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Article

Healing of peristomal lesions through application of a hygiene protocol respecting the skin's physiological pH and natural moisturizing factor: a clinical study

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Abstract. *Background*: Patients with ostomies, and at times also the specialty clinicians, can at times underestimate the importance of a correct peristomal hygiene (PHy). Awareness happens only when peristomal lesions (PSL) occur. The study had the objective to observe whether applying a suitable PHy protocol is a sufficient measure to heal L1-L3 PSL (SACS 2.0).
Methods: 64 patients requiring a specific consulting for managing PHy and the PSL present were enrolled in the study. They were all treated with the same PHy protocol, using a self-balancing® pH soap to restore optimal pH and an isodermic® cream to restore the skin's natural moisturizing factor. The patient's general condition and the peristomal skin condition were assessed using specific device to measure elasticity, pH, sebum, percentage of water contained in epidermis (PWCE) and derma (PWCD) at 3(T1), 7(T2), 15(T3) days and follow-up at 28 days(T4).
Results: Data from 50 patients were analysed (11 withdrew once the lesions were healed, and 3 needed treatment with advanced dressing). Sample composition: F50%, M50%; age range 23-97

years; urostomy 20%, intestinal ostomy 80%; average BMI 25,09kg/m2, normal weight 48%; neoplasia 46%, 78% of patient population were self-sufficient in managing their stoma; 100% presence of PSL. Complete healing was achieved in 98%(49) of monitored patients, and specifically: 42% after 3 days, 80% after 7 days, and 96% at T3. From healing to the end of the monitoring period, no other lesions occurred. At T4 we observed an improvement vs initial assessment of: PWCE in 46% of cases (PWCEAVG: T0=42.8%; T4=44.2%), PWCD in 40% of cases (PWCDAVG: T0-39.3%; T4-40.7%), elasticity in 24% of cases (peristomal elasticityAVG: T0-38.3N/m; T4-40.4N/m) and pH in 70% (pHAVG: T0–6.4; T4AVG -5.9). At follow-up we recorded a 96% compliance to the new protocol.

Conclusions: The combination of therapeutic education, applying a correct PHy, maintaining the peristomal skin hydrated and with a pH around 5.9 jointly contributed to ensure prevention and healing of L1-L2 peristomal lesions.

Keywords: peristomal lesions, stoma complications, ostomy hygiene protocol, peristomal skin disorders, peristomal wound.

Introduction

An intestinal or urinary stoma procedure is very often a consequence of neoplastic or inflammatory pathologies[1-4], which have already deeply upset both patient and loved ones. The management of something that is thought of as a "new organ", with the unwelcome visible exit site of faeces or urine, often is not easy for them to learn and accept.

Although surgical techniques and collecting devices have evolved in time, the presence of lesions on the peristomal skin still has first place amongst the short- and long-term complications in all types of ostomy[2-8], and it is the main reason to seek advice from a stoma care specialist, sometimes involving hospitalisation of the patient[3,9-12].

On returning home, the patient who underwent a new ostomy procedure has to face a new life condition, where attention is often focussed on pain, on the surgical wound and on correct fitting of the collecting devices. The importance of peristomal hygiene is often underestimated.

Currently, even in the guidelines for professionals it seems to receive little attention. Advice on peristomal hygiene is generic[3,14-16], recommending use of a "*delicate*" or "*neutral*" soap to cleanse the peristomal skin, with no specific reference to validated protocols or specific products.

Preserving the peristomal skin integrity is the main prerequisite to allow the adhesion and the staying *in situ* of collecting devices. The patient and his/her care giver often realise the importance of this factor only following the onset of peristomal lesions[13,17], or after a thorough therapeutic education[18-20].

Peristomal hygiene is different from normal intimate cleansing, as one must take care of respecting the physiologic conditions of two very different areas of the body[17,21]:

- the ostomy – is an intestinal mucosa with an acid pH (3.5), and can absorb some of the substances it comes into contact with. Since, unlike the skin, it lacks protection by keratotic cells, it irritates easily if handled in an aggressive way, or if it comes into contact with cytotoxic substances;
- the skin – although it is protected by a corneous layer to enable its barrier function, it can easily be attacked by digestive juices or urine, and normally has a physiologic pH of around 5.5 which has a tendency to become alkaline with ageing. It needs to be constantly hydrated to restore the physiologic acid mantle of the skin[22,23] which is constantly removed with the adhesive devices used continuously to collect the effluents.

Following an empiric observation of the improvement of the peristomal skin condition when following a hygiene protocol aiming to re-establish pH and physiologic skin hydration, we decided to study if this would also be confirmed on a statistically significant patients' sample. In our study we wanted to analyse, by measuring with specific instruments, the skin parameters (epidermis hydration, derma hydration, elasticity, pH, sebum), whether performing peristomal hygiene with a self-balancing® pH soap (Bioderm Stoma Plus® - Farmoderm Srl) to achieve optimal pH reset, and an isodermic® cream (Bioderm Dermocrema® - Farmoderm Srl) to restore the skin's natural moisturizing factor (NMF), together with the patient's therapeutic education, would positively influence the healing of peristomal wounds. The study was performed according to the Declaration of Helsinki and was approved by the Ethics Committee.

MATERIALS AND METHODS

Enrolling and assessment of patients' sample

To carry out the study we decided to enrol all patients requesting consultant support to overcome the difficulties in managing peristomal hygiene, who would agree to participate, for a total period of 12 months (March 2018 - March 2019). Although there were many requests, and the attitude towards the suggested protocol was mainly positive, only 64 patients accepted to participate in the study. The difficulty for patients to come regularly at the pre-established monitoring dates, made it impossible to enrol a larger patients' sample.
The evaluation intervals established after the initial assessment were at: 3 days (T1), 7 days (T2), 15 days (T3) and follow up at 28 days (T4).

On enrolment, a global assessment of the patient was carried out according to the Toven[24,25] method (recording data on gender, age, BMI, self-sufficiency, nutritional status and risk of pressure sores); the evaluation of the ostomy, peristomal skin and any lesions present was also recorded. Moreover, through instrumental measurements we recorded the values of peristomal epidermis hydration, derma hydration, elasticity, pH and sebum. For the data collection we used the TOR Form[26] validated in 2019, integrated with a section on the peristomal measurements recorded.

Skin parameters measured and instruments used

Using appropriate instruments, we measured in this order: the actual values of sebum, percentage of water contained in epidermis and derma, elasticity and peristomal pH; measures were taken at 2cm distance from the stoma site, at an angle of approx. 45° from the horizontal axis, high towards the abdomen (**Figure 1**) This position was chosen in order to avoid the risk of contamination with ostomy effluents during measuring. On enrolment and at follow-up, the same skin parameters were measured at the same height on the opposite (contralateral) side of the abdomen.

The measurements were taken by clinicians trained in the use of the instruments, with the patient at rest, in constant temperature (+25° C approximately) and humidity environment conditions, on intact skin, after removing the collection device and before applying the selected products.

All instruments obtained a certificate of calibration in January 2018.

Since in the available literature no reference values were found for any of the measured parameters in the abdominal skin, absolute values registered were analysed.

<u>Sebum</u>

The Defin SebumScale® (Delfin Technologies Ltd.) is a compact instrument, based on quartz crystal microbalance technology which accurately measures the amount of sebum in micrograms. The disposable measurement sensor has an effective measurement area of 1cm^2, and the brief positioning on the skin is sufficient for measuring the mass of the sebum collected from the skin in 0.1μg resolution (measurement range 0-150μg).

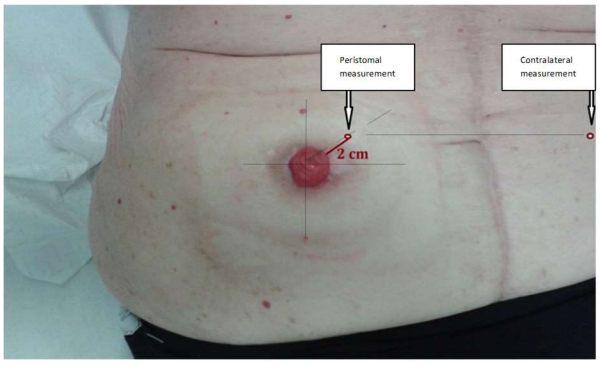


Figure 1. – Skin parameters measuring points

Percentage of water content in the tissues

To evaluate the epidermis and derma hydration we chose to measure the percentage water content (PWC), through the conversion of tissue dielectric constant (TDC).
To measure the epidermis percentage water content we used the *Delfin MoistureMeterEpiD®* (Delfin Technologies Ltd.). The device generates a high-frequency electromagnetic wave of 265MHz and sends it into the coaxial probe and the skin down to 0.5 mm's depth, automatically converting the tissue dielectric constant in percentage of water contained through the formula: PWC=TDC-1/77.5 x 100%. To evaluate the dielectric constant, the widespread dielectric field produced by the probe's head penetrates the skin's first layers, and determines the dielectricity converted in percentage of water actually contained in the tissue. The instrument has a pressure sensor and shows on the display when the right pressure is applied during the measurement, by registering a value only when such pressure is reached, and it doesn't allow any changes of the value recorded regardless of the strength applied by the operator.

The percentage water content in derma was measured using the *Delfin MoistureMeterD Compact®* (Delfin Technologies Ltd.), which works following the same principles as the previous one, converting in PWC, with the same formula, the derma dielectric constant at 2.5mm depth.
In available literature, no reference values could be found on the standard percentage water content in abdominal skin. Various studies that examined values found on other body parts such as forearm, thorax, lower limbs[27-29] pointed out that, regardless of age and BMI, the value of hydration index decreases proportionally to depth (f.i.: in a group of healthy women, age range: 22-83yy: TDC 33.7±5.8, at 0.5mm; to TDC 21.8±3.7 at 5.0mm[29]), and at a depth of 0.5-1.5 mm it's higher in the age bracket 20-40yy as against the over 60 year old.
On the other hand, they all agree on the importance of the natural moisturizing factor[30,31] for maintaining hydration.

Skin elasticity

The instant skin elasticity gives important information on the biophysical properties of the skin; this is the reason why we decided to measure it in the peristomal area using the Delfin ElastiMeter® (Delfin Technologies Ltd.), that uses an indenter which is briefly pressed on the skin. The skin resists the change in shape when an external force is applied and thus the skin's response under a short term load indicates its instant elastic properties.
The Delfin ElastiMeter® consist of a 0.6mm length indenter, a reference plate and built-in force sensors. The indenter imposes a contact deformation when the reference plate is in full contact with the skin. The skin resists the deformation and the instant skin elasticity (ISE) in N/m units is determined.

The shown ISE reading is the mean of five consecutive measurements. The final result wasn't influenced by variables operator-related, since the device is equipped with sensors to ensure correct application (speed of application, pressure applied and length of stay on the skin).

pH

The skin hydrogen potential (pH) is a measure of the hydrogen ion concentration [H+] in the watery solution present on the surface. This solution is obtained by adding water to the skin surface, which is a hydrophobic layer comprising of lipids. In our case, we didn't need to add water on the peristomal skin, since the extended presence *in situ* of the collection devices created the necessary moisture.

Various studies have noted that a relationship exists between the acidity of the skin surface and its antimicrobial activity. The normal values of pH in intact skin range from 4.8 to 6.0 due to presence of the acid mantle, while the interstitial fluids are characterized by neutral values.

pH was measured using the portable pH Water Quality Meter LAQUAact ® (HORIBA Advanced Techno Co., Ltd.). The device is equipped of the flat pH electrode connected to a pH meter, and provides not only excellent contact with the skin but also measurement accuracy within ±0.1 pH.

Products used and application method

While looking for a product suitable for contact with both the skin and the mucosa, we discovered that in the market there are basically two different types of detergents: on the one hand the vegetable-base soaps (which have a low cleansing strength and an alkaline pH), on the other hand the modern surfactants (which have a high cleansing power and can be acidified). Some of the latter, however, can be aggressive for the stoma and at times also for the skin, if they have a low molecular weight and negative electrostatic charge which allow them to penetrate in depth and alter the balance. We considered important features for a product used for stoma hygiene: pH value, ability to restore the skin's natural moisturizing factor and absence of harmful substances that could be absorbed by the mucosa.

Following the application of a hygiene protocol aiming at restoring pH and physiologic skin hydration in a few clinical cases, we observed the improvement of peristomal skin condition. We therefore decided to further the research, and study if such event would be confirmed by a statistically representative patients' sample, and also study if the use of such protocol, together with the patient's therapeutic education, could contribute to healing the peristomal lesions.

Peristomal hygiene was carried out with a self-balancing® pH soap (Bioderm Stoma Plus® - Farmoderm Srl) to restore optimal pH and an isodermic® cream (Bioderm Dermocrema® - Farmoderm Srl) to restore the skin's natural moisturizing factor.

The soap can contribute to restore the physiologic pH of the area it is applied on, does not contain any substances that could lead to unbalances or allergies, nor any harmful substances if absorbed by the mucous membrane (such as petrolatum, parabens, super-greasers, silicones, synthetic perfumes, ethyl alcohol). It is an isodermic® product with "very high affinity",

containing a patented macromolecule, tenside, branched, with high molecular weight and positively charged, naturally rejected by the keratin present in the stratum corneum. It ensures an effective and natural cleansing without being absorbed by the skin or the mucous membranes. This type of detergent has a very low foaming power, a highly appreciated feature since this

simplifies the hygiene procedure. The vegetable extracts contained in the formula (thyme, tea tree oil, sage, mallow, chamomile) contribute to a lasting antifungal, antibacterial, decongestant, soothing and deodorant action, which is important due to the continuous contact of the area with stoma effluents.

After cleansing and accurately drying the skin, we also used an isodermic® cream (Bioderm Dermocrema®) with shea butter, with high lipid content, able to supply all the essential fatty acids and promote the restoring of the physiologic hydro-lipidic contents. It contains vitamins and thermal trace elements, which act as forerunners of many biochemical and enzymatic syntheses and have an important role as co-factors in the processes of collagen and elastin synthesis. A tiny amount of cream was applied on the peristomal skin. Since the product does not leave fatty residues, there is no problem in applying the adhesive device.

All patients observed received therapeutic education from the moment of initial enrolment, in order to allow them to understand the physiology of the stoma and of the peristomal skin (and thus the need to ensure their integrity), and the importance of hygiene, with the aim of allowing them a self-sufficiency in applying the protocol and managing the devices.

In order to achieve the objective of the study we analysed the reaction of the skin following the application of the chosen products, measuring the skin parameters such as: epidermis hydration, derma hydration, elasticity, pH, sebum.

DATA ANALYSIS

Sample Composition

Data analysis was carried out on a sample of 50 patients, since of the 64 that initially agreed to participate 11 withdrew from the monitoring 7 days from enrolment, due to the healing of the lesions, and 3 patients with grade L3 lesions (according to SACS 2.0) had to be treated with advanced wound care dressing.

Although our objective was to observe the healing of peristomal lesions following the application of the new hygiene protocol, we chose to monitor all patients for 28 days, even if the healing occurred earlier. This in order to observe if the result obtained could be maintained, and the evolution of the measured parameters.

The personal and clinical characteristics of the patients observed are contained in **Table 1**.

The gender composition of 50% males/50% females was purely coincidental. As regards age (range 23-97yy), 45% of the sample had an age between 41-80 years and 16% over 80 years.

On enrolment we carried out an accurate nursing assessment and a global assessment according to the Toven Method[24,25] , which takes into consideration the patient in his complexity and besides

the anthropometric data (weight/height/BMI) measures, through the use of accredited scales, parameters such as: self-sufficiency level (*Barthel Index*[24,32]), risk levels (pressure lesions – *Braden Scale*[33,34], malnutrition - *Mini Nutritional Assessment Scale*[35]), pain intensity *Numerical Rating Scale*[36,37] (NRS).

The vast majority of the sample (52%) were self-sufficient, with a Barthel Index of 100, in 92% of cases with a low risk of pressure lesions (Braden >16) and as far as weight is concerned, they were: 48% normal weight (BMI 18.5kg/m^2-24.9kg/m^2), and 38% overweight (BMI 25.0kg/m^2-29.9 kg/m^2). Data on pathologies, type of ostomy, evaluation and monitoring of the stoma and of the peristomal skin (appearance, colour, protrusion, mucocutaneous junction, peristomal skin, complications), evolving of the peristomal lesions and type of hygiene carried out were gathered using the validated Tor Form[26].

From the general clinic point of view, 46% had a neoplasia, 12% diabetes, 12% both neoplasia and diabetes, 8% Crohn Disease. Besides the peristomal skin lesions present in 100% of cases, there were also other stoma complications: retraction 12%(6), prolapse 16%(8), mucocutaneous detachment 2% (1).

Table 1. – Characteristics of the observed sample

Variable	Category	Values
Gender	F	25 (50%)
	M	25 (50%)
Age	<30	2 (4%)
	31-40	6 (12%)
	41-60	11 (22%)
	61-80	46 (23%)
	>80	8 (16%)
BMI	Underweight (< 18.5 kg/m^2)	2 (4%)
	Normal weight (18.5 kg/m^2 - 24.9 kg/m^2)	24 (48%)
	Overweight (25.0 kg/m^2 - 29.9 kg/m^2)	19 (38%)
MNA	<17 (malnutrition by default)	8 (16%)
	17 – 23.5 (malnutrition risk)	7 (14%)
	>24 (normal nutritional state)	35 (70%)
Barthel Index	< 50 (not self-sufficient)	4 (8%)
	99-50 (partially self-sufficient)	20 (40%)
	100 (completely self-sufficient)	26 (52%)
Braden Scale	<12 (high risk)	1 (2%)
	12-16 (risk)	3 (6%)
	>16 (low risk)	46 (92%)
Pathologies	Diabetes	6 (12%)
	Crohn's disease	4 (8%)
	Crohn's disease + Diabetes	1 (2%)
	Neoplasia	23 (46%)
	Neoplasia+Diabetes	6 (12%)
	None of the above	10 (20%)
Type of ostomy	Urinary	10 (20%)
	Intestinal	40 (80%)
Patient with ostomy for	< 2 months	8 (16%)
	3-11 months	5 (10%)
	1-5 years	23 (46%)
	>5 years	14 (28%)
Type of collection device	Single piece	20 (40%)
	Two pieces	30 (60%)
Manages ostomy by his-herself	Yes	38 (76%)
	No	12 (24%)
Complications	Retraction	6 (12%)
	Prolapse	8 (16%)
	Necrosis	0 (0%)
	Hernia	0 (0%)
	Mucocutaneous detachment	1 (2%)
	Skin lesions	50 (100%)
Previous hygiene	Materials	Paper – 19 (38 %) Gauze - 5 (10 %) Sponge – 11 (22 %) Cellulose cloth - 0 (0%) Wet Kleenex – 11 (22%) Cotton wool – 3 (6 %) Other - 1 (2%)
	Detergents	No soap – 8 (16%) Body soap – 23 (46%) Marsiglia soap – 12 (24%) Other – 7 (14%)

The patients examined, whether with urostomy (20%) or intestinal ostomy (80%), had for the most part a good familiarity in using collection device (self-management of the stoma in 76% of cases), as they had a stoma for more than 5 years (28% of cases) and 1-5 years (46% of cases). The majority used two-piece devices (60%) – single piece devices being used by 40%.
Hygiene procedures followed up to enrolling were various, and few patients used products with specific requirements. The vast majority stated that they had not received any indications on the type of materials and detergents to use, and they found themselves in trouble when having to choose. So, 16% (8) didn't use any soap or detergent, 46%(23) used body soap, whereas 24%(12) used "Marsiglia" soap, and 14%(7) other types of detergents. The most common material was paper in 3%(19) of cases, followed in equal proportions by sponge and wet wipes (22%), then gauze (10%) and lastly cotton wool (6%).

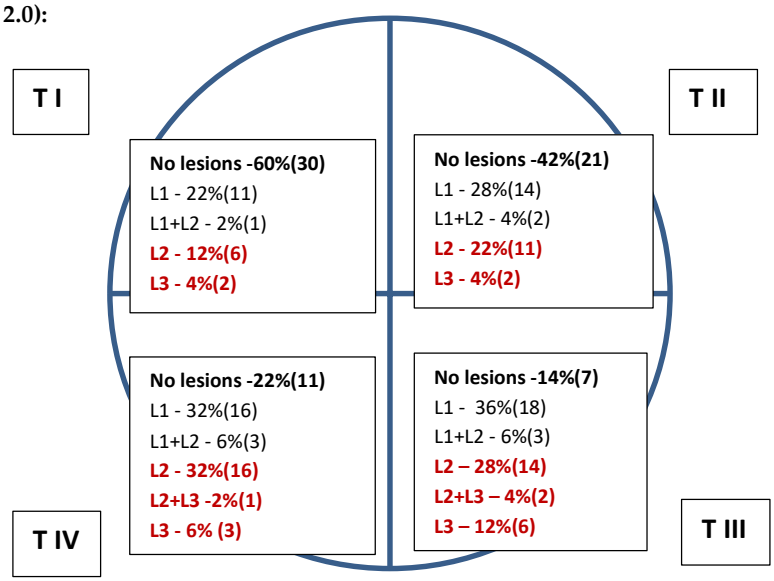
During the enrolment session, we analysed compliance on the protocol in use and on the new protocol we would apply. 32% stated they were happy with the detergent and 35% with the material they were using. Only 38%(19) declared they were happy with the new protocol, the rest expressed perplexity on the use of a cream product, which none of the 64 observed patients had ever used before, fearing that it could prevent adhesion of the collection devices.

Types of peristomal lesions present

All patients had peristomal lesions.
On enrolment, we assessed the peristomal skin condition and that of the lesions present, which were classified according to the SACS 2.0[38,39] Scale. We analysed the presence of peristomal lesions (**Figure 2**) in each of the T sections (TI – higher side of the stoma on the patient's right hand side, TII - higher side of the stoma on the patient's left hand side, TIII – lower side of the stoma on the patient's left hand side, TIV – lower side of the stoma on the patient's right hand side) and their status. As inclusion criterion it had been decided to accept patients with lesions from L1t o L3 according to the SACS 2.0 Scale (L1-hyperaemic lesion, L2-erosive lesion with loss of substance up to the derma, L3–ulcer lesion beyond the derma), since ulcer lesions with slough/necrosis (L4), due to their seriousness call for use of advanced wound care dressing.

As can be seen in Figure 2, the section with less lesions is TI (no lesions 60%; L3 – 4%), while in TIII we observed more lesions and of higher severity (no lesions 14%, L3 – 12%). As we expected, there were a higher number of lesions in the lower part of the abdomen, but, on the other hand, there is a significant difference between TIII and TIV as far as presence and severity of lesions.

Figure 2. – Type of lesions present at enrolment (classified according to SACS 2.0):



Analysis of the measured skin parameters

The skin parameters measurements (epidermis PWC, derma PWC, elasticity, pH, sebum) were taken at all pre-established intervals:

- T0 - enrolment,
- T1 - 3 days from start of treatment,
- T2 - 7 days from start of treatment,
- T3 - 15 days from start of treatment,
- T4 - 28 days from start of treatment (follow-up).

At T0 and T4, measurements of the same parameters were also taken in the contralateral area of the abdomen.

In each of the monitoring sessions, at the same time as the measurements we also carried out a progressive therapeutic education of the patients, on importance of maintaining skin integrity and its physiologic conditions, and on correct application of the collection devices in use. We observed that all patients had little knowledge on the topics, and many wrong habits, although only a few (26%) had had a stoma for less than one year, and therefore had little experience, although they had good dexterity in positioning the adhesive parts.

Percentage of water contents in epidermis and derma

In the available literature, we could not identify studies that gave reference values for skin hydration and water content percentages for the abdomen, therefore we were unable to compare with previous values. The studies had observed different parts of the body[27-31], such as face skin[40] (TDC 0.5avg = 36.2±4.8; TDC 2.5avg = 37.7±4.2), ventral forearms[28] (TDC 0.5avg = 36.2±4.7 ; TDC 2.5 avg = 23.9±4.1), lateral thorax[28] (TDC 2.5avg = 24.1±4.1). Therefore, we registered and analysed (**Figure 3** and **Figure 4**, **Table 2**) absolute values measured at epidermis (depth 0.5mm) and derma (depth 2.5mm) levels.

One can observe, from the PWC values we registered on enrolment (T0) that peristomal skin had a better hydration (PWCE: range 18.1-63.4%, average 42.8%, median 40.2%; PWCD: range 21.9-58.9%, average 39.3%, median 39.4%) when compared to the contralateral skin (PWCE: range 21.3-64.2%, average 37.2%, median 35.8%; PWCD: range 18.7-58.2%, average 35.4%, median 35.5%). This is probably due to the presence *in situ* of hydrocolloid devices. Moreover, following the use of the new hygiene protocol, (Figure 3, Figure 4) we observed at T4 in the values monitored a significant improvement of both (Table 3) PWCE ($p<0.001$) and PWCD ($p<0.001$) of peristomal skin (T4: PWCE range 23.7-70.5%, average 44.2%, median 43.9%; PWCD range 11.1–61.0%, average 40.7%, median 41.0%). The values of the contralateral skin, where the patients didn't regularly use the products in the protocol, register a slight improvement at T4 (PWCE range 21.6–59.5%, average 38.2%, median 35.6%; PWCD range 20.0 – 58.0%, average 36.4%, median 36.6%).

Figure 3. – Evolution of peristomal epidermis PWC

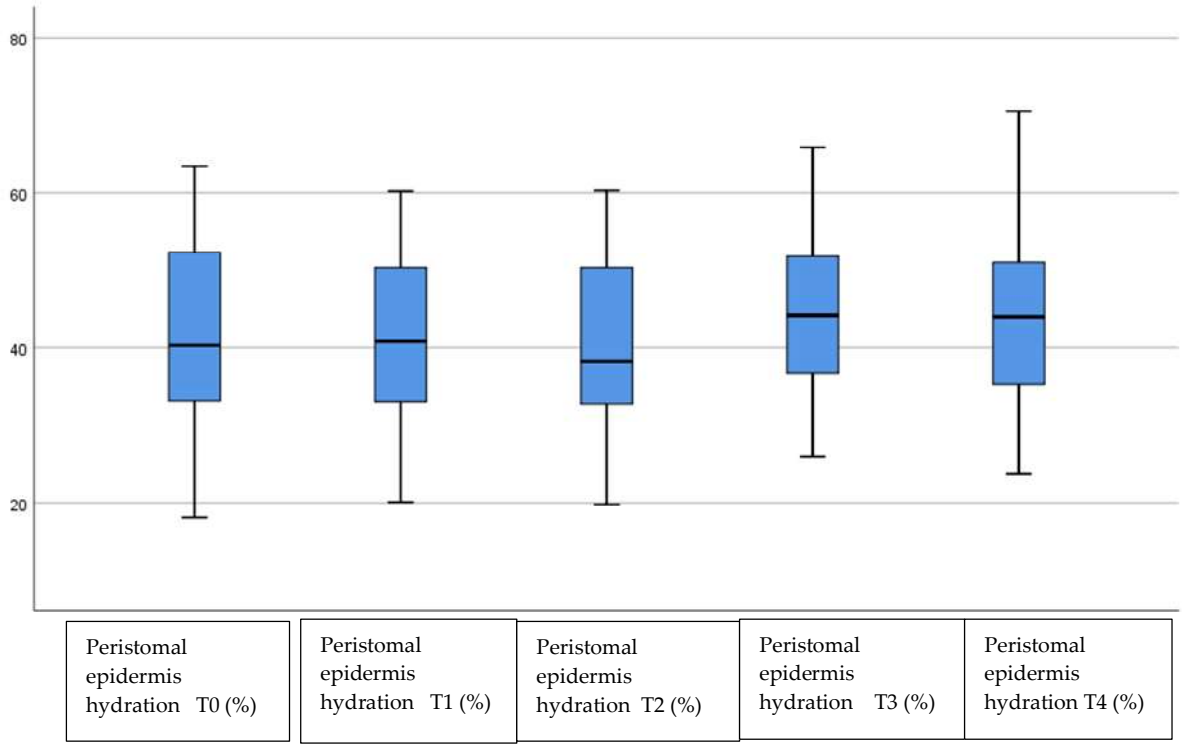


Figure 4. – Evolution of peristomal derma PWC

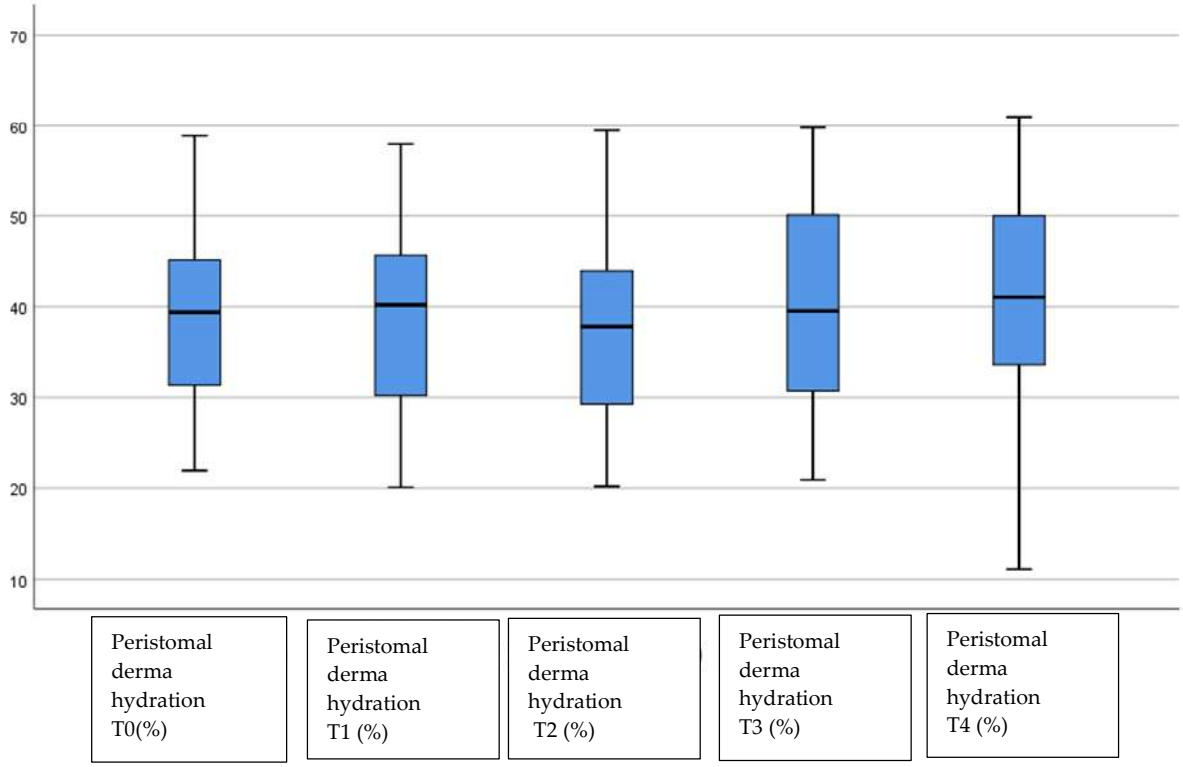


Table 2. – Monitoring of peristomal epidermis -derma PWC

	Peristomal epidermis PWC (%)					Peristomal derma PWC (%)				
	T0	T1	T2	T3	T4	T0	T1	T2	T3	T4
Average	42,818	41,738	40,486	44,102	44,274	39,372	38,710	38,106	40,078	40,708
N	50	50	50	50	50	50	50	50	50	50
Std deviation.	11,3550	10,2681	10,5057	9,8056	11,0681	9,6761	10,2152	11,0087	10,9391	10,6374
Median	40,250	40,750	38,250	44,150	43,950	39,400	40,200	37,850	39,550	41,050
Min	18,1	20,1	19,8	26,0	23,7	21,9	20,1	20,2	20,9	11,1
Max	63,4	60,2	60,3	65,8	70,5	58,9	58,0	59,5	59,8	61,0

Elasticity

Skin elasticity evolution has been monitored at the same intervals, measuring also contralateral values at T0 and T4. To measure skin tissue firmness, the indentation force in N/m units required to indent skin to 0.6 mm.

At enrolment, we observed that peristomal skin elasticity (T0: range 21.3–65.0N/m, average 38.3N/m, median 38.3N/m) had better value than the contralateral skin (range 20.7 – 53.8, average 36.7, median 36.6 N/m). During monitoring (**Figure 5**) we did not observe a significant change in elasticity, however at T4 a good improvement in the peristomal skin was recorded (range 22.0-91.0, average 40.4, median 38.6 N/m) (Table 3) and a discreet improvement in the contralateral skin (range 20.0–73.0N/m, average 37.2N/m, median 33.1 N/m).

Figure 5. – Evolution of elasticity in peristomal skin

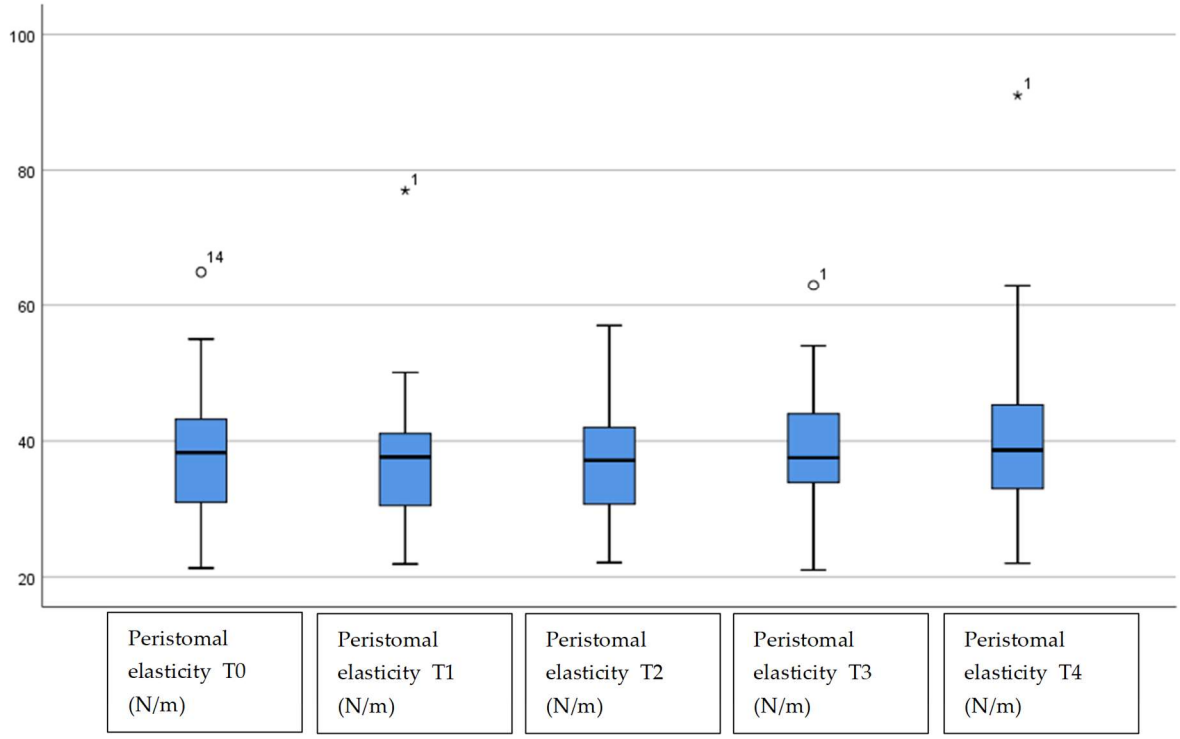


Table 3. – Variation of skin parameters from enrolment to end of monitoring time

	PWC peristomal epidermis (%)		PWC peristomal derma (%)		Peristomal Elasticity (N/m)		Peristomal pH		Peristomal Sebum	
	T0	T4	T0	T4	T0	T4	T0	T4	T0	T4
Average	42,818	44,274	39,372	40,708	38,382	40,420	6,4250	5,9128	,16	,02
N	50	50	50	50	50	50	50	50	50	50
Std. Deviation	11,3550	11,0681	9,6761	10,6374	8,3597	11,2681	,71469	,37853	,370	,141
Median	40,250	43,950	39,400	41,050	38,300	38,650	6,6100	5,8000	,00	,00
Min	18,1	23,7	21,9	11,1	21,3	22,0	4,30	5,02	0	0
Max	63,4	70,5	58,9	61,0	65,0	91,0	7,72	6,80	1	1

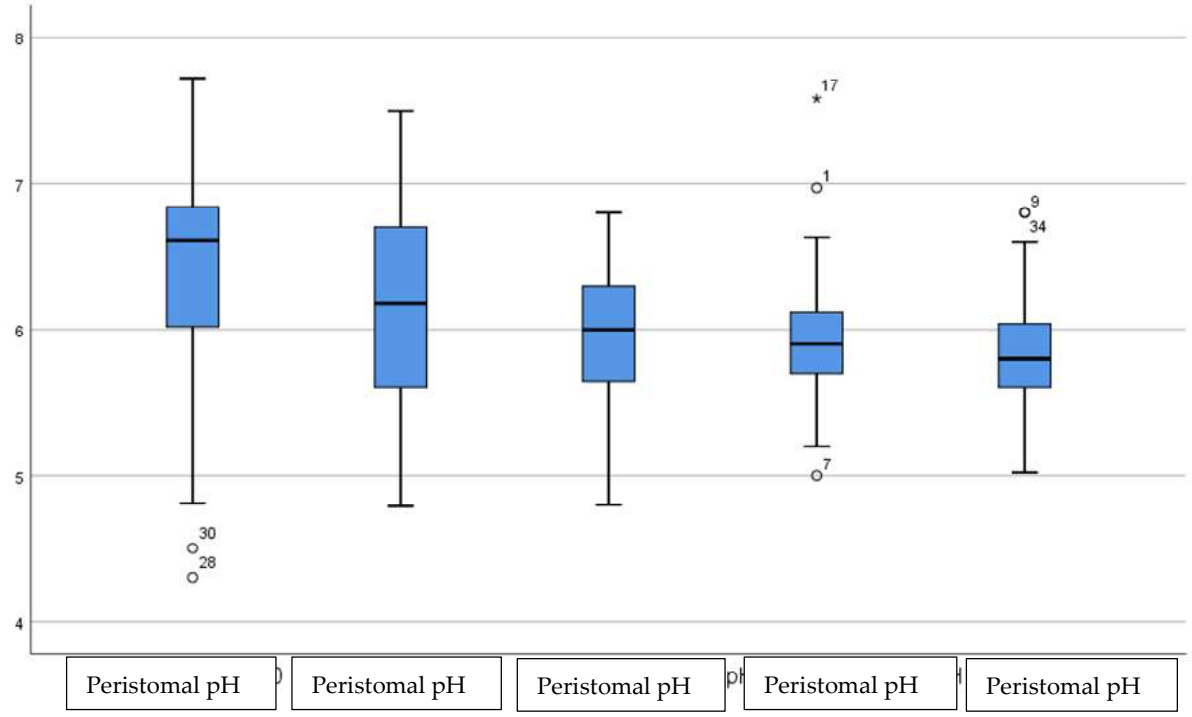
pH.

Skin pH has different values in the various parts of the body[41,42], it's related to race or ethnicity [43] and its maintenance within physiological limits is determined by the ability of the skin to restore the acid mantle. Maintaining an acid pH (5.5-6.0) is paramount for the skin's defence against attacks of pathogens[42,43].

Peristomal skin is continuously exposed to intestinal/urinary effluents, and due to permanent use of adhesive devices it cannot spontaneously restore the acid mantle– it requires a specific management aiming to keep the pH physiologic values.

On enrolment we measured the peristomal pH (range 4.3–7.7, average 6.4, median 6.6) and contralateral skin pH (range 4.3–8.0, average 6.3, median 6.4). During the monitoring period (**Figure 6)** we observed that its variation has been the most significant ($p<0.001$) amongst all parameters measured (**Table 3**). The reduction of both range and average value (peristomal pH T4: range 5.0 – 6.8, average 5.9, median 5.8; contralateral pH T4: range 4.6 – 6.9, average 6.0, median 6.0) coupled with an improvement of initial skin condition, confirms its importance in healing and prevention of peristomal lesions.

Figure 6. – Evolution of peristomal pH.



Sebum

Sebum is a component of the skin's natural moisturizing factor[42,43]. Specifically, in the peristomal skin, it's continuously removed by adhesive devices, and it's difficult to restore spontaneously.

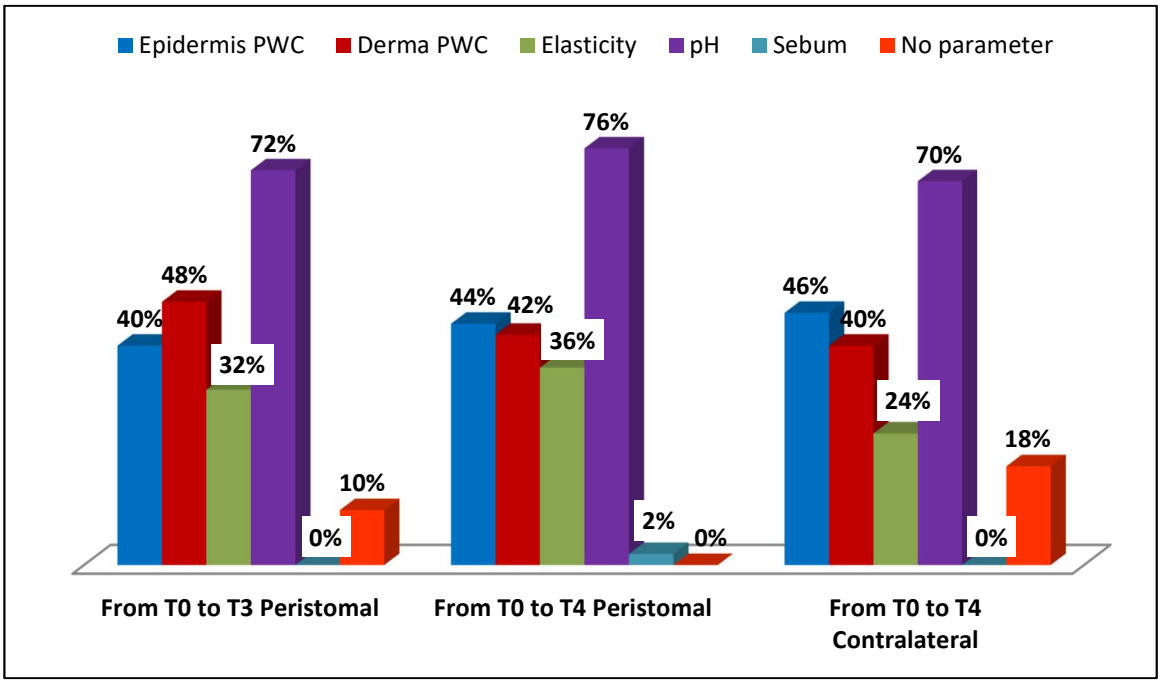
The highest value we founded on both peristomal skin and on contralateral skin has been 1µg.

At the time of enrolment (T0) we identified presence of sebum =1µg on peristomal skin in 8 patients (16%), and absence of sebum in the remaining 42(84%). On the contralateral skin, on the other hand, sebum =1µg was present only in 2 cases (4%), absent in all the others (96%).

During the monitoring period, we observed that only in one patient (2%) the peristomal sebum was maintained at T1, totally absent in all at T2 and T3 both on the peristomal and contralateral skin. At T4 peristomal sebum present only o peristomal skin of 1 patient (**Figure 7**).

The results obtained gave us reason to think, since we expected to find sebum values proportional to the improvement of pH values; the data will need to be further researched in future clinical studies.

Figure 7. – Parameters improved compared to enrolment values



Healing of Peristomal lesions

Besides monitoring the healing rate of all lesions already present, we also wanted to analyse the values of parameters measured at the time of healing and examine if the personal and management factors have a statistically significant influence on healing.

We observed that such factors as gender (p=0,735), didn't have a significant influence on the healing rate of L1-L3 peristomal skin lesions, nor the values of Barthel Index, Braden Scale, MNA and whether the stoma was managed (by the patient him/herself or by the Stoma Care Specialist). Just by following the new hygiene protocol, without the use of advanced wound care pads, healing was achieved on the total number of skin lesions registered at enrolment: at T1–42%, at T2–80%, and at T3-98%; no new lesions appeared (**Figure 8**). Out of all the sample observed, only 1 patient (2%), with peristomal lesions L3, didn't achieve healing at T4.

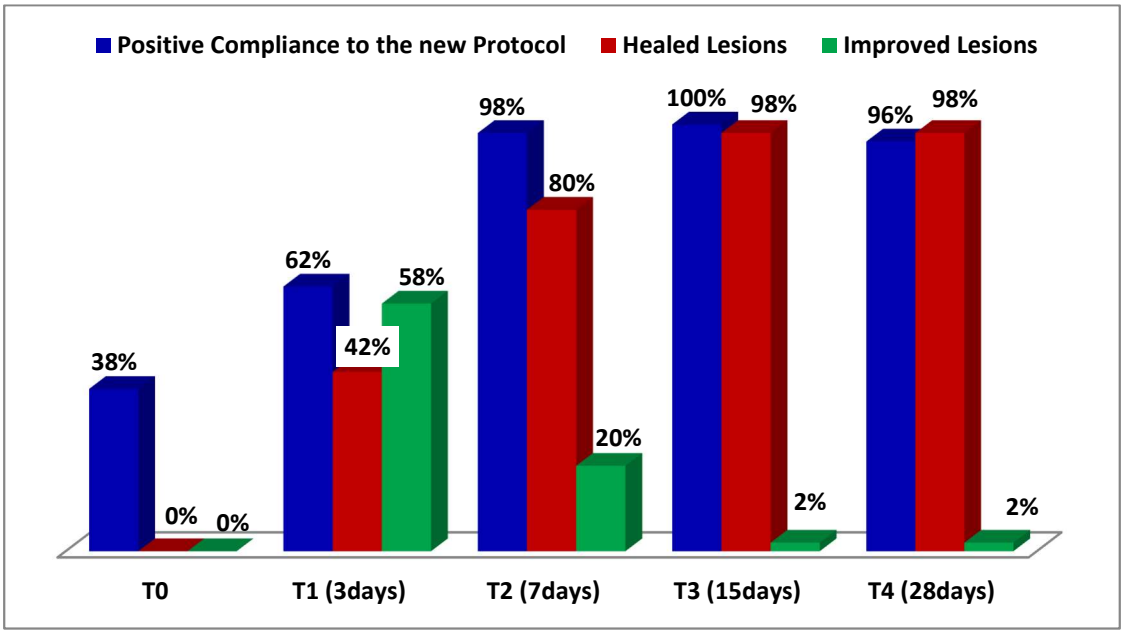
Compliance in using the new protocol increased proportionally to healing of the lesions (Figure 8.) and disappearing of pain. Already at T2 (after 7 days) it had reached 98%, and by T3 100%, having overcome the doubts on using the cream.

From T3 to T4, thanks to the therapeutic education received, all patients managed at home, without the Stoma Care Specialist support, both the new hygiene protocol and the application of collection devices. In the 13 days' interval, there was no recording of new lesions.

Two patients (4%) gave a negative feedback on the new protocol at T4, although their lesions had completely healed (L2, L3) and the fact that during the management session by the Specialist they had expressed a positive opinion. They both had an age between 61-80 years, with a stoma

for less than two months and were not able to manage it by themselves. They both had complications (retraction and prolapse respectively), had neoplasia and undergoing chemotherapy at the time of the study, and they had previously used the same soap they used for body hygiene. They both considered the se of the two products too difficult; their care givers were in disagreement with them.

Figure 8. – Evolution of lesions and compliance status



We wanted to compare the parameters measured at the time of healing, regardless to the time passed since the enrolment (Table 4.), to observe if a common denominator can be found to aim at. Patients with the fastest healing (42% - after 3 days) had, at the time of healing, an average of: epidermis PWC =41.9%, derma PWC =35.9%, Elasticity = 34.4N/m, pH=6.0, sebum=0µg (Table 3.). We observed similar values in case of percentage of water content in epidermis (PWCE: T1=41.9; T2=41.8), pH (always close to 6: T1=6, T2=5.8, T3=6) and sebum (absent).

Further studies are required to research if derma PWC could have a direct role in healing peristomal lesions.

Table 4. – Variation of skin parameters at the time of healing

	PWC peristomal epidermis (%)			PWC peristomal derma (%)			Peristomal Elasticity (N/m)			Peristomal pH			Peristomal Sebum		
	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
Average	41,967	41,853	43,967	35,976	40,826	42,400	34,486	37,821	42,089	6,072	5,867	6,070	,00	,00	,00
N	21	19	9	21	19	9	21	19	9	21	19	9	21	19	9
Std. Deviation	8,731	11,961	12,920	10,151	10,940	9,869	7,642	6,8687	5,3053	,6848	,5057	,2712	,000	,000	,000
Median	41,900	39,200	39,000	38,800	38,300	45,000	33,000	38,000	42,300	6,000	5,900	6,000	,00	,00	,00
Min	24,3	20,4	31,7	20,1	24,3	29,8	21,9	25,1	35,7	5,10	4,80	5,50	0	0	0
Max	53,4	60,0	64,7	55,0	59,0	55,7	48,0	48,3	51,1	7,47	6,80	6,42	0	0	0

Pain assessment

Pain intensity assessment was carried out with the *Numerical Rating Scale* (NRS) support, since in the sample there were no patients with cognitive impairment.
12 participants (24%) declared to feel pain due to skin lesions, with a range 3-7 NRS as follows: 2 people- NRS 7; 4 people - NRS 6; 1 person- NRS 5; 1 person - NRS 4; 4 people - NRS 3.
None of the patients had to take painkiller drugs, since pain decreased already after the first session, and completely subsided at T1 in 4 patients, at T2 in 5 patients, at T3 in 2 patients, at T4 in 1 patient.

DISCUSSION

Following the use on a sample of 50 ostomy patients (urostomy 20%, colostomy 80%) of a new hygiene protocol for peristomal skin used, with a self-balancing® pH soap (Bioderm Stoma Plus® - Farmoderm Srl) to restore optimal pH and an isodermic® cream (Bioderm Dermocrema® - Farmoderm Srl) to restore the skin's natural moisturizing factor, we observed a good answer with healing after 15 days of 98% of the peristomal lesions present on enrolment (L1-3 according to SACS 2.0), without the use of wound care dressing.

Since the available literature we consulted there was no similar studies or reference values for abdominal skin parameters, such as percentage water content in peristomal epidermis and derma, elasticity, pH, and sebum, we were unable to compare the values obtained. However, analysing

the actual values we measured with specific instruments, we were able to observe, from enrolment to the end of the study observation period (28 days), a significant improvement

($p<0.001$) of the average of epidermis PWC (T0-42.8% vs T4-44.2%), derma PWC (T0-39.3 vs T4-40.7), elasticity (T0-38.3N/m vs T4-40.4N/m) and pH (T0-6.4 vs T4-5.9) of peristomal skin (Table 3.).

Moreover, 15 days from the start (T3), we observed an improvement in peristomal skin of PWCE in 40%, of PWCD in 48%, of elasticity in 32%, and of pH in 72% of cases (Figure 7.). At the end of the study, the improvement registered compared with enrolment data was: PWCE in 44%, PWCD in 42%, elasticity in 36%, and pH in 76% of patients.

By applying the new hygiene protocol, and without the use of wound dressings, we observed healing of the recorded lesions at: T1 – 42%, T2 – 80%, and T3 - 98%, with no new lesion occurring.

We can therefore conclude that therapeutic education, in combination with the use of a correct peristomal hygiene, keeping the peristomal skin hydrated and with a pH of approx. 5.9 lead to prevention and healing of peristomal lesions of stage L1-L2.

Authors' contributions

FLT and ET designed of the study, supervised the data collection and drafted the manuscript. GLT performed the statistical analysis, participated in the design of the study and to the manuscript's drafting. ET and MSE planned and collection the clinical data. PP, translator consultant, performed the text translation.

All the authors read and approved the final manuscript.

Disclosure

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Declaration of conflict of interest

The Authors declare to have no conflict of interest.

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