## Sacroplasty Brings Pain Relief, Cuts Use of Opioids

BY BRUCE K. DIXON Chicago Bureau

SEATTLE — Percutaneous sacroplasty seems to be a safe, effective therapy for painful sacral insufficiency, according to a multicenter study presented at the annual meeting of the North American Spine Society.

The rate of improvement is rapid, with a 50% or better reduction in pain even before patients left the office. Pain reduction

pregnancy . Hypersensitivity to any component of this product

WARNINGS

**SEASONIQUE**<sup>™</sup>

(levonorgestrel / ethinyl estradiol tablets) 0.15 mg / 0.03 mg and (ethinyl estradiol tablets) 0.01 mg Brief Summary. See full package brochure for complete information. Patients should be counseled that this product does not protect against HIV-infection (AIDS) and other sexually transmitted diseases. CONTRAINDICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: • Thrombophlebitis or thromboembolic disorders • Q pactivatar or coronary artery disease (surrent beembolic disorders • A past history of deep vein thrombophlebits or thromboembolic disorders • Centerbrowascular or coronary artery disease (surrent bitme). Vietness of the pactivatary disease (surrent table) and the set of the pactivation of the pactivation of the set of the pactivation of the

or history) • Valvular heart disease with thrombogenic complications • Uncontrolled hypertension • Diabetes with vascular involvement • Headaches

with local neurological symptoms • Major surgery with prolonged immobilization • Known or suspected carcinoma of the breast or personal history of breast cancer • Carcinoma of the endometrium or other known or suspected estrogen dependent neoplasia • Undiagnosed abnormal genital bleeding

• Cholestatic jaundice of pregnancy or jaundice with prior pill use • Hepatic adenomas or carcinomas, or active liver disease • Known or suspected

Gigartile smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strong-

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The use of non-cinemative scassculated with increased risk of several serious confiltures including versus and atterial thrombotic in different problem. The risk of serious monobility or mortality is versual in heavy mention underlying risk factors. The risk increases sufficient increases of the control of the underlying risk factors and a contraceptive with higher functions. The risk increases of the control of the underlying risk factors and contraceptive with higher functions (a desception or contraceptive). The risk of a series of the read or the oblowing information or advisory of an other states of the read or the oblowing information or advisory of an other states of the read or the oblowing information or advisory of an other states of the read or the oblowing information or advisory of an other states of the read or the risk of a desce. The read or read or the read or read** 

## Sport, and Occupational Rehabilitation in Fort Meyers, Fla. Sacral insufficiency fractures are a known cause of pain in patients with weakened bone, with a natural history similar to that of vertebral compression fractures. Symptoms gradually resolve, but recovery is slow and patients often resort to opioid analgesics for relief. Previous studies have shown that injec-

occurs primarily within the first 3 months

and is sustained to 1 year," said Dr. Michael

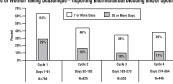
Frey of the Physiatric Association of Spine,

tion of polymethylmethacrylate (PMMA) relieves pain quickly and thoroughly by stabilizing the fracture. However, those studies were small, and their follow-up intervals were 2-16 weeks, Dr. Frey said.

In this prospective, observational cohort study, 25 consecutive sacral insufficiency fracture patients were treated with sacroplasty. There were 17 women and 8 men with a mean age of 74 years and a mean duration of pain of 41 days. Pain level was assessed using the visual analog scale (VAS),

findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogens and progestogens. 8. Carbolydrate and Lipid Metabolic Effects: Oral contraceptives have been shown to cause glucose intolerance in a significant perentage of users. Oral contraceptives containing greater than 76 minorgens of estrogens cause estrogens cause glucose intolerance in a significant perentage of users. Oral contraceptives operating or estorem tands in the sectorem with the persistent in your different progestational agents. However, in the nondiabelic woman, oral contraceptives appear to have no effect on fasting blod glucose. Because of these demonstrated effects, prediabelic and diabelic women should be carafully observed while taking oral contraceptives. As anal proportion of women with have persistent hypertrigicedmain while on the plut As discussed earlier (see WARINGS 1a, and 1d.), changes in surrun trigitoerides and lipoprotein levels have been reported in oral contraceptive users. **9. Exviced Boord Perssure**: Norma unitis spinicant hypertresion should no be stated on hormonal contraceptive users. **9. Exvices Hourd Perssure**: Norma readomized triab have shown that the incidence of hypertension increases with another spin locating persons. The Norma earlies are shown that the incidence of hypertension increases in budo perssure also earlies or progestopers. Women with his discourt inclusives should be enotinged be escare used to a contraceptive users, and dis the is no difference in the courrace of hypertension or hypertension-related diseases, or renal disease should be encuraged to use another method of contraceptives, and the is is no difference in the occurrence of hypertension among ever and never-users. **10. 10. Headback:** (the constort eccestration of microare or everylement disease and with a never users. **11. 10. Headback:** (the constort eccestration of microare or everylement disease in cardinal diseases in a contraceptives and users in contra

Figure: Percentage of Women Taking Seasonique™ Reporting Intermenstrual Bleeding and/or Spotting.



As in any case of bleeding irregularities, nonhormonal causes should always be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy. In the event of amenorthea, pregnancy should be ruled out. Some women may encounter post-pill amenorrhea or oligomenorrhea (possibly with anovulation), especially when such a condition was preexistent.

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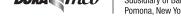
PFECUITONS
1. Scaulally Transmitted Diseases: Patients should be counseled that this product does not protect against HIV infection (ADS) and other sexually transmitted diseases;
2. Physical Examination and Follow-up: A periodic history and physical examination are appropriate for all women, including women using oral contraceptives. The physical examination, theory, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinica. The physical examination, theory, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinica. The physical examination should in clube special reference to blood pressure, breads, adorema and pudged appropriate by the clinica. The physical examination should in clube special reference to blood pressure, breads, adorema and pudged appropriate by the clinica. The physical examination should in contraceptive special effects of they dect to use call contraceptives. Some progestopers may elvate DL levels and may render the control of hyperflipdemias more difficult. (See WARNNGS 1d.) In patients with familial defects of lipoprotein metabolism receiving estroger-containing preparations, there have been case reports of significant devaluos of plasma tigoprotiles leading to paravailis.
4. Liver Fundation: Oral contraceptives may cause as enving such drugs, the medication should be descrimond. Exteroid hormones may be podry metabolized in patients with conditions, which might be agaravated by fluid retention. They should be prescribed with caution, and only with careful montro-ing, in patients with conditions, which might be agaravated by fluid retention. They should be prescribed with caution, and only with careful montro-ing, in patients with conditions, which might be agaravated by fluid retention. They should be prescribed with caution and attempt to determine whether the symptom is drug relates.
8. Fund Retention: Contraceptive effe

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9. Interactions with Laboratory Tesses See Package Insert for complete information.
10. Carcinogenesis: See WARNINGS. 11. Pregnancy: Pregnancy Category X. See CONTRAINDICATIONS and WARNINGS. 12. Nursing Mothers: Small amounts of oral contraceptive steroids and/or metabolites have been index the intermediate and breast enlargement. In addition, roal contraceptives given in the postpartum period may interfere with bactation by decreasing the quantity and quality of breast mik. If possible, the nursing mother should be advised not to use or al contraceptive with bactation by decreasing the quantity and quality of breast mik. If possible, the nursing mother should be advised not to use or al contraceptive with bactation by decreasing the quantity and quality of breast mik. If possible, the nursing mother should be advised not to use or al contraceptive with bactation by decreasing the quantity and quality of breast mik. If possible, the nursing mother should be advised not to use or al contraceptive with bactation by decreasing the quantity and quality of breast mik. If possible is the information.
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ADVERSE REACTIONS: An increase risk of the following serious adverse reactions has been reported in patients receiving or al contraceptives : Messenteric thrombosis. Phyceratic matchem of the associated with the use of oral contracepti

OVERDOSAGE: Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause parsea and withdrawal bleefing may occur in females

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The start is the discontinuition of and contraceptives, although excess risk vas very small. However, both studies very performed with color contraceptive services of the store of the Reference: 1. Data on file. Duramed Pharmaceuticals Inc, Pomona, NY.

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and patient satisfaction and analgesic use were determined. Each procedure was performed under light intravenous conscious sedation and fluoroscopic control, without use of computed tomography. Two bone trocars were inserted between the sacral foramen and sacroiliac joint. About 2-3 cc of PMMA were injected through each trocar under coronal view, Dr. Frey said.

At 1 year, 23 of the 25 patients were available for follow-up. One patient had died from unrelated pulmonary disease. The mean VAS score, which was 7.3 at baseline, plunged to 2.7 immediately post procedure, and at 1 year, was 0.3. Improvement was statistically significant at 1 year and at each follow-up interval (2, 4, 12, and 24 weeks). "We saw a dramatic reduction in the use of opioid analgesics and what we would expect to be an increase in the use of nonopioid pain medications," he said.

## Biologic Doesn't Increase Risk of Infection in RA

RHODES, GREECE — Adalimumab does not appear to increase the risk of serious infection in patients with rheumatoid arthritis, Dr. J. Kent reported at the 15th Congress of the European Academy of Dermatology and Venereology.

There was concern that rheumatoid arthritis (RA) patients, who are more prone to infection than are their healthy peers, would develop more infections while on anti-tumor necrosis factor (anti-TNF) agents like adalimumab (Humira) because of the role these agents play in host defense, Dr. Kent explained in a poster at the meeting.

However, in a study of more than 2,500 patients who participated in North American and European trials of adalimumab which is also approved for the treatment of psoriatic arthritis and ankylosing spondylitis-there was no increased incidence of serious infections in RA patients, compared with the reported incidence of such infections in RA patients naive to anti-TNF therapy.

A total of 378 serious infections-most commonly pneumonia (70 patients), septic arthritis (37 patients), urinary tract infection (34 patients), and cellulitis (30 patients)-occurred in 305 patients (4.3 infections per 100 patient-years). The rates were similar to those reported in RA patients prior to availability of anti-TNF agents (3.1-9.6 infections per 100 patientyears), according to Dr. Kent of Abbott Laboratories (the maker of Humira).

The rate of serious infections also was not affected by diabetes status; a total of 23 serious infections occurred in the 146 patients with RA who had diabetes (4.9 infections per 100 patient-years), compared with 355 of 2,358 patients without diabetes (4.3 infections per 100 patient-years). Of note is a finding that 73% of patients with serious infections were using steroids at the time of the infection. -Sharon Worcester