# Correction

In the article, "The MIST Trial (Migraine Intervention with STARFlex Technology): A prospective, multicentre, double-blind, sham-controlled trial to evaluate the effectiveness of patent foramen ovale closure with STARFlex septal repair implant to resolve refractory migraine headache" by Dowson et al that appeared in the March 18, 2008, issue of the journal (*Circulation*. 2008;117:1397–1404), a number of errors and omissions occurred.

Investigators Drs Peter Wilmshurst and Simon Nightingale did not sign the Copyright Transfer Agreement because of an internal disagreement about the conduct of study. Therefore, they were not listed as authors on the final accepted version of the manuscript that was published in the journal.

The description for assessing intracardiac shunts was brief in the original manuscript because of the limitation of word count. Shunt size was determined using a practical clinical hybrid method based on approximate count and visual appearance of bubbles in the left heart during the first 5 cardiac cycles of contrast entering the right atrium. See the newly posted online-only Data supplement for more details.

For clarification, unsatisfactory implant position was not considered a serious adverse event per protocol. No patent foramen ovale was found or crossed in 5 of the 74 patients (7%) randomized to closure. In one patient a 23-mm device embolized to right atrium after release, and in a second patient the initial implant position was unsatisfactory with prolapse of left atrial arms into the right atrium. This device was withdrawn from the patent foramen ovale but subsequently embolized to the left pulmonary artery while being withdrawn into the delivery sheath. Both devices were successfully retrieved using snares. In a third patient, the initial implant could not be deployed and was retrieved without being detached. All 3 patients had a second device successfully implanted and continued in the study. There are no additional unreported serious adverse events that occurred during the study.

To display the withdrawn patients in more depth, a revised Figure 2 (study flow and patient disposition) has been provided. The original text is correct. Of the 443 patients consented as fulfilling the headache inclusion/exclusion criteria, there were 296 patients who were not eligible for the randomization visit. Eleven patients withdrew before diagnostic transthoracic echocardiogram where 163 (37.7%) were found to have moderate or large patent foramen ovale, 172 (39.8%) had no shunt and, as in amended Table 1, 96 (22.2%) had small shunts or large pulmonary shunts, and 1 (0.2%) had an atrial septal defect. A further 16 patients did not progress to randomization, 6 for personal reasons or because they were lost to follow up, 6 for medical reasons (pregnancy, dental treatment, sinusitis, hysterectomy, steroid treatment, and late declaration of aspirin sensitivity), and 4 others after transesophageal echocardiography. Two patients were diagnosed as having an atrial septal defect, and it was not possible to confirm patent foramen ovale in the other 2.

In the text of the original article under Efficacy, a reference to Figure 3, a histogram of the total number of migraine headache days per month for each patient, was inadvertently calculated on migraine headache hours as opposed to the correctly stated migraine headache days. The original histogram displaying the distribution of outliers in the study is consistent with the corrected text of the manuscript as follows:

Two patients in the implant group were noted to account for 20% of all headache days in the implant group during the analysis period (Figure 3) and differed from the rest of the population

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(Shapiro-Wilk test, $P=0.0014$). When these patients were excluded from the per-protocol population, a significant 2.2 d/mo reduction (from 6.0 to 3.8 d/mo; 37%) was noted in median total migraine headache days for the implant group compared with 1.3 d/mo (from 5.0 to 3.7 d/mo; 26%) in the sham group ($P=0.027$). The statistical calculations were based on headache days as indicated in the manuscript, and the justification of removal of these outliers has not changed.

The authors confirm that they disclosed all relevant relationships and potential conflicts of interest that were present during the 2 years leading up to manuscript submission, as required by the American Heart Association.

The online version of the article has been updated to address these issues. The authors regret the errors and have offered clarification where requested.

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