**CASE REPORT**

**Topical Gels for the Treatment of a Refractory Leg Ulcer**

Alan Israel, RPh, Lee Silsby Pharmacy, Cleveland Heights, Ohio

A 55-year-old man fractured all the bones in his left foot and ankle as well as his left tibia when he fell 12 feet through a trap door. An orthopedic surgeon treated the fractures, but lymphedema and a large ulcer subsequently developed. After 2 years of unsuccessful treatments by a series of specialists, a vascular surgeon lanced the swollen area around the ulcer to remove exudate. The ulcer then increased in size to 12 cm x 12 cm x 1.5 cm, and the surrounding skin split open. After debriding the ulcer, the physician referred this patient to the lymphedema clinic of an orthopedic surgeon. Daily for 21 days, a lymphedema specialist debrided the ulcer; and a massage therapist massaged the injured leg.

The patient had been treated only with oral morphine sulfate, prescribed for 1 month after surgery to relieve postsurgical pain, and oral warfarin sodium (Coumadin), which he continued to take to prevent blood clots.

Since there had been little progress, the orthopedic surgeon consulted us. Although the patient was overweight, he had no other compromising problem. After my son Adam and I had examined him, we recommended two wound gels: a formulation consisting of misoprostol 0.0024% (a gastric antisecretory and antiulcer agent that exerts a protective effect on gastroduodenal mucosa), phenytoin 1% (for wound healing), metronidazole 2% (for odor control), and lidocaine 2% (for pain relief); and the other, nifedipine 16% (to...

**INTERVIEW**

**Innovative Use of Compounded Preparations in a Diverse Patient Population**

An Interview with David S. Klein, MD

David S. Klein, MD, FACA, FACPM, FAAMISMS, is a specialist in diagnostic medicine for patients with unusual medical conditions refractory to prior treatment. An analytical chemist with a specialty in pesticide chemistry, he obtained his medical degree from the University of Maryland School of Medicine and completed an internship in general surgery at the University of North Carolina at Chapel Hill School of Medicine and a residency in anesthesiology at Duke University School of Medicine. While in private practice in central Virginia, Dr. Klein established a referral center for evaluating and treating pain and in 7 years also served as a US Air Force Reserve flight surgeon. Following retirement several years ago, he has now reestablished a general practice. In the following interview, Dr. Klein describes his use of compounded medications.

Describe your practice.

I now have an exclusively office-based solo practice, much of which is devoted to pain management (the treatment of headache, facial pain, discomfort from peripheral nerve injury, and disorders of fibromuscular attachment) and hormone replacement therapy (HRT).

When and how did you become interested in prescribing compounded medications?

I began to appreciate the value of customizing medications in 1990 when I was interviewed by Sam Pratt, RPh, a compounding pharmacist interested in collaborating to identify customized dosage forms that could be prescribed when commercially available medications were ineffective or unacceptable to the patient. Our first preparation was a palatable form of sublingual alprazolam to relieve short-term anxiety, especially helpful to patients who...

**Did You Know?**

Some oral medications can be compounded into a topical preparation to increase peripheral vascular circulation.

**Did You Know?**

A compounding pharmacist certified to prepare sterile compounds can prepare injectables that are in short supply, for your patients.
The patient was able to walk out of the office pushing the wheelchair. She was able to return to work after less than 2 weeks of treatment.

How do you select the vehicle used in a transdermal compound?

Both the medication and vehicle used in a transdermal compound must be appropriately selected, and the target tissue and chemical properties of the medication must be understood. For example, many transdermal HRT preparations I use are based on hormones (which are miscalculed in musculon) can be deposited in the thin fatty tissue of the forearm; the lanolin mates the hormone very well to the target tissue. An aqueous solution such as isopropyl alcohol should be used for a transdermally administered anti-inflamatory drug, because the target (tenosynovial tissue) is primarily water. Antiseizure medications should be compounded in an anhydrous base because the target tissue (Schwann cells) is lipophilic.

How do you monitor the success of treatment?

An improvement in the patient’s level of activity, restfulness, sleep, or quality of life. A triad of cooperative patient education, when the ulcer was 95% healed. During his 6 weeks of treatment, a total of about 240 g of each gel was applied to the wound. After 21 days, he was 95% healed. Only a small scab remained, no additional visits to the clinic were necessary. Occasionally, he applies the nifedipine gel to the ulcer area when he has to go to the bathroom. However, the ulcer is not expected to recur as long as the patient’s nutritional status is maintained, and the underlying problem is resolved. Most patients notice symptom abatement after about 3 weeks of HRT. Then, after an average of 90 to 120 days of therapy, I retest the patient to determine the optimum level of the formerly deficient hormone.

What advice would you offer colleagues who consider prescribing compounded preparations?

Compounds can be extremely effective treatments, but we as clinicians must know when and how to prescribe them, as well as what to prescribe. The vehicle is as important as the selected agent. A triad of cooperative patient education, when the ulcer was 95% healed. During his 6 weeks of treatment, a total of about 240 g of each gel was applied to the wound. After 21 days, he was 95% healed. Only a small scab remained, no additional visits to the clinic were necessary. Occasionally, he applies the nifedipine gel to the ulcer area when he has to go to the bathroom. However, the ulcer is not expected to recur as long as the patient’s nutritional status is maintained, and the underlying problem is resolved. Most patients notice symptom abatement after about 3 weeks of HRT. Then, after an average of 90 to 120 days of therapy, I retest the patient to determine the optimum level of the formerly deficient hormone.