models to address data sparsity, such as multivariate models, but the individual data are needed. Hence, we suggest that Walsh et al reanalyze their adjusted association between previous MRSA carriage and SSIs using the efficient method introduced here to report a more valid and precise measure of association.

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Concerns Associated With Cleaning Robotic Surgical Instruments—Response to Wallace

To the Editor—We acknowledge the letter by Wallace.[1] We are greatly concerned by the fact that the opposite opinion was raised by the principal scientist of the manufacturer of the da Vinci Surgical System. Before our discussion, it should be recognized that the author's argument might be intrinsically biased from the commercial standpoint. We would like to respond to the issues raised in the letter.

Interpretation of "Published Evidence" of Cleaning Efficacy

The author stated that the amount of residual protein in the robotic instruments was too much, referring to the study by Wallace et al.[2] However, the study protocols were different from each other, as mentioned below.

First, Wallace et al[2] did not assess the housing of the instruments connecting to the shaft, in which surgical soil could "travel up by gravity." In fact, our central sterile supply department staff sometimes observe leakage of bloody ascites from the housing after surgical use. Our data values were higher than those in the previous study because our results reflected the protein remaining on the whole surface area of robotic instruments including inside the lumen of shafts and housings.[3]

Second, their study was based on a protocol proposed to assess the cleanliness of robotic instruments.[4] In this article, robotic instruments were soiled with 200–500 μg protein before measurements. The assumed initial contamination was even lower than residual protein after cleaning in our study.[3] Our data clearly demonstrated that this assumption did not reflect the actual case in clinical settings.

Consideration of Experimental Protocol

The author stated that washer disinfectors should not have been used in our study because they are not allowed in ISO 15883-1. However, in this standard, nonthermal disinfection is adopted only for testing the function of machines and not for testing the cleanliness of surgical instruments. This claim does not make sense. The cleaning conditions in our study were based on the method described in the manufacturer's instructions. Our data reflect more precisely the situation of surgical instruments at use in operations.

Negative controls were not employed in our study nor in the Wallace et al study.[2] The author claimed that negative controls could interfere through residues from the manufacturing process.[1] However, the effects could be minimized by 3 reprocessing cycles, as employed in previous studies.[3,5] The robotic instruments we assessed for residual protein had undergone 10 reprocessing cycles followed by 10 clinical uses.[4] Thus, the use of a negative control was not necessary in our study.

The author assumed that the iron and tungsten particles were released in the ultrasonication process and influenced the results in the bicinchoninic acid assay.[1] However, this assumption is not true according to the manufacturer's instructions for the assay kit we used. The author also stated that 30-minute ultrasonication was harsh and could result in instrument damage.[1] However, it is necessary to clean instruments for a total of 150 minutes of ultrasonication prior to each set of 10

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consecutive uses, according to the manufacturer's instructions. It seems that this claim was only made to find fault with our study.

The author was concerned that the water volume for extraction was too large in our study.[1] This claim is not correct because the volume of extraction fluid does not influence the results when the measurement procedure is performed appropriately. On the contrary, it was necessary for the water volume to be sufficient to fill the lumens and cavities inside the instruments for the whole surface of robotic instruments to have direct contact with the extraction fluids. This volume was essential to assess the entire amount of residual protein. We believe that a 100-mL volume is not sufficient to fill the lumen and cavity. Thus, a smaller volume of water may lead to false-negative results because of insufficient protein extraction.

Patient Safety or a Matter of Business

The reason the robotic instruments were cleaned manually with ultrasonication in our hospital was that this method was described in the manufacturer's instructions. We understand that specific types of washing machines may improve the results of cleaning. We speculate that the manufacturer does not insist on using washing machines only because it could interfere with the sales of the robotic system by increasing the cost.

The author changed his focus from a flaw in the device design of robotic instruments to a flaw in the cleaning practice.[6] Again, however, it is virtually impossible to completely clean instruments that have a vast surface area of canals and cavities inside.[4] In conclusion, our top priority is neither manufacturing nor business, but patients and patient safety.

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