## Chondrocyte Implants Give Lasting Benefits

BY NEIL OSTERWEIL

FROM OSTEOARTHRITIS AND CARTILAGE

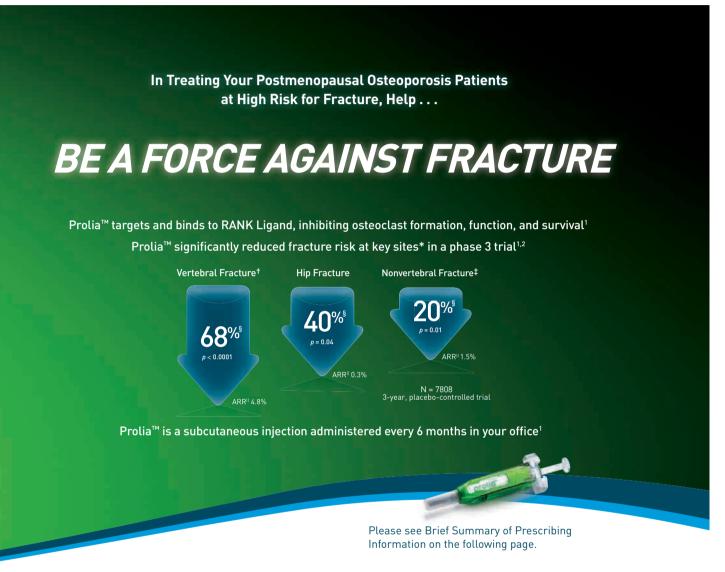
ore than a decade after receiving autologous chondrocyte implants for treatment of fullthickness chondral lesions of the knee, nearly 75% of patients reported continued improvement or stability at their last follow-up, and 90% said they would have the procedure again.

Patients had significant improvement over baseline by objective clinical measures, although there was a slight but significant decline in function from the first to second follow-up period, according to Dr. Haris S. Vasiliadis and colleagues from the University of Gothenburg (Sweden) and the University of Ioannina (Greece).

Neither concomitant injuries to the knee nor prior bone marrow-stimulating surgeries appeared to decrease the overall benefit of chondrocyte implantation at long-term follow-up, the investigators wrote (Osteoarthritis Cartilage 2010 May 5 [doi:10.1016/j.joca.2010.04.003]).

They assessed responses from 224 patients who were treated with ACI in 1988-1998. At intermediate follow-up, the Lysholm scores (on a 0- to 95-point scale, with higher scores equating with better function) had improved by a mean of 14.8 points, compared with baseline (P =.0003). The mean change over baseline at 10 years was a 10-point improvement (P = .0016). Brittberg-Peterson scores (on a 0- to 130-point scale, with 0 being no pain and best function) were significantly lower at final follow-up than at baseline (mean decrease, 14 points; P = .004).

The investigators said no financial support was provided for the study, and they had no conflicts of interest.



be performed by the prescriber prior to initiation of Prolia  $^{\mathbb{N}}$ . A dental examination with appropriate preventive dentistry should be considered prior to treatment in patients with risk factors for ONJ. Good oral hygiene practices should be maintained during treatment with Prolia  $^{\mathbb{N}}$ .

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia™ should be considered based on individual benefit-risk assessmen

- Suppression of Bone Turnover: Prolia™ resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for consequences, including ONJ, atypical fractures, and delayed fracture healing
- Adverse Reactions: The most common adverse reactions (> 5% and more common than placebo) are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. Pancreatitis has been reported with Prolia™.

The overall incidence of new malignancies was 4.3% in the placebo and 4.8% in the Prolia™ groups. A causal relationship to drug exposure has not been established. Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity. **ॐ** Prolia<sup>™</sup> Postmarketing Active Safety Surveillance Program:

The Prolia™ Postmarketing Active Safety Surveillance Program is available to collect information from prescribers on specific adverse events. Please go to www.proliasafety.com or call 1-800-772-6436 for more information about this program.

- \* Key sites: vertebral, hip, and nonvertebral. 12
  † Includes 7393 patients with a baseline and at least one post-baseline radiograph. 12
  ‡ Composite measurement excluding pathological fractures and those associated with severe trauma, fractures of the vertebrae, skull, face, mandible, metacarpals, fingers, and toes. 12
  § RRR = relative risk reduction.

  II ARR = absolute risk reduction.

References: 1. Prolia™ (denosumab) prescribing information, Amgen. 2. Cummings SR San Martin J, McClung MR, et al. Denosumab for prevention of fractures in postmenopa women with osteoporosis. N Engl J Med. 2009;361:756-765.

For more information, visit www.ProliaHCP.com

