## Negative Pressure Speeds Diabetic Foot Ulcer Healing

BY BETSY BATES

Los Angeles Bureau

SAN FRANCISCO — Negative-pressure vacuum therapy appears to speed healing and increase the likelihood of complete closure of nonhealing diabetic foot ulcers, Dr. David G. Armstrong said at the annual meeting of the American Academy of Dermatology.

But negative pressure, like any therapy for nonhealing wounds, should be "married with good common sense" and the critical steps of debridement and pressure offloading.

"In my opinion, what this device does is make complicated wounds [simpler]. Once you get a nice carpet of granulation tissue, then stop," advised Dr. Armstrong, professor of surgery and chair of research at Rosalind Franklin University of Medicine and Science in North Chicago, Ill.

In negative-pressure wound therapy, subatmospheric pressure is delivered to the wound through a pump attached to a foam dressing. A canister collects exudate wicked from the wound.

Dr. Armstrong recommends that a stoma paste or hydrocolloid be placed around the periphery of the wound to prevent maceration from exudate collected during the process.

Although the exact mechanism of action is unknown, negative-pressure therapy reduces edema, uniformly draws wound edges together, and may promote cytokine elaboration and angiogenesis.

The therapy can be performed on an outpatient basis, although the set-up is bulky, Dr. Armstrong said.

At a cost that he likened to a moderately priced hotel stay—\$70-\$100 a day—the therapy is not cheap, but it could reduce the overall cost of healing diabetic foot ulcers if it keeps patients out of the hospital. Diabetic foot ulcer treatment averages \$28,000; 75% of those costs are related to the hospital stay.

In a recently published randomized trial, Dr. Armstrong and Dr. Lawrence A. Lavery of Scott and White Memorial Hospital in Temple, Tex., found that large, deep diabetic foot wounds secondary to amputation healed faster and more completely with negative-pressure therapy than with standard wound care (Lancet 2005;366:1704-10).

Wounds closed completely in more than half of the patients (43 of 77) receiving continuous treatment with the vacuum-assisted closure (VAC) system for the 112-day study period. Just 33 of 85 patients receiving standard moist wound care healed completely.

"Rapid granulation tissue formation provided a clinical 'wow!' factor," in the VAC group, Dr. Armstrong said.

There was a trend to fewer reamputations in patients receiving VAC, although the study was not powered to demonstrate that end point.

Although the study received criticism for allowing clinical judgment to guide therapeutic interventions, Dr. Armstrong said such a design was necessary for studies to have "real world" relevance.

His study enrolled patients with wounds eight times larger than those in previous trials of negative-pressure therapy.

"It may be that in some trials, the less you need [interventions], the better they work," Dr. Armstrong said.

The study used the VAC therapy system made by Kinetic Concepts Inc., which sponsored the research.

Dr. Armstrong stressed throughout his talk the need for matching wound therapies to the right patients and wounds. Not every nonhealing wound needs negative-pressure therapy, for example. Referring to the oft-quoted phrase, "Don't just do something, stand there," Dr. Armstrong noted that physicians are sometimes reluctant to follow that advice.

"You feel like squirting something, spraying something, applying something to the wound. Much of this really helps people, but some of it won't," he said.

Well-designed trials with appropriately selected patients will point the way to "keeping a few more limbs on a few more bodies," he said.

## Women With Diabetes Expected to Increase 40% by 2020 Men Women Women

## Postop PTH Test Unnecessary When Calcium Is Normal

'We propose that

calcium levels be

postoperatively at

1-2 weeks. If

normal, they

should be

repeated at

6 months and

then yearly.'

obtained

BY JEFF EVANS
Senior Writer

LOUISVILLE, KY. — Patients who have undergone surgery for primary hyperparathyroidism do not benefit from routine measures of parathyroid hormone unless they have elevated calcium levels, according to a review presented by Dr. Tina Wei-Fang Yen at the annual meeting of the Central Surgical Association.

"We propose that calcium levels be obtained postoperatively at 1-2 weeks. If

normal, they should be repeated at 6 months and then yearly. If the calcium level is elevated at any time point, we recommend checking the [parathyroid hormone] level," said Dr. Yen.

Her advice is based on the findings of a review that found routine postoperative parathyroid hormone (PTH) testing of questionable benefit, even among the 20%-40% of patients with elevated

PTH levels and normal serum calcium levels after curative parathyroidectomy. Furthermore, this additional testing adds cost and can make patients anxious, commented Dr. Yen of the general surgery department at the Medical College of Wisconsin, Milwaukee.

Dr. Yen and her associates compared the utility of postoperative and intraoperative PTH testing with that of intraoperative PTH testing alone.

The investigators used a prospective database of 328 consecutive patients who had PTH levels measured during and after 330 parathyroidectomies performed in 1999-2004.

In the study, the intraoperative PTH testing criteria used to conclude each operation included a measurement of the PTH level at 10 minutes after resection of the last parathyroid gland. This PTH level was at least 50% lower than the baseline value and was in the normal

range of the intraoperative PTH assay.

Patients' calcium levels were measured at 1 week, 3 months, and 6 or more months after the operation. Normocalcemia at 6 or more months follow-up was considered to be a cure, Dr. Yen said.

In surgeries that met the intraoperative PTH testing criteria, the cure rate was 98.2%, which is similar to values reported in the literature, Dr. Yen said. A normal postoperative PTH level predicted cure, with a positive predictive value of 97.1% at 1 week, 97.3% at 3 months, and 96.5% at 6 months.

However, operative failure was not predicted with much success by failure to meet the intraoperative PTH testing criteria or by elevated PTH levels after surgery. Only 23.2% of the cases that failed to meet intraoperative PTH testing criteria proved to be actual failures. Furthermore, an postoperative elevated PTH level predicted operative failure in 13.7% at 1 week, in 14.3% at 3 months, and in 14% at 6

months. Most patients with elevated postoperative PTH levels were normo-calcemic at follow-up of 6 months or longer, Dr. Yen said.

The percentage of cured patients who had an elevated postoperative PTH level ranged from 16% at 1 week after surgery to 25% at 6 months after surgery. Among the 315 patients who were cured, postoperative PTH measurements followed no distinct trend, regardless of whether the postoperative PTH level was initially normal or elevated at 1 week after surgery. Postoperative PTH values also fluctuated between elevated and normal values among the 15 patients whose operations failed.

"Although we do not have postoperative PTH values for every patient at every time point, our data demonstrate that postoperative PTH values fluctuate over time and do not predict failure well," Dr. Yen said.

## EBRT Controls Local Thyroid Ca

High-dose external beam radiotherapy (EBRT) was effective in controlling locally advanced, differentiated thyroid cancer in a retrospective study.

Dr. Kenyon M. Meadows and his associates at the University of Florida, Gainesville reviewed the records and assessed outcomes in all 42 patients who were treated for advanced or recurrent thyroid cancer with adjuvant high-dose EBRT at their university between April 1962 and January 2003. The median patient age was 58 years. Ten patients died from thyroid cancer during a mean follow-up of 7 years, while 16 died from unrelated causes. The rate of local or regional recurrence at 5 years was 0% for

patients who had no gross residual disease when they underwent EBRT and 30% for those who did have gross residual disease at the time of EBRT (Am. J. Otolaryngol. 2006;27:24-8).

There were no cases of local or regional recurrences in patients who received doses greater than 64 Gy, suggesting a dose-response relationship.

Five-year cause-specific survival was 90% for patients who had no gross residual tumor when they underwent EBRT and 69% for those with gross residual disease. Five-year survival free of distant metastases was 82% for those without evidence of metastasis at the time of EBRT.

-Mary Ann Moon