ± SD level of pressure relief reported at D0' by participants with bunion was 3.74 ± 1.57, and it significantly progressively increased from D2 (4.18 ± 1.43), to D8 (4.88 ± 1.19) to Dlast (5.48 ± 1.00) (Table 2).

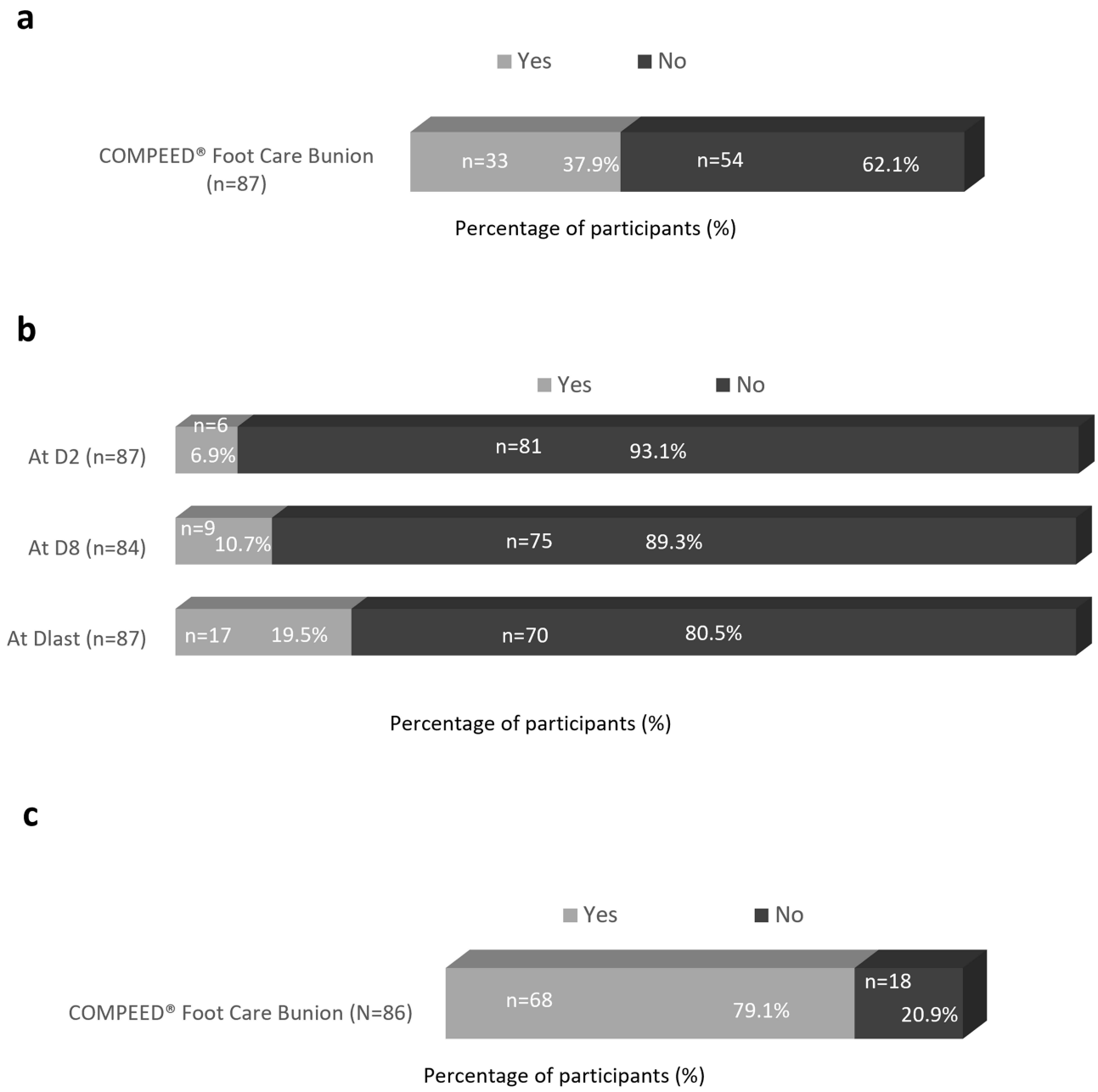

Figure 4 Pain/discomfort relief for bunion condition. (**a**) Instant pain/discomfort relief was defined as a decrease of at least 1 point in the NRS between D0 and D0'. Percentage of participants reporting instant pain/discomfort relief after first plaster application (at D0'). (**b**) Percentage of participants reporting pain/discomfort elimination at D2, D8 (3 missing values) and Dlast. Pain elimination was defined as a score of 0 over the study follow-up. (**c**) Percentage of participants reporting "good overall pain/discomfort relief" (if the overall level of pain/discomfort relief was rated as "good" + "very good" + "complete" relief); 1 missing value.

Cushioning

The overall plaster cushioning capacity was assessed at Dlast by a 7-point Likert scale ranging from 1 to 7 (1: "no cushioning at all" and 7: "excellent cushioning"). Participants in all 3 conditions assessed the overall cushioning effect of plasters against rubbing/friction overall at the end of the study. Mean overall cushioning effect scores ± SD given by participants who applied Corn/Corn between toes and Moisturizing Corn plasters were 5.45 ± 1.17 and 5.83 ± 0.86 (Table 3). For participants with calluses and participants with bunions, reported mean overall cushioning effect score ± SD was 5.58 ± 1.06 and 5.28 ± 1.11, respectively (Table 3).

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Table 2 Pressure Relief Provided by COMPEED® Foot Care Corn/Corn Between Toes, Moisturizing Corn, Callous and Bunion Plasters Over Time, at D0', D2, D8 and Dlast

		At D0'	At D2	At D8	At Dlast
Pressure relief	**COMPEED® Foot Care Corn and Corn between toes plasters**				
	N (mv)	179 (1)	179 (1)	172 (8)	179 (1)
	Mean ± SD	4.28 ± 1.35	4.55 ± 1.31	5.20 ± 1.16	5.93 ± 1.05
	Median	4.00	5.00	5.00	6.00
	Min; Max	1.0; 7.0	1.0; 7.0	1.0; 7.0	2.0; 7.0
	p-value[a]		*<0.0001*	*<0.0001*	*<0.0001*
	COMPEED® Foot Care Moisturizing Corn plasters				
	N (mv)	19 (0)	19 (0)	18 (1)	19 (0)
	Mean ± SD	3.53 ± 1.50	4.00 ± 1.56	5.00 ± 1.41	6.53 ± 0.77
	Median	4.00	4.00	5.00	7.00
	Min; Max	1.0; 6.0	1.0; 7.0	2.0; 7.0	4.0; 7.0
	p-value[a]		*0.0704*	*<0.0001*	*<0.0001*
	COMPEED® Foot Care Callous plasters				
	N (mv)	106 (0)	106 (0)	104 (2)	105 (1)
	Mean ± SD	4.30 ± 1.38	4.60 ± 1.31	5.34 ± 1.08	5.87 ± 1.16
	Median	5.00	5.00	6.00	6.00
	Min; Max	1.0; 7.0	1.0; 7.0	1.0; 7.0	1.0; 7.0
	p-value[a]		*<0.0001*	*<0.0001*	*<0.0001*
	COMPEED® Foot Care Bunion plasters				
	N (mv)	87 (0)	87 (0)	84 (3)	86 (1)
	Mean ± SD	3.74 ± 1.57	4.18 ± 1.43	4.88 ± 1.19	5.48 ± 1.00
	Median	4.00	4.00	5.00	6.00
	Min; Max	1.0; 7.0	1.0; 7.0	2.0; 7.0	3.0; 7.0
	p-value[a]		*0.0001*	*<0.0001*	*<0.0001*

Notes: Data are presented as n (%) or mean ± SD. [a]p-value between first plaster application (D0') and the time point.
Abbreviation: mv, missing values.

Table 3 Overall Cushioning Effect of COMPEED® Foot Care Corn/Corn Between Toes, Moisturizing Corn, Callous and Bunion Plasters at Dlast

		At Dlast
Overall cushioning effect	**COMPEED® Foot Care Corn and Corn between toes plasters**	
	N (mv)	179 (1)
	Mean ± SD	5.45 ± 1.17
	Median	6.00
	Min; Max	1.0; 7.0
	COMPEED® Foot Care Moisturizing Corn plasters	
	N (mv)	18 (1)
	Mean ± SD	5.83 ± 0.86
	Median	6.00
	Min; Max	4.0; 7.0

(*Continued*)

Table 3 (Continued).

		At Dlast
	COMPEED® Foot Care Callous plasters	
	N (mv)	105 (1)
	Mean ± SD	5.58 ± 1.06
	Median	6.00
	Min; Max	3.0; 7.0
	COMPEED® Foot Care Bunion plasters	
	N (mv)	86 (1)
	Mean ± SD	5.28 ± 1.11
	Median	5.00
	Min; Max	2.0; 7.0

Note: Data are presented as n (%) or mean ± SD.
Abbreviation: mv, missing values.

Duration

Participants in all 3 conditions reported the number and dates of plaster changes from the first plaster application (D0') until Dlast. The mean duration of the plaster stuck on skin after first application was thus calculated as the sum of the durations divided by the number of participants. Mean ± SD number of days that the first Corn/Corn between toes and Moisturizing Corn plasters stuck on skin were 3.50 ± 1.68 and 3.84 ± 1.71 days, respectively (Table 4). Mean ± SD

Table 4 Duration of COMPEED® Foot Care Corn/Corn Between Toes, Moisturizing Corn, Callous and Bunion Plasters Use From D0' to Dlast

		At Dlast
Duration of first plaster (days)[a]	**COMPEED® Foot Care Corn and Corn between toes plasters**	
	N (mv)	177 (3)
	Mean ± SD	3.50 ± 1.68
	Median	3.00
	Min; Max	1.0; 12.0
	COMPEED® Foot Care Moisturizing Corn plasters	
	N (mv)	19 (0)
	Mean ± SD	3.84 ± 1.71
	Median	3.00
	Min; Max	2.0; 8.0
	COMPEED® Foot Care Callous plasters	
	N (mv)	105 (1)
	Mean ± SD	3.61 ± 1.54
	Median	3.00
	Min; Max	1.0; 10.0
	COMPEED® Foot Care Bunion plasters	
	N (mv)	85 (2)
	Mean ± SD	3.33 ± 1.30
	Median	3.00
	Min; Max	1.0; 10.0

Notes: Data are presented as n (%) or mean ± SD. [a]Date of first plaster change - date of first plaster application + 1.
Abbreviation: mv, missing values.

number of days that the first Callous and Bunion plaster stuck on skin was 3.61 ± 1.54 days and 3.33 ± 1.30 days, respectively. In all 3 conditions, median duration of plasters was 3 days (Table 4).

Plaster Adhesion

The overall plaster adhesion capacity was assessed at Dlast by a 7-point Likert scale ranging from 1 to 7 (1: "no adhesion" and 7: "excellent adhesion"). Participants in all 3 conditions assessed overall adhesion of plasters at the end of study. Mean overall adhesion scores ± SD given at Dlast by participants having applied Corn/Corn between toes and Moisturizing Corn plasters were 5.50 ± 1.04 and 5.61 ± 0.85, respectively (Table 5). Mean overall adhesion scores ± SD given at Dlast by participants having applied Callous and Bunion were 5.43 ± 1.04 and 5.09 ± 1.03, respectively (Table 5).

Softening and Healing of Corn and Callus

Participants with corns and callus evaluated their plasters' capacity to provide softening and facilitation for corn/callus removal and healing state during the study period, upon plaster change, by a 7-point Likert scale ranging from 1 to 7 (1: "no softening" and 7:"complete softening"). At the last plaster change, 150 participants (83.8%) having applied Corn/Corn between toes plasters and 19 participants (100.0%) having applied Moisturizing Corn plasters assessed softening as "moderate", "good", "very good" and "complete". At the end of the study, corns were completely removed for 111 participants (66.5%) who applied Corn/Corn between toes plasters and 14 participants (73.7%) who applied Moisturizing Corn plasters (Figure 5a). Likewise, at the last plaster change, 87 participants (83.7%) having applied Callous plasters assessed that their softening was better ("moderate", "good", "very good" and "complete" softening). At the end of the study, callus was completely removed for 64 participants (65.3%) who applied Callous plasters (Figure 5b).

Table 5 Overall Adhesion of COMPEED® Foot Care Corn/Corn Between Toes, Moisturizing Corn, Callous and Bunion Plasters at Dlast

		At Dlast
Overall plaster adhesion	**COMPEED® Foot Care Corn and Corn between toes plasters**	
	N (mv)	179 (1)
	Mean ± SD	5.50 ± 1.04
	Median	5.00
	Min; Max	3.0; 7.0
	COMPEED® Foot Care Moisturizing Corn plasters	
	N (mv)	18 (1)
	Mean ± SD	5.61 ± 0.85
	Median	6.00
	Min; Max	4.0; 7.0
	COMPEED® Foot Care Callous plasters	
	N (mv)	105 (1)
	Mean ± SD	5.43 ± 1.04
	Median	5.00
	Min; Max	3.0; 7.0
	COMPEED® Foot Care Bunion plasters	
	N (mv)	85 (2)
	Mean ± SD	5.09 ± 1.03
	Median	5.00
	Min; Max	2.0; 7.0

Note: Data are presented as n (%) or mean ± SD.
Abbreviation: mv, missing values.

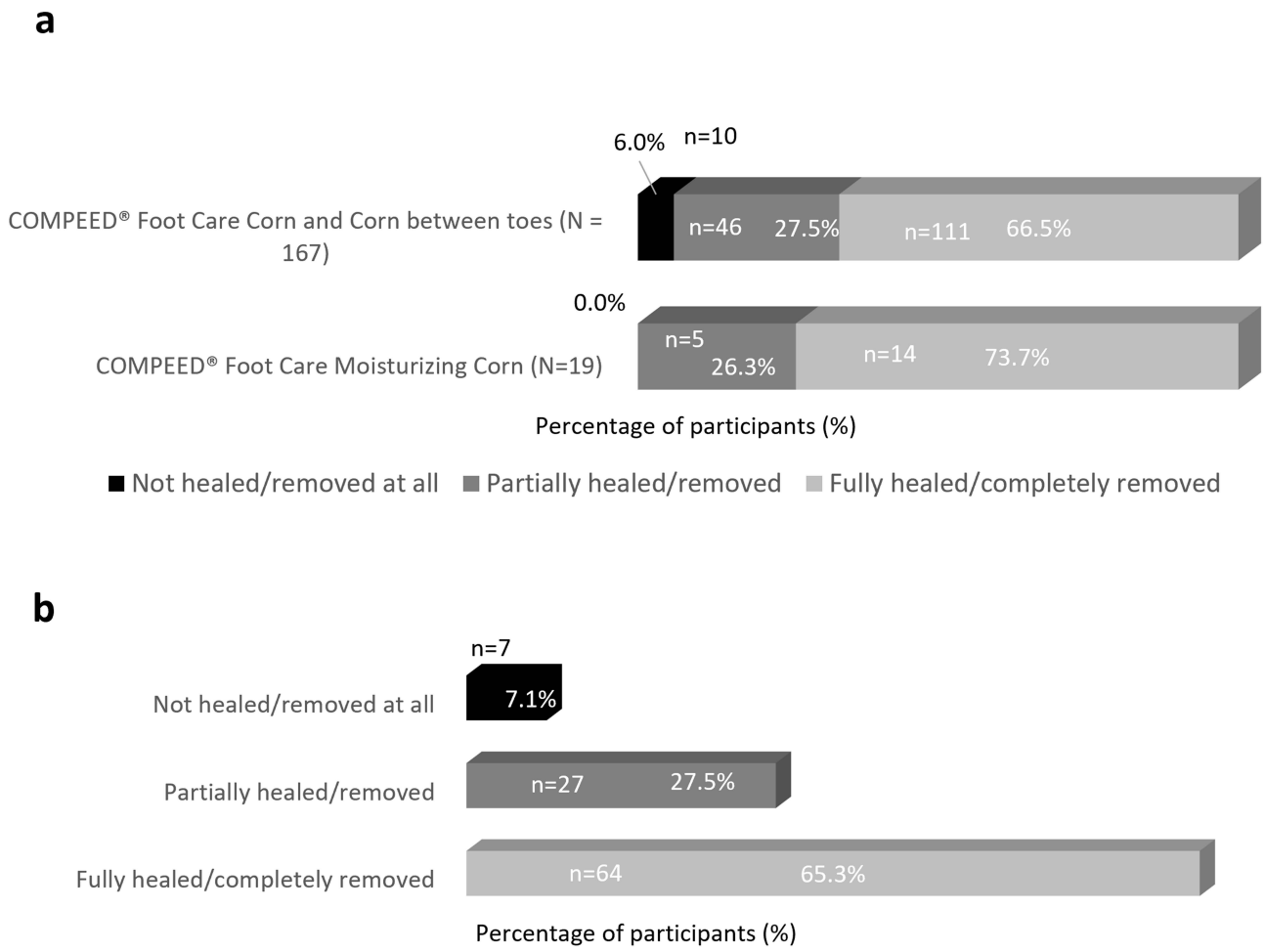

Figure 5 Corn and callus healing states at end of study per plaster type. (**a**) Percentage of participants with corns reporting corn not healed/removed at all, partially healed removed or fully healed/completely removed, at the end of the study (Corn/Corn between toes plasters: 13 missing values for Corn) and (**b**) Percentage of participants with calluses reporting callus not healed/removed at all, partially healed removed or fully healed/completely removed, at the end of the study (8 missing values).

Global Perception and Satisfaction

Among the 199 participants with corn, 172 participants (96.6%) and 18 participants (100.0%) having applied Corn/Corn between toes and Moisturizing Corn plasters, respectively, evaluated, at the end of the study, that their condition was better ("a little" + "much" + "very much" better) (Figure 6a). Overall satisfaction with Corn/Corn between toes and Moisturizing Corn plasters was "good" for 165 (92.7%) and 17 (89.5%) participants, respectively. Over 92.0% of participants (n=163; 92.1% and n=18; 94.7%) would "probably" or "absolutely" recommend, respectively, Corn/Corn between toes and Moisturizing Corn plaster to a member of their family or a friend. Likewise, 167 (94.9%) and 18 (94.7%) participants were willing to use, respectively, Corn/Corn between toes and Moisturizing Corn plaster again to treat their corn.

Likewise, among the 106 participants with callus, 102 participants (97.1%) having applied Callous plasters thought, at the end of the study, that their condition was better ("a little " + "much" + "very much" better) (Figure 6b). Overall satisfaction with Callous plasters was "good" for 98 participants (94.2%) and 97 participants (93.3%) would "probably" or "absolutely" recommend Callous plaster to a member of their family or a friend. Likewise, 100 participants (96.2%) were willing to use plaster again to treat their callus.

Finally, among the 87 participants with bunion, 76 participants (88.4%) having applied Bunion plasters thought, at the end of the study, that their condition was better ("a little" + "much" + "very much" better) (Figure 6c). Overall satisfaction with Bunion plasters was "good" for 75 participants (87.2%) and 81.2% of participants (n=75) would

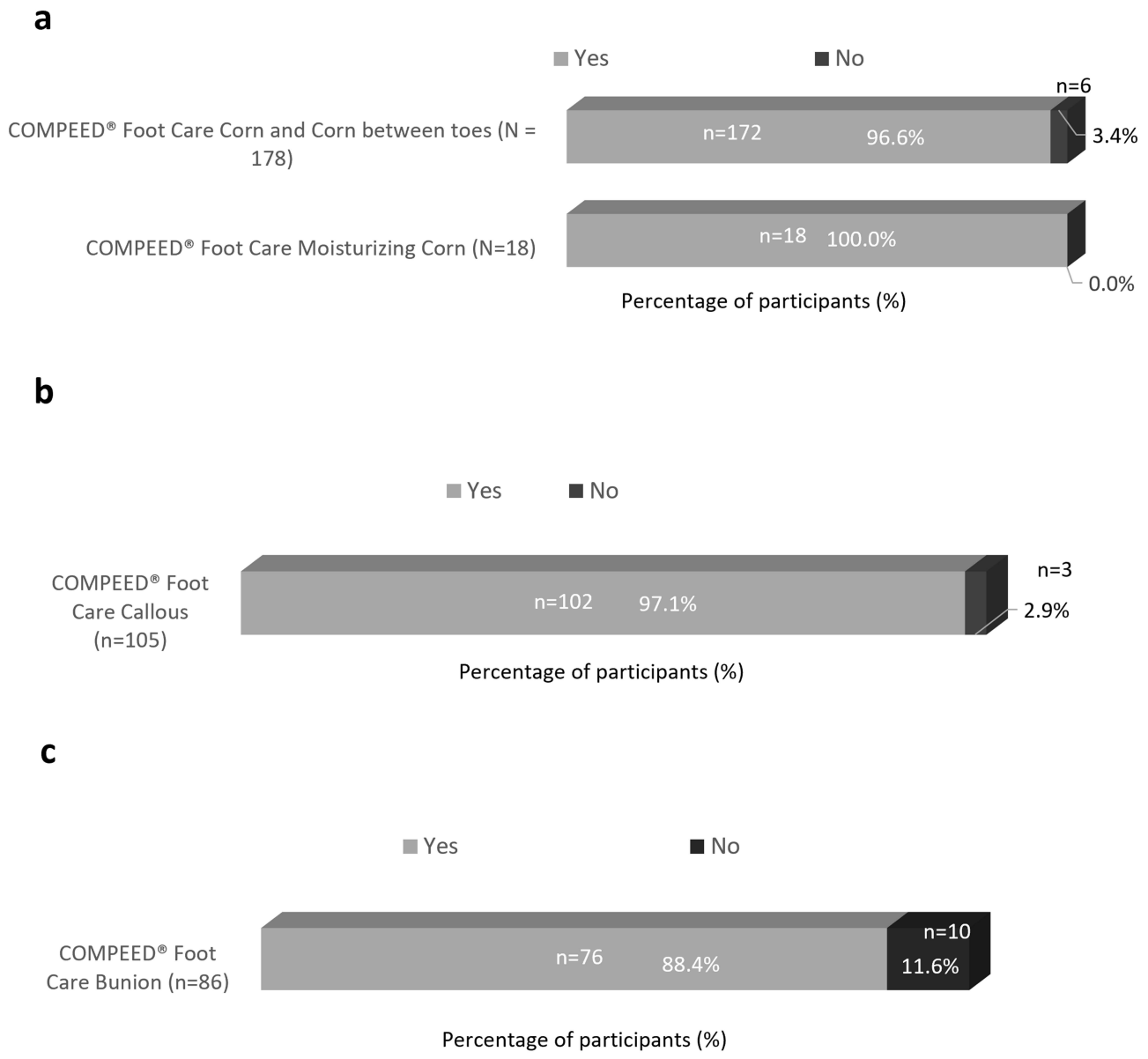

Figure 6 Good impression on plaster's ability to improve condition. Good impression on plaster's ability to improve condition is defined as "a little better" + "much better" + "very much better". (**a**) Percentage of participants who reported "good" impression on Corn/Corn between toes plasters (1 missing value) and Moisturizing Corn (2 missing values) plasters' ability to improve corn. (**b**) Percentage of participants who reported "good" impression on Callous plaster's ability to improve callus (1 missing value). (**c**) Percentage of participants who reported "good" impression on Bunion plaster's ability to improve bunion (1 missing value).

"probably" and "absolutely" recommend Bunion plaster to a member of their family or a friend. Likewise, 75 participants (87.2%) were willing to use Bunion plaster again to treat their bunion.

Adverse Events & Adverse Device Effects

Overall, during the clinical investigation, no ADE was reported by participants who used Corn and Bunion plasters. One participant, who used Callous plaster, reported 3 ADEs: application site irritation (n=1; 0.3%), application site pain (n=1; 0.3%) and condition aggravated (n=1; 0.3%).

Discussion

This longitudinal, non-interventional, multi-center, post-marketing clinical investigation in real life demonstrated and confirmed COMPEED® Foot Care plasters clinical benefits in pain/discomfort and pressure relief, cushioning against rubbing/

friction of corns, calluses and bunions, adhesion to skin, in the general population. To our knowledge, this is the first report thoroughly assessing in real-life settings the clinical effectiveness/safety performance profiles of various hydrocolloid plaster and in our study COMPEED® Foot Care plasters in various conditions of the foot using a dedicated participant-centred design. Also, as presented in Introduction, we have previously published evidence on the clinical performance of COMPEED® Foot Care plasters on a different range of hydrocolloid plasters and foot conditions, intended for foot blisters.[14,15] Our present results show that, in all 3 conditions, ie, corn, callus, and bunion, instant pain/discomfort relief was confirmed by 21.7% to 37.9% of participants, and a statistically significant difference was observed between the levels of pain/discomfort at D0 and D0' for participants who applied Corn/Corn between toes and Bunion plasters. Corns, calluses and bunions are "chronic" conditions with chronic pain rather than acute pain, and pain is often felt progressively while walking, which make pain relief evaluation complex and could explain the percentage of participants who experienced instant pain relief. In that respect, a previously published survey showed mean level of pain in foot corn was 5.29 on a 10 cm NRS,[16] which is in line with the level of pain reported by participants with corn in our study. The time point chosen for evaluation of instant pain/discomfort relief was also complex to determine considering the limited information available in bibliography. We decided to have several early time points to ensure that the pain/discomfort relief was detected early. This approach allowed us to certify that the pain/discomfort relief was observed more intensively starting D2 and increased up to Dlast. Therefore, and considering participants' positive feedback, results of this study support that pain/discomfort relief experienced by participants was most certainly due to COMPEED® Foot Care plasters. We could mention that it was not possible to use a control group of participants who did not apply a plaster here, because it is known that there may be no spontaneous healing or improvement of corns, calluses and bunions. Indeed, if the cause of repeated friction/pressure is not stopped, the skin cannot eventually soften up, and corns and calluses cannot gradually disappear. Moreover, the participant continues to walk (a major hard skin culprit), so it takes time for corn/callus to disappear on their own and sometimes even if treated (moisturizing cream, products with keratolytic agents) corns may come back if the source of the problem persists (tight/small shoes, pressure/friction on foot).[17] In our study, we report that from D2 to Dlast, the percentages of participants reporting pain/discomfort elimination progressively increased in parallel to the daily use of COMPEED® Foot Care plasters.

Significant increases in pressure relief and cushioning were also observed during the study period in all 3 conditions. Considering conditions and their localization, the median duration of all COMPEED® Foot Care plasters staying on skin was excellent (3 days), thus allowing, as described in the indications of use, to provide moistening of hard skin, leading to maceration, and facilitating removal. At the end of the study, 66.0% of participants with calluses and up to 73.0% of participants with corns reported their condition was healed. These positive and significant results were associated with an excellent perception of satisfaction and impression of effectiveness expressed by 96.6%, 97.0% and 88.0% of participants with corns, calluses and bunions, respectively.

The safety profile of all COMPEED® Foot Care plasters was excellent. Finally, during our investigation, there was a high compliance with questionnaire completion; indeed, questionnaires were completed by almost all participants within the Reference set during the study period that lasted 20 days: 100% of participants completed questionnaires at D0', 99.7% at D2, 96.7% at D8 and 99.5% at Dlast.

As usual in this type of studies, there were limitations, many of them mitigated by our study design. Since the studied conditions do not usually require a medical treatment and may be primarily treated with over-the-counter products, the design of the study in the real-life setting by recruiting participants through community pharmacies was the ideal recruitment method. However, since neither randomized nor controlled, one cannot interpret with full certitude the results in terms of causality between pain/discomfort versus COMPEED® Foot Care plasters. Nevertheless, as previously mentioned, improvement of the conditions reported by participants could not be accounted, a priori, to natural healing of these conditions; therefore, and considering the excellent global perception of improvement by the participants, the use of COMPEED® Foot Care plasters is most likely to have led to such outcome results. Furthermore, for the same study design reasons, one could not ensure balanced groups and ended up with unbalanced group sizes among the 3 separate conditions. Nevertheless, even so, results of primary and secondary outcome analyses pointed in favour of COMPEED® Foot Care plaster use in relieving pain/discomfort and reducing pressure etc.

Furthermore, conducting research in primary care is highly innovative because it directly addresses the foundational level of the healthcare system where the majority of patient interactions occur. This approach allows for the development

and implementation of evidence-based practices that can significantly improve patient outcomes. This type of research also encourages the integration of preventative care and early intervention strategies, which are crucial in dermatological care.

Finally, in this field, no validated questionnaire exists for the therapeutic areas under investigation; thus, a novel, unvalidated questionnaire was the only solution to collect outcome data with good compliance and quality.

Conclusion

In conclusion, this investigation emulated real-life use of COMPEED® Foot Care plasters in the environment of participants. The very low restrictive eligibility criteria, together with the elevated participant response rate, both in terms of quantity and quality, ensured an excellent external validity/generalizability and reliability of our results.

Abbreviations

MTP, metatarsophalangeal; EC, Ethics Committee; eCRF, electronic Case Report Form; NRS, Numeric Rating Scale; SAS, Statistical Analysis Systems; CI, Confidence Intervals; ADE, Adverse Device Effect; MV, missing values.

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Disclosure

JZB (Global Head of Clinical Operations), PA (Scientific Affairs Assistant & Clinical Operations Assistant), HP (Senior Clinical Project Manager) and CAA (Head of Scientific Affairs for Global Skincare and Clinical Operations) are employees at Laboratoire HRA Pharma (manufacturer of the COMPEED® brand of products). MK (Medical writer), VC (Head of Biometrics Department), CP (Chief Operating Officer & Head of Clinical Operations), SW (Head of Medical and Scientific Affairs Department), RG (Head of Business Operations) are employees at ICTA, the organization to which the study conception, operational set-up and conduct, analysis, article writing were subcontracted. The authors report no other conflicts of interest in this work.

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