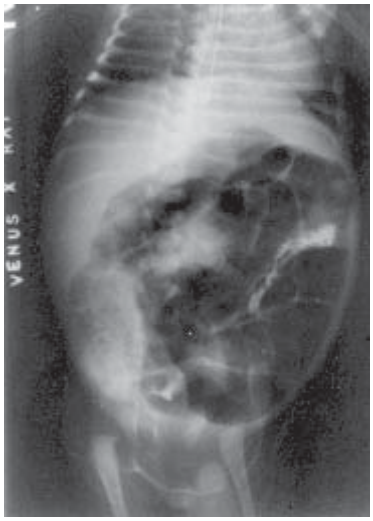

Fig. 1. Plain X ray showing dilated bowel loops and mottled soft tissue density appearance in the region of the right iliac fossa.

osmotic reduction, two have been unsuccessful, one of which resulted in perforation. Upon exploration, the most common location of the milk curd is the terminal ileum. Typically, the plug is 2 to 3 cm long and can be manually milked through the ileocaecal valve. Occasionally, the plug involves the proximal bowel so that an enterostomy and acetylcysteine irrigation are needed(2). Rarely, the obstruction is in the transverse colon. Perforation has been reported(1,2).

The etiology of the inspissation is still not clear. Analysis of the surgically removed plugs has shown a preferential absorption of water and protein, and a concentration of fat and calcium(2). This would explain why infants who are breast fed do not develop inspissation; the fat in breast milk is 92% absorbed while that in formula is only 65% abosrbed.

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Clinical Significance and Type II Errors under the Magnifying Lens

The article by McGlone, *et al.*(1) attempting to simplify the insertion of umbilical artery catheters (UACs) by use of a magnifying lens kindled our interest. We pen this letter in an effort to prevent a good idea being discarded due to inappropriate interpretation of the p value.

Unquestionably both the time for insertion of a UAC as well as success rate will depend on the experience of the clinician(s) performing the procedure. Depending on the institution, this group may be as diverse as

pediatric house-staff interns, neonatal-perinatal fellows and registered nurse practitioners. The average time taken to insert a UAC as noted in the pilot study undertaken by the authors(1) as well as previously(2) is about 310-330 seconds if employs the conventional method. Squire, *et al*.(2) found that use of the side-entry technique greatly decreased the average UAC insertion time to 143 seconds. In the current study(1), the authors report that in half their total study population, UACs were inserted in 88 seconds or less with or without the use of the magnifying lens. Although it is possible that the registrars who participated in the study were extremely skilled, as the authors note, results so highly divergent from the pilot data raise the possibility that the study was contaminated by *attention bias* (the so-called *Hawthorne effect*)(3); we suspect that the greatly diminished power of the study (to 6%) is a result of the compounded effect of both these variables. Given that all clinicians attempting to insert UACs will not be as skilled as the group of registrars that participated in the study, the use of a magnifying lens may still prove valuable. Indeed, in training situations, with inexperienced clinicians, the use of a magnifying device may be invaluable. In the paper, the authors have done an excellent job of describing in detail the methods employed and the results obtained; while they make appropriate comments as part of their discussion to ponder their results, they fail to correctly state their conclusion or the key message for readers. Their conclusions that there was no difference between the two study groups fall into the realm of possible Type II errors(4).

A more appropriate method of presenting the same results would be to begin, as is traditionally done(5), with the null hypothesis that use of a magnifying lens would not decrease the time of insertion of UACs, and then conclude that given the limitations of power (due to overestimation of effect, underestimation of variation in operator skills and the *Hawthorne effect*), the null hypothesis could not be rejected. When analyzing data, it is vital to distinguish between results that demonstrate a treatment had no effect from results that are inconclusive. A non-significant difference should always be accompanied by a confidence interval (CI). If a 95% CI for the difference contains no clinically important values, then "no difference" has been demonstrated. If the interval contains values that would be considered clinically important, then the result is inconclusive. The authors did not provide such an interval and doing so requires access to the raw data. However, enough information was provided to estimate an approximate 95% CI for the individual medians since, for the sample sizes used (23 and 21), a 95% CI is approximated by the inter-quartile range. Thus, approximate 95% CI's are 50-192 for the 88 sec median and 55-222 for the 70 sec median. These intervals are very wide and they emphasize the fact that, even though the difference is not statistically significant, the true difference might be clinically important.

In closing, we would like to remind the readers and ourselves that one should always make a distinction between clinical significance (which may vary on a case by case basis) and statistical significance that may be difficult to prove in the clinical setting. We submit that this report of a 'negative' trial still has clinically useful information. Inasmuch as pediatric and microvascular surgeons routinely employ magnifying devices for their procedures, perinatal clinicians may find a relatively inexpensive, yet potentially useful piece of equipment such as a magnifying lens a worthwhile addition to their armamentarium.

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Reply

We appreciate the use of the magnifying lens by Fernandes, *et al*. to facilitate the understanding of the significance of clinical significance and type II errors in relation to our trial(1). Despite our best efforts we are however not convinced that their statistical arguments are relevant to the real clinical issues raised by the trial results and their interpretation. We hope our comments will alleviate their disappointment as well as their concern that a good idea may be discarded due to inappropriate interpretation of the p value.

Our trial(1) was designed to find out whether we could improve the UAC insertion time by using a magnifying lens. The 'superiority' design was based on our prior positive experience with the device and its safety and simplicity(2). It was also based on the fact that most clinicians would regard UAC insertion time 2-3 minutes as satisfactory. The desired 'clinically significant' improvement was clearly prespecified as reduction in UAC insertion time from 330 to 200 seconds (common std dev: 144, a priori power: 82%)(3). Given the dramatic improvement in the median insertion times (88 and 70 seconds) in both groups, the very purpose of conducting/continuing the study was defeated. The temptation to comment on the possible benefits of the lens to others ("soft advocacy") was best avoided and it was left to the readers to interpret the results and decide what may still be useful for them. Despite the tradition, the confidence interval (lens-no lens median difference: 18 seconds; 95% CI: [–89.49, 125.49] seconds) was not provided simply because the overall dramatic decrease in the insertion times made the original question about the magnifying lens clinically almost irrelevant(4). However, we did provide sufficient data to construct the 95% CI and more importantly the conditional power estimate of how likely were we to declare the superiority of the magnifying lens over the conventional method if the trial was continued.

The Hawthorn effect was indeed operational during our trial as indicated by the