level. We therefore performed a power analysis.[4] * Using Eichhorn's patient injury incidence of 1/75,700 for cases done before adoption of the Harvard monitoring standards, and his patient injury incidence of 1/244,000 for cases done following adoption of the standards, we found that 5,707,181 cases before plus 1,839,424 cases following implementation of standards would have had to be reviewed to achieve a statistical power of 0.80 (probability of detecting a statistically significant difference between two groups) to detect a $P < 0.05$ difference in the rates Eichhorn observed. Eichhorn would have needed a total of 7,546,605 cases; 6,545,605 more than actually reported for these ratios to have a reasonable chance (0.80) of achieving a statistically significant difference ($P < .05$). Seventy-five intraoperative patient injuries before and eight injuries following adoption of standards would have had to occur in this expanded population. On the other hand, if the "pre-standards" cohort is assumed to be fixed, it would take 3,361,080 "post-standards" cases with 14 intraoperative accidents to achieve statistical significance at the "post-standards" occurrence rate Eichhorn reported. Assuming the current Harvard caseload is maintained and records of injuries archived, an appropriate sample size would not be available until approximately 2030! The above assumes no changes in medical practice, no new drugs, no new monitors etc., during all this time. The differences in rates reported by Eichhorn are not statistically significant, and achievement of significance is not "just around the corner."

Finally, many studies are published where n = 10 or 20, and where the authors try to say ". . . the differences did not achieve statistical significance," implying that just a few more experiments are needed. Here, with a database of 1,001,000, Eichhorn's results are not significant. The reported differences in incidence could have occurred by chance alone. Perhaps the Eichhorn study is valid as it really stands, namely that the standards did not influence the incidence of poor outcome. We wonder why the insurance companies, with their vaunted actuarial skill, jumped to reduce rates based on these numbers. We speculate that they did so because of a real (*i.e.*, significant) trend toward a declining incidence, not with any clear-cut step down just at the time of imposition of the mandatory standards. We also speculate that pulse oximetry/capnometry had an equal if not greater role than the standards.

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In Reply:—I urge both sets of commenters not to focus on the standards, pieces of equipment, or statistics. All these are merely vehicles. Rather, the emphasis should be on the behaviors that constitute safety monitoring, which will, by definition, provide the earliest possible warning of untoward intraoperative anesthetic developments.

Contrary to the assertion of Drs. Cook, Woods, and McDonald, safety monitoring does not consider single independent elements. Regardless of the precipitating events, the final common pathway to all intraoperative anesthetic catastrophes involves derangement of ventilation, oxygenation, and/or circulation. Safety monitoring targets exactly this "highly connected and interdependent" path in order to provoke early remedial intervention.

"Hindsight bias and weak counterfactual reasoning," of course, are not desirable. However, these seem unnecessarily harsh charges when: 1) there is agreement that the large majority of major accidents involve unrecognized hypoventilation; and 2) guaranteed continuous monitoring will identify ventilation mishaps as soon as they occur and before the patient exhibits the changes in vital signs that previously were the first signal of a problem. Likewise, matched-control studies of incidents with monitored and unmonitored patients would be beneficial, but the "no monitoring" control group is now legally and ethically impossible. Critical incidents detected by monitoring are being sought for study (reports welcome); but would a summary of these be subject to the same charge of bias? Further, it would be interesting to have mobile "crash teams" (analogous to the FAA teams that rush to the scene of an airliner crash to investigate) available to immediately visit the site of an anesthesia catastrophe and do an in-depth reconstruction of the event. Medical legal issues must be considered, but interest from potential sponsors and participants is welcome. Finally, Dr. McDonald's department has an interest in computerized anesthesia records that automatically capture monitoring data. When free of artifacts, these records, of course, would be a major asset in analysis of intraoperative catastrophies.

Drs. From, Pearson, and Tinker are concerned about the statistics. It might have been better to present the data in textual form rather than a table because they are closer to epidemiologic observations than the more traditional physiologic data with which Dr. Tinker and his colleagues are so familiar. I never implied statistical significance was

soon achievable. I had done the power analysis and was well aware of the need for over 3 million more cases. Because of this impracticality, the data were offered now as an observation on the evolution of our practice in a manner not tied to $P < 0.05$ but more like a case conference presentation that can be an equally valid way to arrive at the "truth."

The last sentence from Dr. From reveals a lack of understanding. Pulse oximetry and capnography cannot be separated from the standards because the standards mandate behavior and using this equipment is one appropriate, effective way to implement the behaviors of continuous monitoring. Neither the standards nor the equipment can stand alone and neither directly "causes" improved outcome. The actuaries and insurers lowered our premiums because, I believe, this trend is real. It is a reasonable conclusion that the concepts and behaviors embodied in the principles of safety monitoring have contributed to improved outcome of anesthesia care.

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Protecting Teeth during Endotracheal Intubation

To the Editor:—Every anesthesiologist has experienced difficulty during tracheal intubation, and many have been unfortunate enough to damage teeth, gums, lips, or other mouth structures during a difficult (or even routine) intubation. Damaged teeth result in the largest number of lawsuits filed against anesthesiologists.[1] Several products have been designed to protect the teeth from damage, however these are usually cumbersome full upper-mouth guards that place a loose foreign body in an already cramped working area.

Since most anesthesiologists use a Macintosh blade as their primary intubation instrument, it is reasonable to place the padding directly on the flange. After trying several products for this purpose (including cut layers of Microfoam* tape), I found polyurethane sheeting with an adhesive backing† (fig. 1). This material is soft, resilient, and has a firm adhesive backing that sticks well to the metal of the blade without leaving a residue when it's removed so the blade can be easily cleaned. It is available in a variety of configurations, including sheeting and rolls. I have used strips cut about 1-cm wide and 3–4-cm long (fig. 2) and find that they fit well on the flange of the Macintosh 3 blade. The strips should be somewhat longer for use with the Macintosh 4 blade. They will work well with the Miller series of blades, but the narrower flange makes it important to adhere the pad firmly.

Fully cured polyurethane is essentially inert if ingested.[2] The pad should be inspected upon removal to make certain that none of it has torn off. The material is available in several colors; however, bright green or yellow show up best in the mouth should the pad become dislodged.

No amount of padding or other protective equipment is a substitute for proper intubation technique; however, several of my colleagues have found this extra bit of protection well worth the few seconds it takes to apply the pad. In addition, they make valuable teaching aids since more than a slight amount of pressure will leave a visible dent in

* 3M Manufacturing, Medical-Surgical Division, St. Paul, Minnesota.
† Success Polymers, Paramount, California.

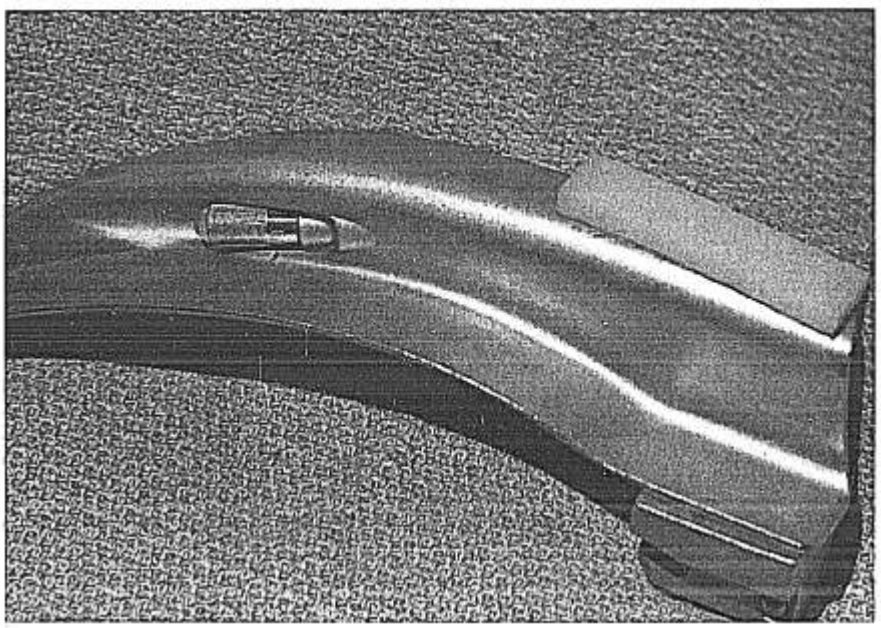

FIG. 1. Macintosh 3 blade with polyurethane sheeting in place ready for use.