



ATI TransDerm Solutions™ Treatment System **for** **Resolution of Plantar Porokeratosis (PK) Lesions**

There are two common maladies that appear as calluses on the plantar surfaces of peoples' feet. In many cases these calluses can result in painful conditions that are difficult to resolve.

The maladies are: **Plantar Porokeratosis** and **Plantar Warts**

Since the etiologies for each condition fundamentally differ, effective treatments must address them differently to resolve the conditions.

Plantar Warts are caused by a human papilloma virus infection in the skin covering the plantar surface of the foot. The infection forms benign tumors that develop their own capillary blood supply and extend from basal layers and rise up through the dermis and epidermis. The tumor (wart) rapidly develops an overlying callus layer that is very sticky, loaded with virus particles, and does not slough off as rapidly as normal skin. The plantar wart continually generates ever-thickening callus tissue that starts to feel like "rocks" embedded in the bottom of the foot. These calluses can then begin to cause traumatic pain with each and every step.

The following techniques described in the treatment and removal of Plantar Porokeratosis lesions will also dramatically improve the comfort and mobility of patients suffering the same debilitating effects caused by Plantar Warts.

ATI TransDerm Solutions™ is also developing and testing very promising treatment modalities to address the underlying viral etiology of the Plantar Wart.

In this presentation, we will focus discussion on the primary treatment target:

Plantar Porokeratosis (PK)

Plantar Porokeratosis calluses are generated by mechanical stresses on the plantar skin either caused by short-term conditions such as ill-fitting shoes, not wearing socks in shoes while playing sports, etc. or due to longer-term stress traumas caused by anatomical foot structure issues that are ultimately correctable only by surgery or are treated as chronic conditions with various palliative approaches such as salves, creams, pads, shoe orthotics, foot soaks, etc. When patient pain is not

sufficiently controlled by non-surgical palliative measures, a clinical visit to the physician is indicated to have the calluses reduced by scalpel/curette use or other debridement methods to “thin” the calluses to achieve pain relief as the size of the “rocks” on the foot are minimized. This chronic palliative cycle consisting of multiple self-treatments and physician revisits typically produces less than satisfactory results and no definitive treatment endpoint.

While Plantar Warts are amenable to surgery, albeit a somewhat crude and uncomfortable process, the Plantar Porokeratosis (PK) lesions are singularly difficult to resolve and surgery can sometimes present more problems than viable solutions.

The often hopeless prognosis for treating PK cases changes when the **ATI TransDerm Solutions™ Treatment System** is introduced, making a painless, non-invasive, topical treatment system possible that can resolve the condition in just two days. Even though the treatment is simple and effective, it does require careful attention to detail in its method of application to achieve consistent results - this can best be attained in a clinical environment such as a podiatrist’s office.

PK is often misdiagnosed and treated as a Plantar Wart case by non-professionals and even family physicians who do not regularly treat both conditions.

Most of the Plantar Wart treatments available today, especially OTC products, are not effective in treating PK cases. This misdiagnosis and subsequent inappropriate treatment can result in ulcerations and/or infections with potentially serious health consequences. Since podiatrists deal with both conditions on a daily basis, they can readily make the correct diagnosis and pursue the proper treatment utilizing the **ATI TransDerm Solutions™ Treatment System** and techniques.

ATI TransDerm Solutions™ Treatment System & Treatment Cycle

The **ATI TransDerm Solutions™ Treatment System** is composed of specially compounded topical solutions that are applied in a 3-Step Treatment Cycle that spans approximately 2 days. To obtain optimum results, it is important for the treating professional and the patient to carefully follow the simple instructions and the timing of each step in the treatment. Deviations from the prescribed procedures and timing can compromise the clinical results and may necessitate an additional treatment cycle to achieve the desired outcome.

The **ATI TransDerm Solutions™ Treatment System** normally resolves a PK condition in a single treatment cycle. A well-run treatment cycle brings effective relief through the removal of the plantar lesions and their associated calluses.

ATI TransDerm Solutions™ Treatment System

3-Step Treatment Cycle Overview:

3-STEP Treatment Cycle	STEP 1 PK Topical Treatment	STEP 2 PK Cure Period	STEP 3 PK Removal
ATI TransDerm Solutions™ : TDS-1 = Green Cap TDS-2 = Yellow Cap TDS-3 = Red Cap	Debride/Thin PK calluses to be treated. Apply TDS-1 and TDS-2 solutions in sequence to calluses. Cover calluses with a bandage, its gauze wetted with TDS-3.	Keep the treated area as dry as possible and covered with a cotton sock. Do not take a bath or shower. Do not “peek” under the bandage.	2-3 hrs. before clinic revisit, take a shower and wet the bandage area for 10-15 min. Leave bandage on and pat dry the area. Return to the clinic for PK removal.
Timing	20-30 minutes	24–48 hrs.	2-3 hrs.*

*Actual clinic time for PK Removal should average less than 30 minutes.

Note: Do **not** store or use the **TransDerm Solutions™** below 70° F.

3-Step Treatment Cycle (Step-by-Step Details)

STEP 1. PK Topical Solutions Treatment

When the PK diagnosis is made and the **ATI TransDerm Solutions™ Treatment System** is selected, the 3-Step PK Topical Treatment Cycle can commence.

The patient's foot bearing the PK lesions is presented for initial debridement to “thin” the calluses enough that a single 3-Step Cycle of treatment will be effective.

The degree of tissue debridement should approximate the tissue removal accomplished in a traditional palliative pain relief treatment. It can be effected through a number of different reduction techniques including utilization of a scalpel/curette or even a debridement tool such as a Dremel®.

Once the initial debridement is completed, application of the **ATI TransDerm Solutions™ Treatment System** compounded solutions can begin.

Application Technique: ATI TransDerm Solutions™ are individually labeled TDS-1(**Green**), TDS-2 (**Yellow**) and TDS-3 (**Red**). While wearing disposable latex gloves, wet separate applicators supplied with the treatment kit, in the **ATI TransDerm Solutions™** TDS-1 and TDS-2. In sequence, each solution-wetted applicator should be repeatedly pressed against only the callus tissue for about 1.5 minutes each – continue to rewet each applicator and press the tip to the treated tissue. If a mistake is made, for example, and # 2 is applied first, simply start over and apply them in the proper sequence.

Do not expect the calluses where the solutions are applied to ever appear dry. Though the calluses look wet, penetration of the solutions into the callus will continue through the mechanical action of the wet swab tip pressing on the tissue. After the TDS-2 solution is fully applied to the calluses, the absorbent gauze of a **non-waterproof** bandage should be wetted with the TDS-3 solution and the bandage applied with the gauze pad covering the treated calluses completely. Being careful not to displace the adhered bandage, a cotton sock should be pulled onto the treated foot. (*Note: Any solution on the adhesive portion of the bandage will compromise its ability to adhere to the foot.*)

Patient Instructions: Once the bandage has been applied, the patient is directed to keep the bandage dry and preferably protected by a cotton sock. The patient can wear a shoe but should avoid movements that might dislodge the bandage. Following these instructions patients can go about their normal activities.

FAQ's

Q. “What happens if I do get the bandaged area wet?”

A. Moisture applied prematurely reduces the efficacy of the treatment and may require another properly completed treatment cycle to achieve satisfactory results.

Q. “What happens if my feet just sweat and wet the bandage?”

A. This has not been found to be a problem as long as the bandage remains in place. If the bandage is dislodged replace it with another of the same type.

Handling of Solutions: All solution components are safe and easily metabolized, but the special anhydrous physical chemistry employed in the treatment process can dehydrate any soft tissue contacted by the solutions. To reduce the risk of a possible dehydration burn, any solution that spills or drips and makes contact with exposed normal skin should be blotted up with a paper or

cotton towel. The affected area of skin should then be patted with a water-dampened towel. Since the dehydration process occurs slowly, a careful deliberate pace can be used to remedy any spill.

Wet applicators should only rest or be placed on glass or polyethylene surfaces during treatment and disposed of as soon as treatment is completed.

Solution spilled on clothing will leave an oily spot that does not evaporate. However, the spots can be removed from most fabrics by washing or dry cleaning.

STEP 2. PK Solutions Cure Period

The PK Cure Period of 24-48 hours is an important part of the treatment sequence. This time period allows the deep penetration of the applied topical solutions into the calluses. The penetration is many times faster than would occur by standard diffusion.

As long as the topical application site is not exposed to significant amounts of water, the penetration through the calluses will proceed rapidly. Premature exposure of the site to water during this Cure Period will slow or stop the penetration and make the treatment less effective.

Once complete penetration is achieved in 24-48 hours, all the required elements of the applied solutions are in place to effect a resolution of the keratoses.

Hydration from naturally occurring moisture in the calluses and skin will begin the breakdown process of the sticky callus tissue and underlying lesions.

Following the Cure Period the final step involves the intentional application of water to the treatment site:

With the bandage still in place, the patient should take a shower or soak the bandaged foot in water for 10 to 15 minutes. The treatment solution infused in the callus is hygroscopic, and in response to the addition of water, causes the callus to swell to several times its previous size.

After showering, the patient should pat the bandaged area dry with a towel and gently put on a cotton sock over the wet bandage. Although a shoe can now be worn, the swollen calluses can be a little uncomfortable.

Solution components are further activated by this final addition of water and accelerate the collagen breakdown that ultimately results in the transformation of each callus into a soft gelatinous mass that is readily debrided and removed.

The in-office debridement can be initiated within 2-3 hours of the water application performed by the patient as described above.

STEP 3. PK Removal

The attending professional will take off the bandage and remove all the gelatinous PK lesions and associated calluses through debridement. In some cases, much of the gelatinous mass may separate from the foot before debridement and any remaining portion of the mass will simply be cleaned up during the office visit.

The skin tissue underlying the calluses is not adversely affected by the treatment and is left essentially intact and wound free.

This procedure minimizes the typical postoperative complications and discomfort that would usually be associated with a debridement or enucleation procedure – a welcome change for both patient and clinician.

When the PK calluses are completely eliminated, any edematous skin tissue in the treatment area will return to normal with a concurrent relief of the pain that was associated with the PK lesions - usually in just a matter of a few days, or even hours.

If the PK tissue is particularly refractory and total removal of the PK tissue is not achieved with the first course of treatment, a second round of treatment utilizing the **ATI TransDerm Solutions™ Treatment System** should successfully complete the process.



Dr. Dwight Bates, Podiatrist

RE: Porokeratosis: How do YOU treat it?

I used to wonder what all the excitement was about until I developed a porokeratosis on my own foot. It felt like a needle in my foot. I have frozen them with liquid nitrogen, and also used Cantharon. I now use debridement with urea 40% ointment in the void after and Plastizote inserts, I claim only fair success with this method...