

PCCA EctoSeal P2G[™]

Case Studies

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Management of Foot Chronic Wounds with an Innovative Topical Powder (EctoSeal P2G)

Submitted by: Jack Dunn, R.Ph., Jasper Drug Store, Jasper, Georgia, USA.

Case Report:

A 53-year-old healthy female suffered an accident while standing next to her car to let the dog out. The car rolled over her right foot causing extensive wounds and rupture of her Achilles tendon. Following two surgeries, the chronic wounds located on the back of the heel (Achilles tendon), ankle (right side), and sole were still extensive and infected. The largest wound was on the ankle at 3 inches by 1 ½ inches wide (photos below). The wound on the back of the heel measured 1 ½ inch. When the local compounding pharmacist was consulted, an innovative topical treatment was recommended, including pentoxifylline, phenytoin, naltrexone HCl, misoprostol, arginine HCl and beta glucan in the topical base, PCCA EctoSeal P2G Powder (Table 1).

Rx	
Pentoxifylline USP	2 g
Phenytoin USP	2 g
Naltrexone Hydrochloride USP Anhydrous	Calculate
Misoprostol 1% (HPMC Dispersion)	0.24 g
Arginine Hydrochloride USP	1 g
Beta Glucan (1,3) NQ	0.2 g
Base, PCCA EctoSeal P2G™ Powder	q.s. 100 g

Table 1. Pentoxifylline 2%/Phenytoin 2%/ Naltrexone HCl 0.1%/Misoprostol 0.0024%/Arginine HCl/Beta Glucan Topical Powder (EctoSeal P2G): PCCA Formula 14899.

A. Before treatment

B. 1 week post-treatment

C. 6 weeks post-treatment

Ankle (right side)



Back of the heel (Achilles tendon)



D. End of treatment: full recovery



Sole



Management of a Scalp Chronic Wound with an Innovative Topical Powder (EctoSeal P2G)

Submitted by: Jack Dunn, R.Ph., Jasper Drug Store, Jasper, Georgia, USA.

Case Report:

A male patient in his sixties was diagnosed with scalp melanoma, a type of skin cancer that is associated with high mortality rates and is accountable for 5% of all melanomas (Figure 1). Early diagnosis and adequate surgical margins are particularly important in managing scalp melanomas. The patient had no underlying conditions and he was only taking blood pressure medication at the time of diagnosis. Despite being a relatively small melanoma, the lesion was excised with large safety margins to ensure complete removal of the skin cancer cells. Wound healing took longer than anticipated and an epibole chronic wound developed, which is characterized by lack of epidermal margins and rolled edges, as shown in Figure 2A. Despite its appearance, the patient reported no local pain post-surgery so the wound was only mildly affecting the patient's quality of life.

The local compounding pharmacist was consulted and an innovative topical powder was recommended including phenytoin, aloe vera, misoprostol, arginine and beta glucan in the proprietary base, PCCA EctoSeal P2G Powder. Treatment took place at the compounding pharmacy three times per week (Monday, Wednesday and Friday) for a total duration of about 2.5 months (Figures 2B-2C). At each visit, the scalp wound was debrided with saline solution and the topical compounded medication was directly applied to the wound. Upon contact with the wound exudate, the compounded powder converted into a gel, which facilitated the topical application. Soon after, the gel converted into a film, which facilitated protection of the wound. Following about 1 month of treatment, the scalp chronic wound had been reduced to about half an inch. After approximately 2.5 months of treatment, the scalp chronic wound was fully closed and healed, as displayed in Figure 2C.

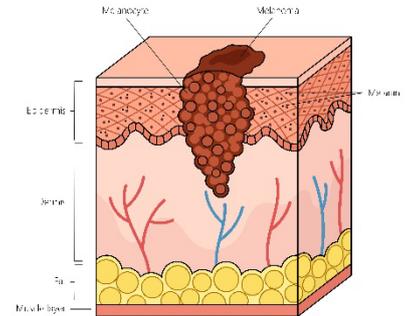


Figure 1. Melanoma, Shutterstock Illustration ID: 2440252443.

Rx	100 g
Phenytoin USP	2 g
Aloe Vera Powder Freeze Dried 200:1	0.2 g
Misoprostol 1% (HPMC Dispersion)	0.24 g
Arginine Hydrochloride USP	0.2 g
Beta Glucan (1,3) NQ	0.2 g
Base, PCCA EctoSeal P2G™ Powder	97.16 g

Table 1. Phenytoin 2%/Aloe Vera 0.2%/Misoprostol 0.0024%/Arginine HCl/Beta Glucan Topical Powder (EctoSeal P2G): PCCA Formula 15283.



Figure 2. Scalp chronic wound before treatment (A), during treatment (B), and about 2.5 months after treatment (C).

Management of an Abdominal Chronic Wound with an Innovative Topical Powder (EctoSeal P2G)

Submitted by: Jack Dunn, R.Ph., Jasper Drug Store, Jasper, Georgia, USA.

Case Report:

A 74-year-old healthy male presented with a chronic wound in his abdominal area due to multiple past surgeries, including hernia operations prior to 2016, a blockage removal in 2016 and a scar tissue removal in 2018. During this latest surgery, an accidental cut to the intestinal wall led to sepsis and a long hospitalization until full recovery. Despite multiple treatments, the chronic wound remained in the patient's abdominal area and measured about 1 ½ inch long by 1 inch wide. The skin in this area was very thin but there was no infection.

The patient was at his local compounding pharmacy and overheard the pharmacist in charge talk about an innovative wound treatment. Following a consultation, the patient was recommended a compounded topical powder including phenytoin, aloe vera, misoprostol and beta glucan in the proprietary base, PCCA EctoSeal P2G Powder (Table 1).

To complete the diagnosis, a health-related quality of life questionnaire was completed by the patient: Wound-QoL-17 (Blome *et al.*, 2014). This is a validated questionnaire composed of 17 items which are classified according to 3 subscales: body, psyche and everyday life. Each item is scored from 0 (not at all) to 4 (very much). A minimum of 75% of the items must be answered for a valid assessment. The higher the global score obtained, the greater the impairment on the patient's self-reported quality of life. Permission was requested and obtained by the license holder to use this questionnaire for the purpose of individual case studies.

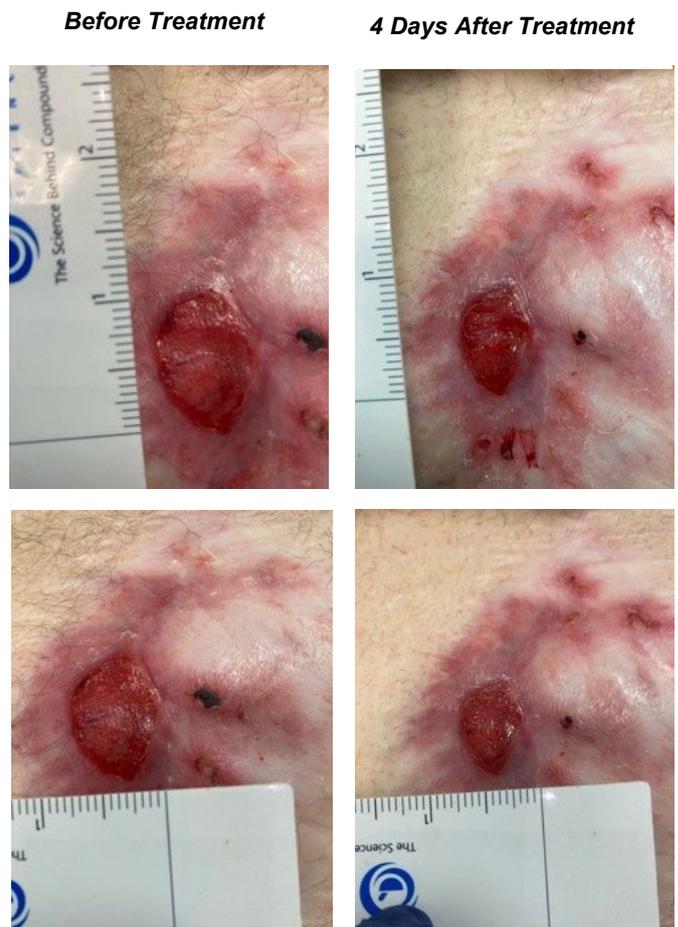
Before topical compounded treatment, the patient scored all items as "not at all" or "a little," yielding a global total score of 10. The most affected subscales were "psyche" and "everyday life" but overall, the patient's quality of life was only mildly affected by the abdominal chronic wound.

The compounded topical powder was the only medication taken by the patient. Besides, he also took supplementation of zinc 30 mg, vitamin D3 5,000, and hyaluronic acid to further support the healing process. In just 4 days of treatment, there were visible clinical improvements. The abdominal chronic wound decreased in size considerably, as displayed in Figures 1 and 2.

Blome C, Baade K, Sebastian Debus E, Price P and Augustin M (2014). The "Wound-QoL": A short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen* 22:504–14.

Rx	
Phenytoin USP	2 g
Aloe Vera Powder Freeze Dried 200:1	0.2 g
Misoprostol 1% (HPMC Dispersion)	0.24 g
Beta Glucan (1,3) NQ	0.2 g
Base, PCCA EctoSeal P2G™ Powder	97.36 g

Table 1. Phenytoin 2%/Aloe Vera 0.2%/Misoprostol 0.0024%/Beta Glucan Topical Powder (EctoSeal P2G): PCCA Formula 14942.



Figures 1 (left) and 2 (right). Digital photographs of the abdominal chronic wound, before treatment (left column) and 4 days after treatment (right column).

Recovery from Toes Amputation with an Innovative Topical Powder (EctoSeal P2G)

Submitted by: Jacob Sweet, R.Ph., Elite Pharmacy, Garrettsville, Ohio, USA.

Case Report:

A 66-year-old male diabetic patient had all his toes amputated from the right foot because of diabetes and vascular disease. Surgery was performed to remove tissues and bones which were preventing wound healing. The surgery went well but there were concerns with regard to the patient's full recovery. As such, a health-related quality of life questionnaire was completed by the patient: Wound-QoL-17 (Blome *et al.*, 2014). This is a validated questionnaire composed of 17 items which are classified according to 3 subscales: body, psyche and everyday life. Each item is scored from 0 (not at all) to 4 (very much). The highest possible global score is 68 (17x4). A minimum of 75% of the items must be answered for a valid assessment. The higher the global score obtained, the greater the impairment on the patient's self-reported quality of life. Permission was requested and obtained by the license holder to use this questionnaire for the purpose of individual case studies.

Rx	100 g
Phenytoin USP	2 g
Piperacillin and Tazobactam for Injection, USP (3.375 g vial)	1.48 g
Misoprostol 1% (HPMC Dispersion)	0.24 g
Aloe Vera Powder Freeze Dried 200:1	0.2 g
Beta Glucan (1,3) NQ	0.2 g
Base, PCCA EctoSeal P2G™ Powder	95.88 g

Table 1. Phenytoin 2%/Piperacillin 1.255%/Tazobactam 0.157% (CADP)/Misoprostol 0.0024%/Aloe Vera/Beta Glucan Topical Powder (EctoSeal P2G): PCCA Formula 15317.

The physician discussed treatment options with the local compounding pharmacist who offered to visit the clinic to present an innovative topical powder: PCCA EctoSeal P2G. Subsequently, the physician prescribed a compounded medication including phenytoin, ceftriaxone, aloe vera, misoprostol and beta glucan in the proprietary topical powder (Table 1). The first application of the compounded medication took place at the clinic. A few days later, the wife of the patient removed the medication at home and re-applied it herself. For a period of about 5 weeks, the wife of the patient removed the medication and re-applied it twice weekly (Tuesdays and Fridays).

Before topical compounded treatment, the patient scored most items as "very much," yielding a global total score of 58, which is only 10 points below the highest possible score. The most affected subscales were "psyche" and "everyday life." This result shows that the patient's quality of life was very much affected by the wound-healing difficulties. At the end of the treatment with the topical compounded medication, the patient achieved full recovery from the toes amputation and related wound-healing difficulties, as shown in Figure 3, without any reported complications.



Figure 1.
Right foot following toes amputation.



Figure 2.
Right foot following debridement.



Figure 3.
Right foot at the end of the topical treatment.

Blome C, Baade K, Sebastian Debus E, Price P and Augustin M (2014). The "Wound-QoL": A short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen* 22:504–14.

Recovery from Cyst Removal with an Innovative Topical Powder (EctoSeal P2G)

Case Report:

A male patient in his fifties with no underlying conditions suffered from a recurrent cyst on his right sole. The surgeon removed it again but cut the surrounding tissue a lot deeper this time to attempt a complete removal without recurrence. As a result, a larger wound was formed, and the patient was concerned that it would not heal correctly. The wound affected day-to-day activities such as moving about, walking, climbing stairs and also sleeping. The patient is very active, and the wound limited his leisure activities.

A clinical compounding pharmacist recommended an innovative topical powder including pentoxifylline, phenytoin, naltrexone, misoprostol, arginine and beta glucan in the proprietary base, PCCA EctoSeal P2G Powder (Table 1). The patient was instructed to apply the topical powder twice a day, in the morning and upon bedtime, according to the following routine: to clean the wound, to apply the topical powder, to seal the wound with a large waterproof band aid. No other medications were taken or applied. To further understand the impairment of quality of life, the patient completed the Wound-QoL-17 by Blome *et al.* (2014), a validated questionnaire composed of 17 items which are classified according to 3 subscales: body, psyche and everyday life. Each item is scored from 0 (not at all) to 4 (very much). Permission was requested and obtained by the license holder to use this questionnaire for the purpose of individual case studies. Before treatment, the patient scored a total of 32 points. Considering that the maximum total score is 68 (17x4), it is concluded that the wound had a moderate impairment on the patient's quality of life. The most affected subscales were "psyche" and "everyday life." According to the patient, the wound care routine was quick, painless and straightforward.

I did not anticipate the wound to heal as quickly as it did.

Figure 1A shows the sole of the patient's right foot following removal of the cyst, on November 4, 2023. Three days later, the patient took another digital photograph which shows a wound measuring about 1.1 cm (Figure 1B). Topical compounded treatment was initiated on November 7, with twice daily applications of the innovative powder. The wound decreased to about 0.8 cm (Figure 1C) and then 0.4 cm (Figure 1D) following 1 day and 5 days post-treatment, respectively. The wound was fully closed by day 7, measuring only 0.2 cm as shown in Figure 1E.

Blome C, Baade K, Sebastian Debus E, Price P and Augustin M (2014). The "Wound-QoL": A short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen* 22:504-14.



Figure 1. Digital photographs of the patient's right foot (sole) before treatment (A-B) and upon topical compounded treatment (C-E) for 7 days.

Rx

Pentoxifylline USP	2 g
Phenytoin USP	2 g
Naltrexone Hydrochloride USP Anhydrous	Calculate
Misoprostol 1% (HPMC Dispersion)	0.24 g
Arginine Hydrochloride USP	1 g
Beta Glucan (1,3) NQ	0.2 g
Base, PCCA EctoSeal P2G™ Powder	q.s. 100 g

Table 1. Pentoxifylline 2%/Phenytoin 2%/ Naltrexone HCl 0.1%/Misoprostol 0.0024%/Arginine HCl/Beta Glucan Topical Powder (EctoSeal P2G): PCCA Formula 14899.

Recovery from Burn Injury with Innovative Topical Formulations (EctoSeal P2G and PracaSil®-Plus)

A scalding incident resulted in a second-degree burn which was treated with two topical formulations including innovative compounding bases (EctoSeal P2G and PracaSil-Plus). Following 14 days since the injury, the burnt skin was almost fully recovered. According to the patient, the treatment outcomes were beyond expectation.

Introduction:

According to the World Health Organization (WHO), burns are a global public health problem, accounting for an estimated 180,000 deaths annually. Burns occur mainly in the workplace and at home, with domestic kitchens being at higher risk.¹ Scalds are a type of thermal burn caused by heat from hot liquids or steam. Scalding can be very painful and may cause red or peeling skin, blisters, swelling, white or charred skin.²

Burns are classified as first-degree (superficial), second-degree (partial thickness), or third-degree (full thickness), in relation to how deep and severely they penetrate the surface of the skin (Figure 1).³ If not too serious, it may be possible to avoid the emergency services and treat the burns at home.²

The purpose of this case study is to present the management of a second-degree burn with two topical formulations including innovative compounding bases.

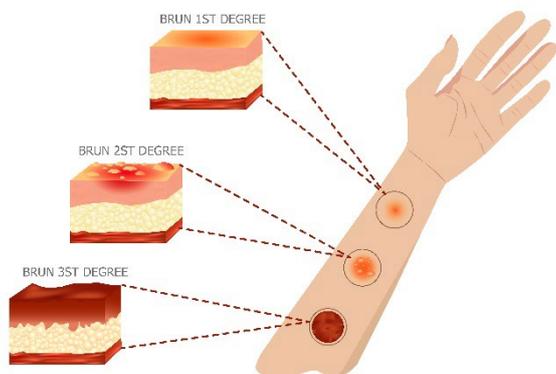


Figure 1. Types of burns. Adapted from Songtum Prakobtieng /Shutterstock.com (stock vector ID 1327467386).

Case Report:

A 49-year-old woman was cooking bacon on a sheet pan in the oven. As she was pulling the pan out of the oven to set on top of the stove, the sheet pan bumped on the corner of the stove and the bacon grease spilled all over the floor and her wrist/forearm. A second-degree scalding burn developed immediately, and it was very painful for several days.

The patient was recommended two topical formulations to be applied as follows: In the morning, Mupirocin 2% Topical Gel (PracaSil-Plus) (Table 1), for the local treatment of a potential skin infection. At night, before bedtime, Phenytoin 2% and Aloe Vera 0.6% Topical Hydrogel (EctoSeal P2G) (Table 2), to manage the pain and to facilitate the healing process. The topical compounded treatment was initiated 2 days post-injury.

The patient completed a burn-specific metric, the Adult Burn Outcome Questionnaire (ABOQ)⁴, to evaluate the outcomes of the topical compounded treatment. This validated questionnaire comprises 14 items plus 2 additional items, a stem question and a branch question both related to returning to work. The ABOQ addresses multiple domains including pain, itch, perceived appearance, emotion, physical function, social function and family function.⁴

Rx	
Mupirocin USP Micronized	2 g
Propylene Glycol USP	2 mL
Base, PCCA PracaSil®-Plus	q.s. 100 g

Table 1. Mupirocin 2% Topical Gel (PracaSil-Plus): PCCA Formula 10843.

Rx	
Phenytoin USP	2 g
Aloe Vera Powder Freeze Dried 200:1	0.6 g
Base, PCCA EctoSeal P2G™ Powder	20 g
Benzyl Alcohol NF	1.5 g
Propylene Glycol USP	10 g
Purified Water, USP	65.9 g

Table 2. Phenytoin 2%/Aloe Vera 0.6% Topical Hydrogel (EctoSeal P2G): PCCA Formula 15309.

Recovery from Burn Injury with Innovative Topical Formulations (EctoSeal P2G and PracaSil-Plus)

Results and Discussion:

The patient followed the treatment as prescribed and took photographs of the burnt skin up to 1 month post-incident (Figure 1A-1E). The patient also completed the ABOQ twice, with reference to before and after treatment. The burnt injury affected mainly the domains of pain, itch and perceived appearance, which were scored the highest. Following the topical compounded treatment, the scores were reduced to the minimum which shows the best possible treatment outcomes. These results are consistent with the clinical improvements observed with the photographs. By day 14, the burnt skin was almost unnoticeable (Figure 1D). According to the patient, the treatment outcomes were beyond expectation: *I am so pleased with the results. You can't even see that I had an injury!*

References:

1. WHO (2023) Burns. Available at: <https://www.who.int/news-room/fact-sheets/detail/burns> (Accessed: 07.08.2024).
2. NHS (2022) Overview: Burns and Scalds. Available at: <https://www.nhs.uk/conditions/burns-and-scalds/> (Accessed: 07.08.2024).
3. Johns Hopkins Medicine (2024) Health: Burns and Wounds. Available at: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/burns> (Accessed: 07.08.2024).
4. Chen L, Lee AF, Shapiro GD, Goverman J, Faoro N, Schneider JC, Kazis LE, Ryan CM. The Development and Validity of the Adult Burn Outcome Questionnaire Short Form. *J Burn Care Res.* 2018 Aug 17;39(5):771-779. doi: 10.1093/jbcr/irx043.



Figure 2. Digital photographs of the patient's left arm before treatment (A), during treatment (B,C) and after treatment (D,E).

Treatment of Decubital Ulcer in a Dog with an Innovative Topical Powder (EctoSeal P2G)

Summary: Decubital ulcers, also known as pressure sores, pose a significant health concern for senior dogs and those with mobility problems. The wounds can be difficult to heal and can burden both pets and pet owners. In this case report, we present the successful treatment of a decubital ulcer in a senior dog using an EctoSeal P2G-based formulation. As a result, the wound healed within 2 weeks after 5 applications offering an effective and convenient option for pet owners in wound management.

Introduction:

Decubital ulcers in dogs, similar to human bed sores, are local wounds on the skin or underlying tissue that develop over bony prominences against a surface, such as bedding. Prolonged compression on the capillaries in the skin restricts blood supply and oxygen to this area, leading to cycles of ischemia and reperfusion which ultimately cause cellular injury.¹ Senior dogs and those with conditions like paralysis, nerve injury, obesity, arthritis and cardiovascular disease are at higher risk of developing a decubitus ulcer.² Timely wound healing and infection prevention are critical for a good prognosis and restoration of quality of life.

The purpose of this case study is to present the effectiveness of a compounded topical wound care formulation (Table 1) in managing a decubital ulcer in a senior dog.

Rx	
Mupirocin	2 g
Tranexamic Acid	1 g
Tetracaine HCl	0.1 g
Base, PCCA EctoSeal P2G™ Powder	q.s. 100 g

Table 1. Mupirocin 2%/Tranexamic Acid 1%/Tetracaine HCl 0.1% Topical Powder (EctoSeal P2G): PCCA Formula 14951.

Case Report:

Bingbing, a 15-year-old male Border Collie, developed a decubitus ulcer on the bony part of his right hip due to limited mobility following a stroke (Figure 1 left). The wound initially presented as inflamed skin, rapidly progressing into a larger open wound with bleeding and necrotic skin tissue (Figure 1 right). Bingbing takes prednisone daily for Addison's disease, which also contributed to delayed healing of the wound. Four days after the ulcer's onset, a formulation containing 2% mupirocin, 0.1% tetracaine and 1% tranexamic acid was prepared with EctoSeal P2G Powder and provided to Bingbing's owner in a collapsible bottle (Figure 2 left).



Figure 1. Bingbing, after stroke, with limited mobility (left). Bingbing's decubital ulcer, before treatment, at day 0 (right).

The owner was instructed to clean the wound, apply a thin layer of the powder formula, lightly spray it with purified water to create a gel on the wound's surface, and repeat until the entire wound was effectively covered. The image after the first application is shown in Figure 2 right. No bandage was needed, as the formulation created a firm and thick protective film over the wound. The wound area was flushed with purified water, cleaned up and reapplied with the same formulation every 3 days.



Figure 2. Compounded topical wound care formulation (left). Bingbing's wound area after the first topical application (right).

Results:

During the initial 3-day treatment, the protective film remained securely in place, eliminating the need for a bandage. After cleaning the wound, as is shown in Figure 3 left, the wound had completely closed, forming a firm scab, and the surrounding skin inflammation had resolved.

Treatment of Decubital Ulcer in a Dog with an Innovative Topical Powder (EctoSeal P2G)

A full-body image was included to show the well-protected wound (Figure 3 right, red circle). By day 12, only a small piece of scab remained loosely attached to the skin. New skin and hair had regrown in the healed area (Figure 4 left). On day 15, the scab naturally fell off, leaving the skin intact, so treatment was discontinued (Figure 4 middle). Throughout the treatment, Bingbing's daily prednisone dosage and diet remained unchanged. No adverse reactions were observed during the treatment.

Discussion and Conclusion:

In this formulation, mupirocin served as the active ingredient to reduce bacterial load and prevent wound infections caused by MRSA or streptococcal bacteria. It also stimulated growth factors and keratinocytes proliferation.³ Decubital ulcers are often associated with pain, making pain management with tetracaine a crucial addition. Tranexamic acid was used in this case because of initial bleeding from the wound. Drug delivery vehicles also play a crucial role in managing a wound through creating an optimal environment for healing and keeping active ingredients in place for prolonged period. In this case, EctoSeal P2G was the base that applied as a powder but transformed into a hydrogel when moistened and then a protective film. The film can be easily converted back into hydrogel and washed off during wound cleaning. Ectoin and trehalose, the extremolytes in EctoSeal P2G, have potent water-binding properties, acting as cell protectants and promoting keratinocytes recovery under stress.⁴⁻⁶ The role of the microbiome during wound healing cannot be underestimated. Therefore, EctoSeal P2G delivered a prebiotic, inulin, to the wound area to help restore beneficial microflora and regulate the immune response. Consequently, all active ingredients and base components work together within the wound, under the protective film, to facilitate natural healing of a wound from multiple dimensions.



Figure 3. Bingbing's wound area after 3 days of treatment (left). On day 4, the well protected wound was located on the right hip, indicated by the red circle (right).



Figure 4. Bingbing's wound area on day 12 (left), day 15 (middle) and day 21 (right).

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6. Tomic-Canic M, Burgess JL, O'Neill KE, Strbo N, Pastar I. Skin Microbiota and its Interplay with Wound Healing. *Am J Clin Dermatol.* 2020 Sep;21(Suppl 1):36-43. doi: 10.1007/s40257-020-00536-w.

Treatment of a Dog Pad Chronic Wound with an Innovative Topical Powder (EctoSeal P2G)

Case Report:

Bandit, an 8-year-old female Irish Wolfhound dog (Figure 1), suffered from a tumor and was hospitalized to undergo surgery. The dog developed pneumonia during the recovery post-surgery and was hospitalized for a few days. Bandit was unable to walk for 6 days and took the antibiotics ceftazidime and Clavamox® (amoxicillin/clavulanic acid) for 2 weeks. As a result, Bandit's pads became very sensitive and she lost the right pad at the back, which led to a chronic wound (Figure 2A1-A3). An innovative topical compounded medication was recommended including diphenhydramine, mupirocin, triamcinolone and ketotifen in PCCA EctoSeal P2G Powder (Table 1). The dog owner applied the topical compounded medication every 3 days for a total period of 4 months. The wound decreased in size gradually throughout the course of treatment, as shown in Figures 2B-2D, until complete recovery (Figure 2E).



Figure 1. Bandit, an 8-year-old female Irish Wolfhound dog.

Rx	
Diphenhydramine Hydrochloride USP	3 g
Mupirocin USP Micronized	1 g
Triamcinolone USP Micronized	0.25 g
Ketotifen Fumarate EP	0.069 g
Base, PCCA EctoSeal P2G™ Powder	q.s. 100 g

Table 1. Diphenhydramine HCl 3%/Mupirocin 1%/Triamcinolone 0.25%/Ketotifen 0.05% Topical Powder (EctoSeal P2G): PCCA Formula 14952.

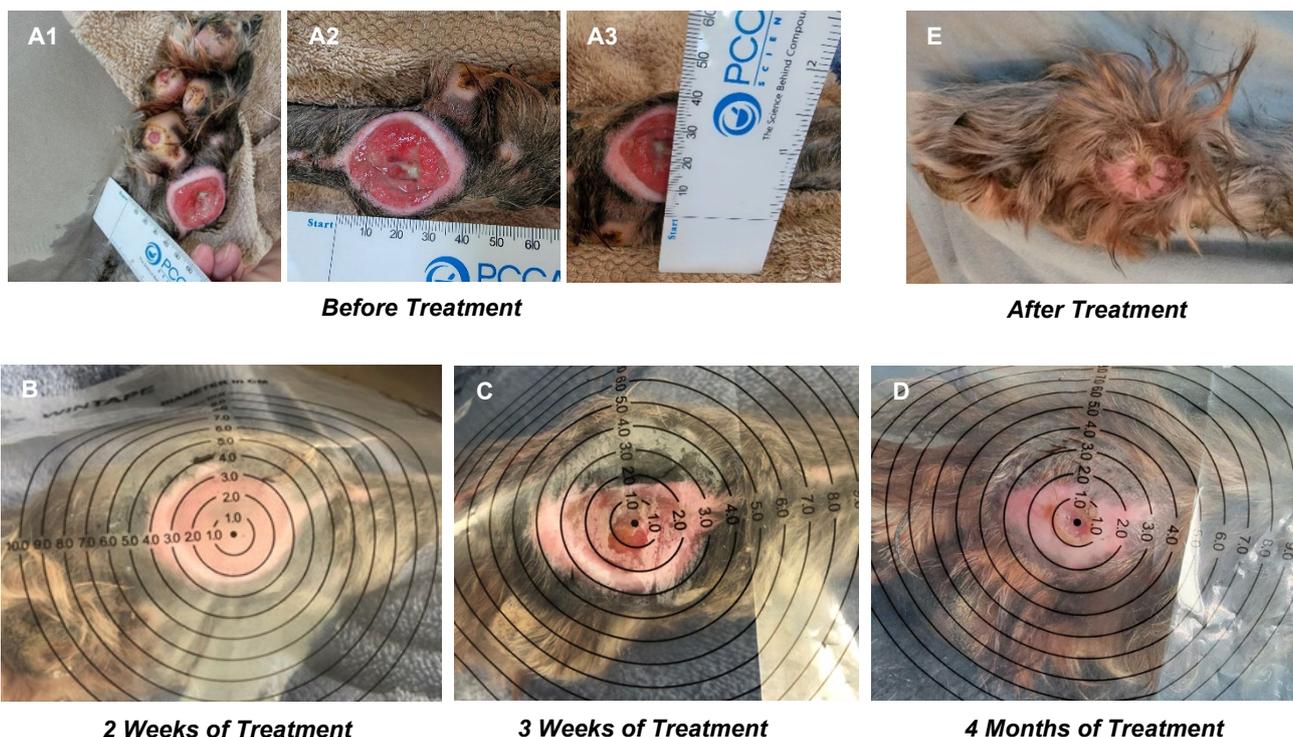


Figure 2. Bandit's pad wound before treatment (A1-A3), during treatment (B-D) and after treatment (E).