**Eyes survive nail-gun injuries**

Pippa Wysong
in Fort Lauderdale

INJURIES to the eyeball from nail guns are not an uncommon occurrence. But what surprised researchers who studied vision loss among patients who ended up with nails lodged in the globe was how few of them actually lost significant sight.

Michelle Andreoli MD, Loyola University in Chicago, presented a study on the topic of open-globe injuries at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO).

The study began when ophthalmologists at the Massachusetts Eye and Ear Infirmary (MEEI) checked their records to determine the most common causes of traumatic eye injuries. Findings come from a retrospective chart review covering a period of five years. Researchers found that a total of 648 patients with open-globe injuries had presented to the centre, but of these, a total of 80 (12.3 per cent) were due to nail-gun-related injuries.

Nail guns are power-tools commonly used by people doing carpentry or related work. The devices eject nails with enough force to shoot a nail into a piece of wood without having to hammer it in. Some nail guns can launch nails at speeds up to 427 metres per second, and are either spring-loaded, have a pneumatic design, or are air-powered.

**AREDS at 10 years**

Ten-year follow-up of the landmark Age-Related Eye Disease Study (AREDS) confirms the value of the combination of vitamins and antioxidants used in that study for reducing the risk of AMD, reported Emily Chew MD, deputy director, division of epidemiology and clinical research, National Eye Institute, Bethesda, Maryland, US, at the annual meeting of the AAO.

AREDS was one of a very small number of randomised studies to ever show a significant health benefit associated with nutritional supplement use. The study did show a risk reduction in patients who began the study at high risk for developing advanced AMD – those with intermediate AMD, and those with advanced AMD in one eye only – after more than five years. Those taking antioxidants plus zinc had the lowest risk of developing advanced stages of AMD and its accompanying visual loss. Those in the zinc-alone or antioxidant-alone groups also reduced their risk of developing advanced AMD, but at moderate rates compared to the antioxidant plus zinc group.

The numbers have held up after 10 years of follow-up, reported Dr Chew. At 10 years, patients in the placebo group had 44 per cent rate of advanced AMD compared with 34 per cent of those who had received the combination supplement, a 27 per cent reduction in risk. Visual acuity loss was also minimised by the treatment.

Based on these results, Dr Chew advised that patients with large drusen in both eyes, and those with advanced AMD in one eye be given the supplement therapy. Smokers should not take these supplements owing to concerns about increased rates of lung cancer in patients taking beta-carotene reported in previous studies.

Moreover, she stressed that recent suggestions that the vitamin E component of the regimen might increase mortality risk were simply wrong based on “statistically dubious” analysis.

**Sirolimus promising in DME treatment**

Sirolimus injection shows promise as a treatment for diabetic macular oedema, suggests a preliminary trial presented at the annual meeting of the AAO.

The study randomised 30 patients with DME to receive single injections of various doses of sirolimus (MacuSight) by the intravitreal or subconjunctival route. Patients in the study had long-standing severe DME. Most had failed previous laser treatment, reported Pravin Dugel MD, Phoenix, Arizona, US.

At 90-day follow-up, both approaches were associated with improvement in best-corrected visual acuity and decreases in OCT thickness. Interestingly, the two most effective doses were also the two lowest doses.

The researchers observed no dose-limiting toxicities. Intracranial pressures remained stable and there was no tendency to cataract formation. Systemic exposure to the drug was “minimal.”

“We found that sirolimus was safe by both the subconjunctival and intravitreal routes at all doses tested. The subconjunctival injection was at least as effective as the intravitreal injection with prolonged benefit up to 180 days following a single injection,” said Dr Dugel.

He mentioned that he and his colleagues were also “very encouraged” by the results of Phase I study of sirolimus injection in patients with exudative macular degeneration.

He announced that Phase II studies, one for DME and one for exudative macular degeneration via the subconjunctival route, are now beginning.

Sirolimus is an immunosuppressant used to prevent rejection in organ transplantation. More recently it has been used as a coating for stents used in angioplasty procedures.

**WMA invites comments from physicians to revise Declaration of Helsinki**

The World Medical Association (WMA) is inviting ophthalmologists and physicians in all other specialties to suggest revisions to the Declaration of Helsinki (DoH), the landmark international ethical guide for clinical research.

The comment period, which ends February 25, centres on a number of changes proposed by a special working group. The DoH, which physicians generally regard as the leading ethical guide for clinical research ethics worldwide, was adopted by the WMA in 1964; it has been revised five times, the last time being in 2000.

Among the proposed changes are a number of new safeguards for patients involved in medical research and for the public in general. The changes include provisions to:

1. Make it clear that the wellbeing of the individual should take precedence over the interests of the sponsors of research, science, and society;
2. Ensure that any patient who suffers an injury from participating in a clinical research trial receives all appropriate remedial treatment and care;
3. Allow the public to obtain access to a register of all clinical trials;
4. Promote the inclusion in clinical trials of patient populations that have previously been under-represented in medical research, such as children and pregnant women.

Based on the comments it receives, the association’s working group will prepare a new draft for the association’s Medical Ethics Committee and Council for their next meeting in May.

Based on the outcome of the May meeting, the association then plans to submit a revised DoH to the association’s General Assembly for adoption at its annual meeting in Seoul, South Korea, in October of 2008.

For more information about the proposed changes to the Declaration of Helsinki, visit: www.wma.net.