The enrollment phase of the study also showed that right-to-left cardiac shunts occurred in 60% of the patients with migraine who were screened. Dr. Peter Wilmhurst reported at the annual meeting of the American College of Cardiology that this prevalence is "very, very high," commented Dr. David O. Williams, director of interventional cardiology at Rhode Island Hospital in Providence. The usual prevalence (in the general population) is 19 to 20%,” he said.

Insertion of a STARFlex septal repair implant provided complete migraine relief in 3 of 7 patients (44%) during 6 months of follow-up, the same rate as in the 73 patients who received a sham procedure. Thus the device, developed by NMT Medical (also which sponsored the study), failed to achieve the primary end point of complete headache relief.

"However, using more conventional migraine trial end points, significant differences were found," noted study investigator Dr. Andrew Dowsett, a headache specialist at King's College Hospital in London. Overall, 42% of patients receiving the implant had a 30% reduction in headache days, compared with 23% of sham-treated patients, a statistically significant difference.

The Migraine Intervention with STARFlex Technology (MIST) trial was a randomized, placebo-controlled, double-blind study that initially screened 432 individuals with migraine. The study was done in 2003 at 13 centers in the United Kingdom. The inclusion criteria were patients between 18 and 65 years of age, minimum 1-year history of migraine with an age onset not later than 50 years, frequent migraines (at least 5 days per month but at least 7 headache-free days per month). The study was restricted to those with migraine, with aura, because previous studies showed that there was evidence of migraine and PFO and these types of migraine, Dr. Dowsett said.

Contrast transthoracic echocardiograms showed that 72 patients had small shunts (atrial and pulmonary), 22 had large pulmonary shunts, 3 had atrial septal defects, and 16 had large patent foramen ovales (PFOs), for a total of 260 shunts, said Dr. Wilmhurst, a coinvestigator and cardiologist at Royal Shrewsbury (U.K.) Hospital.

The 163 patients with large PFOs were targeted for the study, and after 16 were excluded 147 patients were randomized to receive either PFO closure or a sham operation. Patients underwent a 3-month healing period after surgery, followed by a 3-month analysis phase in which migraine occurrences were continually monitored. Patients continued their prophylactic migraine medications, but those patients who overused migraine medication were excluded from the study. Other exclusion criteria included prior stroke or transient ischemic attack, and cardiac contraindications.

Continued on following page

Handicapped Child Scopes Brain Hematomas

A n investigational near-infrared imaging technology in a hand device can detect brain hematomas soon after trauma.

The Infrascanner detects hematomas based on the differential near-infrared light absorption of hemoglobin in the bleeding versus the surrounding brain tissue. The user-friendly device that maps out the location of the hematoma with graphical interfaces can be used by paramedics and emergency room personnel in attending to those injured in traffic and sports accidents, falls, and on the battlefield, said Bank Omal, Ph.D., director of the school of biomedical engineering, science, and health systems at Drexel University in Philadelphia.

The scanner is a hand device based on a PDA platform with a wireless probe. The signals are digitized and transmitted by wireless link to the hand unit.

Multicenter clinical trials are underway. Pending approval by the Food and Drug Administration, the device could be available by the end of the year.

—Kerri Wachter
In addition to the significant reduction in headache days, the implant also provided a significantly greater reduction than did sham in headache burden, a measure that incorporates both the frequency and duration of headaches.

Patients receiving the implant achieved a 37% reduction in headache burden, from 136 at baseline to 86 at last follow-up, whereas those receiving the sham operation improved from 117 at baseline to 96 at the last 6-month follow-up, a 17% reduction. The investigators noted that the difference in the magnitude of the reduction between the implant and sham groups was statistically significant.

The high prevalence of cardiac shunts in patients with migraine suggests that screening selected patients with transthoracic echocardiography and then performing repairs when indicated may be a good idea. “It’s something to consider for disabled patients,” Dr. Williams said. “In skilled hands, the risks of PFO closure are very low. The procedural risk is like that for cardiac catheterization.”

In the implant group, five serious adverse events occurred in one patient each: cardiac tamponade, pericardial effusion, retroperitoneal bleeding, atrial fibrillation, and chest pain. In the sham group, one patient had effects of antiplatelet therapy (anemia, nosebleed), and one patient had a brainstem ischemic stroke 4 months into the follow-up.

The researchers plan to evaluate residual shunting in patients who had repairs. Longer follow-up may show greater benefits from implants, Dr. Dowson noted. Philadelphia bureau chief Mitchel L. Zoler contributed to this report.