sonography causes damage to bypasses? We think not.

Another interesting fact which can be extracted from the data is the difference of the ratio of amputation/occlusion between the two series of publications. Here again we have only taken into account the articles which give us complete data. For the non-surveillance group this ratio is 355/804 (44%), for the bypasses with surveillance 69/103 (67%). The difference between these two ratios is 23% (99% confidence interval 10–36%).

All this leads to the conclusion that comparing these two groups of publications was wrong, because the more modern series of publications describing bypasses with surveillance which are different from those described in the historical series of articles without surveillance.

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Author's Reply

We thank Drs Bruijnen and Wölfle for their comments. We are not aware of any evidence to suggest that using the difference of proportions provides superior assessment of the data compared to the Chi-squared test.[1] We are also well aware that the control group is historical and this was pointed out in the second paragraph of the discussion. Such disparity is unavoidable, given that most vascular units now employ duplex surveillance. Duplex surveillance has important economic and workload implications, and we therefore feel that the value of duplex surveillance in improving outcome following infrainguinal vein bypass needs to be demonstrated. Simply to explain any failure to demonstrate improvement in outcomes by a more aggressive intervention policy is unsatisfactory.

It was suggested that the total occlusion rate was higher in the control group as a result of improved intraoperative control measures. As discussed in our paper this seems unlikely, as there was no difference in the perioperative occlusion rates for the two groups (Table 4). As stated in our paper "In order to have some measure of ischaemia, rest pain and gangrene have been grouped together as critical ischaemia and compared to claudication" (p. 391).

Why does a total occlusion rate of 27% only lead to an amputation rate of 13%, i.e. 50% of occluded bypass grafts require amputation of the leg despite critical ischaemia being present in 70%? Clearly the eventual outcome following graft occlusion in the presence of critical ischaemia will depend on a large number of factors such as the outcome of any secondary procedure, the state of run-off vessels following occlusion, the medical condition of the patient and therefore their suitability for further reconstructive surgery. Let us assume that 100 grafts occlude, with 50% eventually come to amputation (i.e. 50). Assuming the same rate of critical ischaemia in the occluded grafts, then 30 patients with occluded grafts may not require further intervention to avoid amputation. This leaves 20 patients (20%) in which secondary intervention achieves limb salvage. We do not feel such a scenario is so unlikely.

We emphasised in our article that the reporting rates of amputation are different in the two groups "Hence the importance of comparing the definite end point of limb salvage or amputation. However, since this outcome measure is rarely documented in surveillance series, this has been extremely difficult." (p. 391). The figures quoted for the publication of Thompson *et al.* have been correctly quoted. The 206 reconstructions also include prosthetic grafts which were not included in our analysis. Only 110 of the reconstructions were vein grafts, the five amputations are stated in their related publication.[2]

The subset analysis performed on our data has been calculated incorrectly. If we study Tables 2 and 3 and if we concentrate only on the articles reporting amputation rates, the figures should be as follows: without surveillance 804 occlusions in 2957 (27%), with surveillance 133 occlusions in 664 (20%), while the amputation rates are 357/2957 (12%) for non-surveillance and 85/664 (13%) for the surveillance series. The ratio of amputation to occlusion is 357/804 (45%) for non-surveillance and 85/133 (64%) for surveillance series, i.e. a difference of 19%, not 23%. It is implied that the occlusion to amputation rate should be the same for series with similar rates of critical ischaemia. Is this necessarily the case? Let us study the few surveillance series which quote amputation rates. In the publication of Sayer *et al.*,[3] in which all patients are stated to have critical ischaemia, 25 of the 33 (75%) occluded grafts resulted in amputations. Whereas in the article of Berkowitz and Greenstein,[4] in which all patients are stated to have severely ischaemic legs, only 11 of the 25 (44%) occluded grafts resulted in amputation. Clearly there appears to be variation in the outcome of graft occlusion in the presence of critical ischaemia. Thus any analysis based on the hypothesis that the ratio of occlusion to amputation is equal must be invalid.

As stated in the discussion of our publication, we accept that the summation analysis has a number of difficulties. The results do not demonstrate that duplex surveillance has no role following infrainguinal bypass, but they do indicate that a large randomised trial is warranted to establish that the considerable cost and workload required for surveillance is worthwhile. Surely this is the only scientific way of establishing the role of duplex surveillance rather than any hypothesis that the ratio of amputation to occlusion should be equal for disparate groups or the demonstration that secondary patency is significantly better than primary patency.[5]

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Iloprost

Sir,

Having been involved with the early trials of iloprost as an adjunct to distal bypass surgery, we were naturally disappointed that the multi-centre trial reported in this journal failed to show any benefit of the agent in this role.[1] We believe, however, that the results of the study should be interpreted with great caution for a number of reasons.

Initial experience with iloprost was carried out using a single bolus dose of the agent via a vein graft to a single calf vessel on completion of the procedure. Addition of intravenous iloprost before and after surgery is without proven benefit and may, as the authors discuss, even be disadvantageous. It is further disappointing that 45 patients failed to receive iloprost as planned.

Our major concern relates to the study design. The initial power calculations for the study were based on the results of patients undergoing arterial bypass to a single calf vessel using long saphenous vein. In the reported study only 73.9% of patients received such a procedure, and the inclusion of patients with composite and prosthetic grafts invalidates the initial calculations. Subsequent subgroup analysis of the different grafts is not valid due to the small numbers and is possibly one of the factors contributing to the surprising lack of benefit found for vein compared to prosthetic grafts.

Patient selection and surgical technique are of fundamental importance in distal bypass surgery, and the variation in number of procedures performed by each centre (one unit contributing only one) suggests considerable differences existed. This point is reinforced by the variable use of dextran, antiplatelet agents, heparin and anaesthetic technique. All of these factors introduce further variables which reduce the power of the study.

It is likely that publication of this study will kill further interest in the role of iloprost as an adjunct to distal bypass surgery. We think that this may be a pity and suggest that what the study most strongly illustrates is the need for robust study design before interpreting the results from multi-centre trials.

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Transcranial Doppler

Sir,

We read with interest the article of Giannoni *et al.*[1] regarding the changes seen on transcranial doppler compared with clinical condition when performing a