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Efficacy of gel containing organic extra virgin olive oil for peristomal skin hygiene: A pilot randomised controlled trial☆

César Hueso-Montoro [a,b,c], Noelia Moya-Muñoz [d], Josefa Martín-Cebrián [d], Rosa Huertas-Fernández [e], Inmaculada Sánchez-Crisol [e], Francisco Pedro García-Fernández [a,*], Concepción Capilla-Díaz [b,f]

[a] Department of Nursing, University of Jaén, Jaén, Spain
[b] Instituto de Investigación Biosanitaria (ibs.GRANADA), Granada, Spain
[c] Centro de Investigación Mente, Cerebro y Comportamiento (CIMCYC), Granada, Spain
[d] Virgen de las Nieves University Hospital, Granada, Spain
[e] San Cecilio University Hospital, Granada, Spain
[f] Department of Nursing, University of Granada, Granada, Spain

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ABSTRACT

Aim: To assess the efficacy and safety of the application, during stoma hygiene, of a pH-neutral gel containing organic EVOO (oEVOO) for the maintenance of peristomal skin integrity.
Method: Patients with a colostomy or ileostomy were enrolled in a pilot randomized controlled trial and assigned treatment with a pH-neutral gel made from natural products including oEVOO or usual stoma hygiene gel. The primary outcome was three domains of abnormal peristomal skin: Discolouration, Erosion and Tissue overgrowth. Secondary outcomes that were evaluated included skin moisture; oiliness; skin elasticity; water-oil balance; patients' perceptions; difficulty inserting and removing the pouching system; pain, any other chemical, infectious, mechanical, or immunological complications of concern. The intervention lasted 8 weeks.
Results: Twenty-one patients were recruited for the trial and randomly assigned to either the experimental group ($n = 12$) or the control group ($n = 9$). The groups did not differ significantly in terms of patient characteristics. No significant differences between groups were identified either at baseline ($p = 0.203$) or at the end of the intervention ($p = 0.397$). In the experimental group, domains of abnormal peristomal skin improved after the intervention. The difference observed before and after the intervention was statistically significant ($p = 0.031$).
Conclusion: The use of a gel containing oEVOO has shown similar levels of efficacy and safety to other gels commonly used for peristomal skin hygiene. It is also relevant to highlight that a significant improvement in skin condition was observed in the experimental group before and after the intervention.

1. Introduction

It is estimated that 1.3 million people worldwide have an ostomy. In North America, there are approximately 750,000 people with an ostomy, with 13,000 new cases each year in Canada alone [1]. In Spain there are approximately 70,000 individuals with an ostomy and each year there are 16,000 new cases, the most frequent being colostomies (55.1%) and ileostomies (35.2%) [2].

The creation of an ostomy significantly affects the individual, as it has an impact on functional aspects from a physical point of view, as well as considerable psychological and social repercussions [3]. One of the main concerns among patients and professionals is maintaining the integrity of the peristomal skin, i.e. the skin surrounding the stoma, covered by the adhesive layer of the pouching system used for the evacuation of feces or urine.

Peristomal skin complication can be defined as inflammation, injury, or damage occurring within approximately 7 cm of the surface of the skin surrounding the stoma [4]. Recent studies indicate that up to 80% of patients have a peristomal skin complication [5]. Peristomal dermatitis is the development of erythema, edema, possible vesicles,

☆ This trial was registered in the ClinicalTrials.gov under ID no. NCT05289765.

* Corresponding author. Department of Nursing, University of Jaén, Campus de Las Lagunillas, s/n, 23071, Jaén, Spain.
E-mail address: fpgarcia@ujaen.es (F.P. García-Fernández).

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maceration and loss of skin integrity as a result of contact with a number of substances including urine, feces, medicaments, ostomy pouch systems, and stoma skin care products, and the common forms of peristomal dermatitis include irritant contact dermatitis, mechanical dermatitis, and allergic contact dermatitis [6]. Therefore, depending on the type of ostomy, peristomal skin may be extremely or substantially compromised. As well as impacting the quality of life of these individuals, these complications result in higher healthcare costs. The cost of a standard treatment over a seven-week period is estimated to be 77 Canadian dollars higher for individuals with peristomal skin complications than for individuals without complications [1].

Intact peristomal skin provides a protective barrier between the body and its environment. Frequent application and removal of stoma pouching system can damage the skin by stripping it of the epidermal layer [7]. To avoid this, good hygiene and care must be exercised, using the appropriate pouching system and ensuring a good fit of the pouching system adhesive. For stoma hygiene, the gold standard is the use of a pH-neutral soap or gel [8]. However, a systematic review has shown that there is a lack of standardised evidence on stoma skin care [9].

The use of extra virgin olive oil (EVOO) products for peristomal skin care has been inadequately studied. However, there is some evidence of the efficacy of EVOO for general skin care. The essential fatty acids in EVOO and its antioxidant, anti-inflammatory, and antimicrobial properties make it an excellent product for skin hydration, protection, and regeneration [10].

The aim of this pilot randomised controlled trial (RCT) was to assess the efficacy and safety of the application, during stoma hygiene, of a pH-neutral gel containing organic EVOO (oEVOO) for the maintenance of peristomal skin integrity. Given the lack of studies on the subject, we deemed it necessary to conduct a pilot RCT to provide evidence on the use of EVOO on skin as vulnerable as the peristomal skin and to assess the feasibility of the study design before embarking on a large-scale research project. A non-inferiority hypothesis is proposed in which the incidence of peristomal skin involvement in the group treated with oEVOO gel is no higher than that in the group receiving the usual intervention, establishing a non-inferiority margin of 7% [11].

2. Methods

A pilot RCT was conducted at the ostomy practices at the Virgen de las Nieves University Hospital and San Cecilio University Hospital in Granada, Spain. The protocol was registered on ClinicalTrials.gov (NCT05289765) and approved by the Granada Research Ethics Committee (see minutes taken on July 21, 2021). Patients were informed about the study and signed an informed consent form. The CONSORT guidelines were followed during preparation of the report [12].

Patients were included in the study if they had a colostomy or ileostomy with a one- or two-piece pouching system (for one-piece, patient usually replace the entire pouch at least once a day, for two-piece, patient usually replace the baseplate every two or three days [13,14]) and demonstrated knowledge and skill in caring for their stoma, achieving a score of 4 or 5 (maximum = 5) on the stoma hygiene-related indicators included in the Nursing Outcomes Classification (NOC) outcomes [15] *Knowledge: Ostomy care* (1829) and *Ostomy self-care* (1615). Patients were excluded if they presented any alteration in the peristomal skin area, using a guide to identify these alterations [16]. Patients undergoing chemotherapy, radiotherapy, or any other treatment impacting the skin; terminally ill patients; and patients with a known allergy to any of the ingredients in the experimental gel were also excluded.

The experimental group was treated with a pH-neutral gel made from natural products including oEVOO (*Picual veraison* type). The composition of the gel is in compliance with the International Nomenclature of Cosmetic Ingredients (INCI). The participants in the control group were instructed to use their usual stoma hygiene gel, in this case a pH-neutral gel that did not contain EVOO or any other product derived from olive oil (the gold standard in the scientific literature). Patients in both groups applied the gel during stoma cleaning, without applying any other product to the peristomal skin. Both groups followed a standardised guide to removing and placing the pouching system and washing the stoma and peristomal skin [8].

The intervention lasted 8 weeks. This follow-up period is adequate to assess skin changes, as it complies with the 40–56 day epidermal regeneration period [17] and, according to expert consensus, is sufficient time to detect the appearance of skin lesions. During follow-up, each patient was provided with a complication record sheet. The research team kept in contact with the patients by telephone and they attended a scheduled consultation at 4 weeks to monitor changes and identify potential complications.

2.1. Primary outcome

Three domains of abnormal peristomal skin were assessed: Discolouration (D), Erosion (E), and Tissue overgrowth (T). The DET score [18] is a standardised peristomal skin assessment tool, which was used to measure the percentage of peristomal skin involved and the degree of severity of the complication according to the aforementioned domains. The final score ranges from 0 to 15, whereby 0 = optimal skin and 1 to 15 = mild (up to 3.5), moderate (up to 7) or severe alteration (up to 15).

2.2. Secondary outcomes

Skin moisture and oiliness were measured and expressed as percentages. Skin elasticity was measured on a Likert scale ranging from 1 to 5 (with higher scores indicating better outcomes) and water-oil balance was measured on a scale ranging from 0 to 100 (with higher scores indicating better outcomes). These parameters were measured with two digital pen-type skin analysers using beam-based technology, which had previously been tested according to the information provided by the manufacturers and calibrated on healthy skin areas of the patients at the beginning of the study.

Patients' perceptions of their stoma were assessed using the indicators *Appears comfortable viewing stoma (161503)* and *Expresses acceptance of ostomy (161519)* included in the NOC outcome *Ostomy self-care (1615)* [15]. Both indicators are measured using a Likert scale from 1 to 5 (with higher scores indicating better outcomes).

The intervention was considered to be safe in the absence of the following adverse effects: difficulty inserting and removing the pouching system; pain (measured on a visual analogue scale from 0 to 10, with higher scores indicating poorer outcomes); any other chemical, infectious, mechanical, or immunological complications of concern [16].

Additionally, participants in the experimental group were asked about their perceptions of product safety and their satisfaction with the gel they used before the intervention. Satisfaction with the product was measured using the indicator *Assistance with toileting [300606]* included in the outcome *Client satisfaction: physical care (3006)* [15]. This indicator is measured using a Likert scale from 1 to 5, with higher scores indicating better outcomes.

Finally, data on sociodemographic, clinical, and other variables of interest selected by consensus by stoma therapy experts and influencing the assessment of peristomal skin were collected [19].

2.3. Procedure

Patients were recruited by telephone one month before the start of the intervention using a list of patients provided by the ostomy practices where the research was conducted. After selection, patients were randomised using a list of random numbers generated by computer software.

Three observers independently assessed the peristomal skin using the DET score. The first observer assessed the skin in the consultation room. The second observer assessed it using photographs taken in the consultation room from three different angles (normal, horizontal, and

zenithal) using a high-resolution digital camera. Any conflicting scores were addressed by the third observer using the photographs. All three observers involved were stoma therapy experts who were familiar with the DET scoring instrument.

To measure skin parameters, a protocol was established on the basis of the topographical location proposed by the SACS instrument (*Studio sulle Alterazioni Cutanee Peristomali*) [20], which recommends assessing four quadrants: TI (upper left), TII (upper right), TIII (lower right), TIV (lower left).

All other variables were recorded in an ad hoc data notebook.

Both the observers and the researchers responsible for data analysis acted under blinded conditions.

2.4. Statistical analysis

For continuous variables, means, standard deviations, medians and interquartile ranges were calculated. For categorical variables, frequencies and percentages were calculated. Normality tests were performed using the Shapiro-Wilk test.

The frequency, estimated proportion, and 95% confidence intervals (CIs) were calculated for patients with a DET score of 1 or higher in each group.

Statistical analyses of the primary outcomes between the two groups were performed using the chi-squared test or Fisher's exact test, while McNemar's test was used to compare the groups pre- and post-intervention.

Parametric variables were analysed using Student's *t*-test, and non-parametric variables were analysed using Mann-Whitney's *U* test or Wilcoxon test.

A per-protocol analysis was carried out, setting the statistical significance threshold at 0.05. Data were analysed using SPSS© v. 26 software from IBM (IBM Corporation, Armonk, NY, USA) with the University of Granada's corporate licence.

3. Results

Twenty-one patients were recruited for the trial and randomly assigned to either the experimental group (n = 12) or the control group (n = 9) (Fig. 1). The groups did not differ significantly in terms of patient characteristics (Table 1).

In both groups, peristomal skin involvement was mild both at baseline and at the end of the intervention as per the classification proposed by the DET score. Concretely at baseline, the mean DET score in the experimental group was 2.5 (±2.1; min = 0, max = 6), which decreased to 0.6 (±1.3; min = 0, max = 4) after the intervention. In the control group, the mean at baseline was 1.7 (±2.3; min = 0, max = 6), remaining the same after the intervention. The number of patients with a DET score of 1 or higher in the experimental group went from 9 (estimated proportion = 0.75; 95% CI = 0.46–0.91) at baseline to 3 (estimated proportion = 0.25; 95% CI = 0.08–0.53) after the intervention. In the control group, the number of patients remained the same at baseline and at the end of the intervention (n = 4) (estimated proportion = 0.44; 95% CI = 0.18–0.73). No significant differences between groups were identified either at baseline (p = 0.203) or at the end of the intervention (p = 0.397). In the experimental group, the difference observed before and after the intervention was statistically significant (p = 0.031).

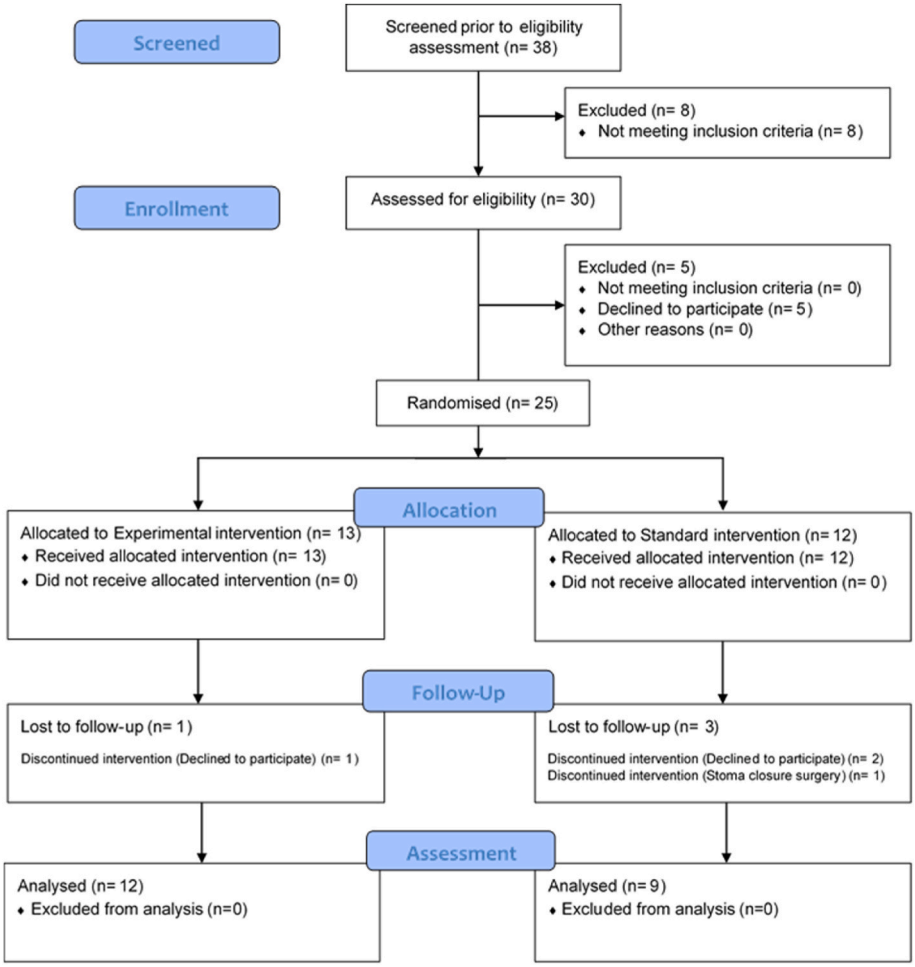

Fig. 1. 2010 CONSORT flowchart [12].

Table 1
Patient characteristics.

Number of patients (n = 21)	Experimental Group (n = 12)	Control Group (n = 9)
Age	50.1 (±11.9)	55.9 (±14.2)
BMI	27.3 (±4.7)	21.2 (±12.9)
Sex		
Male	4 (33.3%)	7 (77.8%)
Female	8 (66.7%)	2 (22.2%)
Member of Patient Ostomy Association	5 (41.7%)	6 (66.7%)
Has a family member with an ostomy	3 (25%)	1 (11.1%)
Medical diagnosis		
Oncological	6 (50%)	4 (44.4%)
Other	6 (50%)	5 (55.6%)
Stoma complications	1 (8.3%)	2 (22.2%)
Stoma site marking	7 (63.6%)	6 (66.7%)
Pouching system		
One-piece	3 (25%)	3 (33.3%)
Two pieces	9 (75%)	6 (66.7%)
Type of ostomy		
Colostomy	9 (75%)	6 (66.7%)
Ileostomy	3 (25%)	3 (33.3%)
Use of skin barrier	4 (33.3%)	5 (55.6%)
Irrigation	3 (25%)	1 (11.1%)

Table 2 shows the results for the secondary outcomes.

No complications associated with pouching system placement or removal were reported. At 4-week follow-up, an adverse event consisting of the appearance of severe discolouration and itching of the peristomal skin was reported in one of the patients in the experimental group. Once the case had been analysed, it was established that this event was not related to the use of the gel but to a change in the pouching system used. The pouching system was switched to the previous pouching system and no further problems were reported by the patient. Apart from this complication, no other chemical, infectious, mechanical or immunological complications of interest were reported.

All 12 patients in the experimental group described the gel used in the intervention as safe. Nine (75%) of the patients stated that the experimental product was better than the product they had been using before, three (25%) felt that it was the same, and none considered it worse. A median score of 5 (IQR = 1) was obtained for the satisfaction indicator used.

4. Discussion

In this pilot RCT, no significant differences in terms of peristomal skin involvement were identified between groups, although it was observed that, after the intervention, the incidence of complications was lower in the experimental group than in the control group. Therefore, these data support the initial non-inferiority hypothesis of the new product.

Although the peristomal skin involvement was mild both at the beginning and at the end of the intervention, according to the classification proposed by the DET score [18] we can see that the improvement in the intervention group is clear while in the control group it remains the same, suggesting a possible beneficial effect of the product. No change was observed in the control group, while in the experimental group there was a significant positive change in favour of the intervention, as the number of patients with impaired peristomal skin decreased after application of the oEVOO gel.

The skin parameters measured showed normal results for moisture, oiliness, and elasticity in both groups before and after the intervention. With regard to the W/O balance, the results obtained were normal, although it should be noted that a lower score was observed in the right upper quadrant in both groups after the intervention, which was more pronounced in the control group, with signs of statistical significance. It was also observed that the baseline status of this quadrant was worse in the experimental group than in the control group, with statistically significant differences, while at the end of the intervention the results improved in the experimental group, which reinforces the hypothesis of the efficacy of the oEVOO gel.

Taking the limitations inherent to a pilot study into consideration, the findings of this study suggest that the use of oEVOO gel during peristomal skin hygiene is effective in maintaining the integrity of the skin and preventing deterioration. The preventive properties of EVOO

Table 2
Secondary outcomes.

Variables	EG (n = 12)		CG (n = 9)		p^a	p^b	p^c	p^d
	*Baseline**	*8 weeks**	*Baseline**	*8 weeks**				
Moisture (%)								
TI	51 (34)	41.5 (15)	37 (40)	42 (22)	0.669	0.831	0.155	0.674
TII	47 (15)	46.5 (21)	47 (34)	37 (18)	0.859	0.144	0.563	0.192
TIII	47 (56)	44.5 (14)	49 (14)	52 (18)	0.498	0.187	0.091	0.406
TIV	46 (58)	43.5 (16)	46 (18)	45 (18)	0.802	0.695	0.583	0.859
Oiliness (%)								
TI	27 (17)	28.5 (19)	33 (20)	26 (24)	0.543	0.694	0.969	0.482
TII	21 (16)	21.5 (18)	24 (19)	34 (25)	0.393	0.200	0.918	0.109
TIII	22 (13)	24 (16)	18 (14)	19 (12)	0.254	0.200	0.919	0.612
TIV	24.5 (18)	25.5 (21)	23 (22)	24 (18)	0.775	0.886	0.875	0.593
Elasticity (1–5)								
TI	4 (2)	3.5 (1)	3 (3)	4 (3)	0.399	0.794	0.490	0.527
TII	4 (1)	4 (3)	4 (4)	3 (3)	0.970	0.098	0.671	0.196
TIII	4 (2)	4 (1)	4 (2)	4 (2)	0.597	0.185	0.272	0.603
TIV	3.5 (3)	4 (2	4 (2)	4 (2)	0.912	0.775	0.936	1.000
W/O Balance (0–100)								
TI	92.5 (40)	91.5 (16)	98 (33)	96 (4)	0.328	0.068	0.533	0.574
TII	92.5 (26)	88 (38)	98 (9)	83 (28)	0.030	0.498	0.289	0.058
TIII	81.5 (30)	92.5 (16)	96 (18)	96 (14)	0.175	0.371	0.173	0.866
TIV	88 (50)	84.5 (52)	95 (17)	97 (15)	0.412	0.221	0.878	0.400
Pain (0–10)	0 (1)	0 (0)	0 (1)	0 (1)	0.721	0.178	0.102	0.480
Comfortable viewing stoma (1–5)	4.5 (2)	5 (2)	5 (1)	5 (0)	0.314	0.153	0.157	0.317
Acceptance of ostomy (1–5)	4 (4)	5 (1)	5 (0)	5 (0)	0.024	0.254	0.034	0.317

EG = Experimental group; CG = Control group. TI = upper left quadrant, TII = upper right quadrant, TIII = lower right quadrant, TIV = lower left quadrant. *Values for medians and interquartile ranges; p^a = Between-group difference at the beginning of the intervention; p^b = Between-group difference at the end of the intervention; p^c = Within-group difference for the experimental group before and after the intervention; p^d = Within-group difference for the control group before and after the intervention.

for skin care have already been demonstrated in other studies [21–23].

In addition, the improvement observed in the experimental group points to the product's potential reparative properties for slightly deteriorated peristomal skin, i.e. the type of skin examined in this study. In this regard, previous research has highlighted the reparative properties of oleic and linoleic acids in olive oil, which improve the permeability of the skin barrier [24]. These acids have also been shown to accelerate the wound healing process [25], and the compound oleocanthal has been proven to act as a natural anti-inflammatory [26]. In addition, clinical studies have demonstrated the efficacy of EVOO creams in reducing the risk of dermatitis in neonates [27] and their analgesic effect on the skin of caesarean section scars [28]. The literature also describes the properties of ecological EVOO, similar to the product used in this research, which is obtained by using more sustainable cultivation procedures that strengthen its natural components and enhance its effects. The effectiveness of organic EVOO in preventing and treating pain and cracked nipples in women during breastfeeding has been demonstrated in previous research [29].

With regard to the safety outcomes of the product, a safety profile equivalent to other commonly used products is acceptable. It is important to note that no complications related to pouching system placement and removal were reported. This is at odds with a number of recommendations on stoma and peristomal skin cleansing that discourage the use of oily products [30–32] because of potential pouching system adhesion problems, among other reasons. Direct application of creams and other oily ointments can cause problems with adhesion, maceration, etc. However, this gel product contains a surfactant in the formula that evenly distributes the various components. The surfactant prevents the components of the formula from separating and keeps the system dispersed between the aqueous and oily phase, thus leaving no oily residue. Without this agent the aqueous and oily components would separate leaving oily residues, which thanks to its formulation does not occur in the gel used in this research. This raises the possibility of recommending these products for routine stoma hygiene, with the resulting potential benefits offered by the skin care properties attributed to EVOO.

The limitations of this study include the small sample size, which makes it necessary to extend the study to attain the sample size necessary to confirm the findings and already significant results in support of the initial hypothesis. This pilot study can serve as a basis for determining the necessary sample size and other methodological issues for future trials. Future studies will also need to employ more precise measurement technology to analyse peristomal skin cell behaviour in relation to the oEVOO in the gel and to measure more accurately the effect of the product on skin issues as well as subjective assessment of the product.

The strengths of this research include the use of a rigorous design with a standardised data collection protocol based on widely recognised instruments to assess peristomal skin. It is also important to note that this is an organic product obtained through an environmentally friendly cultivation process with low potential toxicity, which can contribute to the challenge of reducing pollution set out in the Sustainable Development Goals drawn up by the United Nations General Assembly [33].

5. Conclussions

In this pilot study, the use of a gel containing oEVOO has shown similar levels of efficacy and safety to other gels commonly used for peristomal skin hygiene. It is also relevant to highlight that a significant improvement in skin condition was observed in the experimental group before and after the intervention.

These findings offer an opportunity to revise a number of stoma hygiene recommendations in favour of this type of product and serve as a basis for further research into the efficacy of EVOO products for peristomal skin care.

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Declaration of competing interest

There are no conflicts of interest to disclose.

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