plied an average of 10% larger sample size with specific methods of calculation.1

Regarding our estimate of the likely SSI rate in the control group (required to calculate the number of patients to be included), we used our previous routine SSI surveillance obtained with traditional hand-scrubbing (cited in the article as reference 13).2 In fact, we assumed that our SSI rate would be lower, as we chose to study only clean and clean-contaminated procedures. However, when we simulated a lower prevalence of SSI in the control group, we found no reduction of statistical power. For example, with an SSI rate of 2.48% (which was actually observed in the control group), only 2618 patients would have been required.1 In any event, we included 4387 patients, yielding a power higher than 99%.1

Type II error is the risk of wrongly accepting the null hypothesis when the alternative hypothesis is true. We rejected the null hypothesis by showing that the 2 protocols were equivalent (alternative hypothesis in an equivalence trial). This is a positive outcome (χ²=19.5; P<.001) as shown in Table 2 of our article. Consequently, regardless of the power of the study, it cannot be a type II error as Sosis suggests.

The weakness of equivalence trials lies elsewhere. Because it is impossible to prove an exact equality, the calculation of statistical power in even the best designed study contains an irreducibly subjective element, namely the clinically significant difference that the study was designed to exclude. A value of 10% is usually chosen for bioequivalence studies. However, after discussions with the study group surgeons, epidemiologists, and clinical investigators, we set the maximal limit at 2%, which is particularly low for an equivalence trial. Moreover, the 95% confidence interval of the SSI rate difference between the 2 protocols we observed was less than 1%.

In response to the second point, the decision to omit simple hand-washing including subungual space cleaning was made by choice rather than by chance. Thus, as discussed in our article, it is difficult to compare the SSI rate we observed in these cases. On the other hand, we observed no omission of the antiseptic alcohol-based hand rub in the hand-rubbing protocol, which is quite reassuring.

Finally, our study contributes to the scientific evidence base for hand-hygiene guidelines in surgery. Because improving the surgical team’s compliance and tolerance are both desirable, we believe that the hand-rubbing protocol for presurgical hand disinfection should be considered as a good alternative to traditional hand-scrubbing.

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CORRECTION
Incorrect Author First Name: In the Original Contribution entitled “Hand-Rubbing With an Aqueous Alcoholic Solution vs Traditional Surgical Hand-Scrubbing and 30-Day Surgical Site Infection Rates: A Randomized Equivalence Study” published in the August 14, 2002, issue of THE JOURNAL (2002;288:722-727), there was an incorrect author first name. On page 722, the sixth author, Hervé Bensadoun, MD, DCh, should be Henri Bensadoun, MD, DCh.