The pioneers of joint replacement recognized the serious consequences of an infected arthroplasty and soon adopted the practice of incorporating antibiotics into acrylic bone cement. Antibiotic bone cement provides unique benefits not achieved through other forms of antibiotic administration. It provides local delivery of therapeutic levels while maintaining safe, nontoxic levels in the bloodstream.\(^1,2\) It also allows for sustained delivery at the exact site most critical for preventing implant sepsis: the cement/bone interface. The homogeneous addition of up to 1 g of antibiotic does not interfere with the primary function of the cement, which is mechanical fixation of the prosthetic joint.\(^3\)

Although commercially prepared antibiotic bone cements have been available in international markets since the 1970s, it was not until 2003 that the Food and Drug Administration cleared such a product for use in the United States. Prior to FDA approval of Simplex With Tobramycin\(^\text{a}\) (Stryker, Mahwah, NJ), the standard of care called for hand-mixing powdered antibiotics into standard bone cement in the operating room at the time of surgery.

Surveys on the practice of hand-mixing antibiotics into bone cement show the most frequently used formulation was tobramycin sulfate admixed into Simplex bone cement.\(^4,5\) Commonly, a 1.2-g vial of antibiotic (historically Eli Lilly’s Nebcin\(^\text{a}\)) was added to a standard 40-g packet of bone cement powder. More recently, the use of generic sources of tobramycin sulfate has become widespread.

One of the greatest concerns of adding antibiotics by hand is the uncertainty in achieving a homogeneous mixture free of clumps, which may lead to a weaker bone cement. These fears have become highlighted with the introduction of generic tobramycin sulfate, which often is received as a solid crystalline mass (Figure 1). Incorporation of this newer form of tobramycin has proven difficult for many nurses, who are challenged to remove the antibiotic from the vial and grind it into the cement in a homogeneous manner, while maintaining the sterile field.

This study compared the mechanical properties of commercially prepared antibiotic bone cement (Simplex With Tobramycin; Stryker, Mahwah, NJ), cement with generic tobramycin (Pharma-Tek, Huntington, NY) blended in by the orthopedic nursing staff, and standard nonantibiotic bone cement.

**MATERIALS AND METHODS**

A single lot of Simplex bone cement powder (Stryker, Mahwah, NJ) was used for this study and divided into three experimental groups:

- Commercial Simplex With Tobramycin (1 g of tobramycin per 40-g packet),
- Nurse-blended generic tobramycin

This study compared the mechanical properties of Simplex With Tobramycin bone cement, hand-mixed bone cement with generic tobramycin, and nonantibiotic bone cement.
(1.2 g vial per 40 g packet) in standard Simplex P, and
- Standard (nonantibiotic) Simplex P control.

For the nurse-blended tobramycin bone cement, generic tobramycin (Pharma-Tek; Huntington, NY) was added to standard Simplex powder by nurses from three local hospitals. The tobramycin was obtained from the pharmacy and dry-blended into the cement following the standard aseptic practices used at each hospital. The typical method involved the circulating nurse holding the vial over the cement mixer, while the scrub nurse used a curette to break the antibiotic up and mix it into the cement powder. The antibiotic powder was vigorously mixed into the cement powder until the nurse was confident a smooth blend had been achieved.

After the nurses were satisfied the antibiotic was free of large clumps, the monomer was added and the cement was vacuum-mixed following the manufacturer’s instructions (ACM; Stryker, Kalamazoo, Mich). After vacuum-mixing, the cement was delivered into plastic molds to produce ASTM-type tensile samples (ASTM D638-IV). Seven samples free of surface defects, or internal voids >1 mm in the gage area, were selected for testing. In parallel with the hand-blended antibiotic cement, tensile samples were prepared from the commercial antibiotic cement formulation and the control cement.

After aging in saline for 1 week at 37°C, all samples were tested using an Instron Mechanical Test System (Model 4502) controlled by an Instron Series IX Automated Tester. Tensile stress and strain were determined for each of the sample groups. Stress was determined as the maximum force at specimen failure.
divided by the cross-sectional area of the specimen. Tensile strain was determined as the elongation in the sample gage region divided by the original gage length.

**RESULTS**
A significant decrease in the mechanical properties was observed for the generic tobramycin hand-mixed into the bone cement (Table). The tensile strength of the hand-blended cement relative to the control was reduced by $>36\%$, and the elongation to failure was reduced by approximately $28\%$. Student’s $t$ test demonstrated these differences were significant ($P<.001$).

The commercially blended antibiotic cement was equivalent to the nonantibiotic control cement. No change was observed in the mechanical properties ($P=.28$ and .06 for stress and strain until failure, respectively).

Scanning electron microscope images of the fractured surfaces showed the presence of large antibiotic agglomerations in some of the hand-blended formulation samples. In contrast, the commercially blended product had consistently dispersed fine granules of antibiotic powder (Figure 2).

**DISCUSSION**
This study found the nonhomogeneous addition of “clumpy” antibiotic powder was detrimental to the mechanical strength of acrylic bone cements. This issue is more relevant today than it was in earlier years as the newer generic forms of tobramycin. Given the serious impact these antibiotic agglomerations can have on the mechanical strength of acrylic bone cement and the recent availability of commercially formulated antibiotic bone cement, orthopedic surgeons should reconsider the practice of admixing tobramycin in the operating room.

**REFERENCES**