

Imaging Data From Phase III Study Support Parathyroid as Bone Builder

BY HEIDI SPLETE
Senior Writer

WASHINGTON — Imaging data from a phase III study confirm that treatment with parathyroid hormone significantly improves bone microarchitecture in postmenopausal osteoporotic women, David W. Dempster, Ph.D., reported in a poster at an international symposium sponsored by the National Osteoporosis Foundation.

The use of micro-CT supports research by Dr. Dempster, professor of clinical pathology at Columbia University, New York, and director of the regional bone center at Helen Hayes Hospital, West Haverstraw, N.Y., and his colleagues on the use of parathyroid hormone (PTH) as a bone builder.

The Treatment of Osteoporosis with Parathyroid Hormone (TOP) study, sponsored by Salt Lake City-based NPS Pharmaceuticals, included about 2,600 women treated daily with 100-mcg injections of PTH or a placebo for 18 months. In addition, all patients received 700 mg of calcium and 400 IU of vitamin D daily. The researchers obtained iliac crest biopsies from women in the PTH and placebo groups.

Based on the micro-CT data, the mean cancellous bone volume was significantly higher (45%) among women treated with PTH, compared with the placebo group. This increase also was associated with 12% and 17% increases in mean trabecular number and thickness, respectively, in the PTH

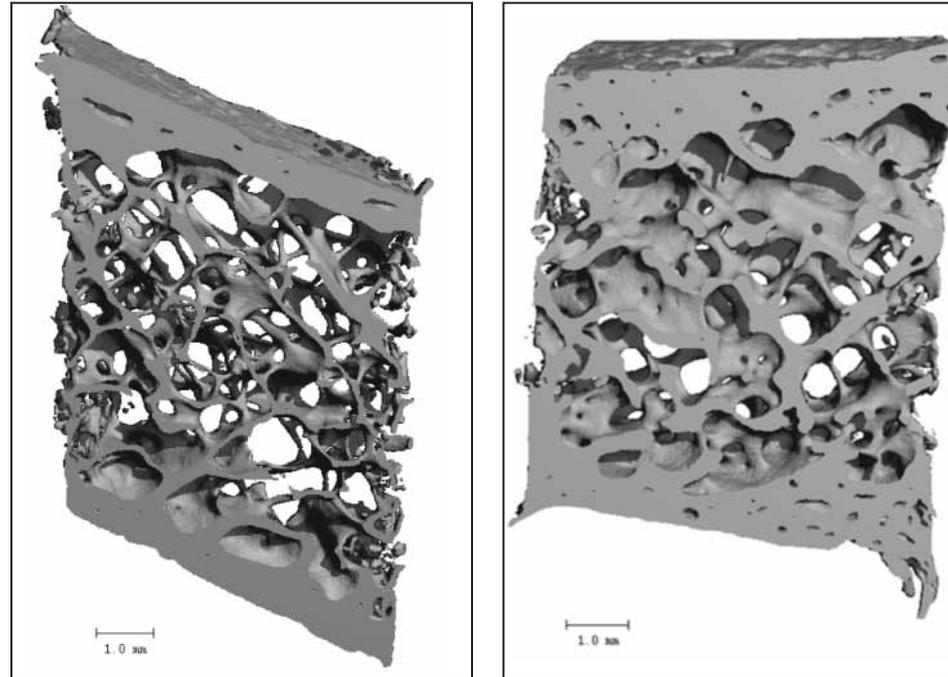
group, compared with the placebo group.

Dr. Dempster and his colleagues had reported similar results when they used histomorphometry to assess iliac crest biopsies in TOP study patients: 48%, 24%, and 17% increases in cancellous bone volume, trabecular number, and trabecular thickness, for the PTH group versus the placebo group.

Although both techniques similarly illustrated improvements in bone volume and

thickness in the PTH group, they each contribute some unique information and thus complement each other. Micro-CT is rapid and nondestructive, and provides quantitative information on the 3-D architecture of the bone, while histomorphometry provides details about the impact of PTH on bone turnover and bone cell populations.

Dr. Dempster is a consultant for NPS Pharmaceuticals. ■



The micro-CT image of the iliac crest biopsy from a placebo subject, left, shows significantly less cancellous bone volume, compared with the PTH-treated subject, right.

Patch Takes On Surgical Menopause

SAN FRANCISCO — An investigational testosterone patch applied twice weekly improved sexual functioning in as little as 4 weeks in surgically menopausal women, Sheryl Kingsberg, Ph.D., reported in a poster presentation at the annual meeting of the American College of Obstetricians and Gynecologists.

Two randomized, double-blind, placebo-controlled studies together involved 1,095 women aged 20-70 years with hypoactive sexual desire disorder (HSDD) an average of 9 years following oophorectomy. The women applied patches delivering 300 mcg/day of testosterone or placebo, twice a week for 24 weeks.

Patients kept a log of their sexual activity and completed questionnaires related to their sexual desire and distress, stated Dr. Kingsberg of Case Western Reserve University in Cleveland, and her coauthors, including an employee of Procter & Gamble Pharmaceuticals. The company plans to market the Intrinsica testosterone transdermal system pending approval by the Food and Drug Administration.

At the end of the 24 weeks, women on a placebo patch experienced an increase of 33% or 23% in total satisfying sexual activity in the two studies. Women on the testosterone patch experienced 74% and 51% increases respectively, a significant increase.

Similarly, the patch increased sexual desire (29% and 18% increases for placebo vs. 56% and 49% for testosterone) and decreased patients' distress relative to their lack of interest in sex (40% and 48% decreases for placebo vs. 65% and 68% for testosterone). All differences were statistically significant.

Increases in sexual desire and decreases in distress became statistically significant 4 weeks after the start of study medication, and increases in total satisfying sexual activity became statistically significant at 6 weeks. All three measures achieved maximal effects at 12-16 weeks, and this level was sustained until the conclusion of the study at 24 weeks.

The investigators observed no adverse events attributable to the study medication. The most common adverse event was an application site reaction, experienced by approximately 30%-40% of women using testosterone or placebo patches.

—Robert Finn

Teens Tap Rutgers Web Site With Questions On Sex; Site Visitors Pegged at 60,000 per Day

BY TIMOTHY F. KIRN
Sacramento Bureau

LOS ANGELES — If one goes to Google on the Internet and types in the word "sex," the first Web site listed is the place where about 60,000 adolescents a day go for their sex information, with the kinds of questions they are not likely to want to ask their parents.

The site is called Sex, Etc., and it is written by adolescents, under the supervision of experts at Rutgers University.

Sex, Etc. started as a newsletter in 1994, and 2.2 million copies of the newsletter are still distributed annually. But, because some of the topics touched on have included masturbation, lesbianism, and even French kissing, the newsletter has been banned by some school districts, which is one of the reasons why the Web site was started.

And, it is on the Internet that Sex, Etc. is now having its biggest impact, Nora Gelperin said at the annual meeting of the Society for Adolescent Medicine.

The number of daily visitors to the Sex, Etc. Web site has grown from an average of a little more than 10,000 a day in December 2002 to an average 60,000 a day now, 70% of whom are individuals aged younger than 21 years.

The fact that so many young people turn to this source is evidence of its need, said Ms. Gelperin, director of training and education for the Network for Family Life Education at Rutgers, the State University of New Jersey, Piscataway.

Adolescents today live in a confusing culture, where sex is freely discussed, but much basic information is scarce. Sexual content appears on television, at the same time that an increasing number of school districts are adopting abstinence-only sex education programs, Ms. Gelperin said.

"Teachers aren't free to talk about anything more than the plumbing, and parents generally aren't saying anything at all," Ms. Gelperin said.

According to one survey, 97% of persons 15-24 years of age have gone on the Internet for any reason, two-thirds have gone on the Internet for health information of any kind, and 4 of 10 who have searched out health information there have changed some kind of behavior as a result.

Currently, the Web site has more than 200 teen-written articles online, more than 250 frequently asked-questions and answers, and a glossary of about 440 different terms, ranging from "areola" and "vulva" to "choad" and "smash" (choad is slang for a penis that is wider than it is long and

smash is slang for sex). There are interactive diagrams of male and female anatomy, and also an "ask-the-experts" service, for which questions are answered within 72 hours, and a "help-now" service for crisis questions, which are answered in 24 hours.

According to the Web site records, the most frequently asked questions by males are about masturbation and penis size. The most frequently asked questions by females are about "can I get pregnant if ..." and painful sex. Questions asked have included whether it is normal to shave one's pubic area and whether it is true that the yellow dye in Mountain Dew soda pop kills sperm.

Females ask about twice as many questions as males, and the average age of those who submit questions is 16 years, the records indicate.

Although the ask-the-experts questions are not answered by adolescents, most of the rest of the content in the newsletter and on the Web site is written by teens, and that is something the Rutgers administrators consider very important because adolescents listen to each other differently from the way they listen to adults, Ms. Gelperin said.

Anyone who visits the site cannot help but notice the Rutgers logo on the home page, and that is what gives the site credibility in the visitors' minds, she said. ■