

# Assessment of Reprocessed Arthroscopic Shaver Blades

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**Purpose:** The purpose of this study was to evaluate the level of contaminants on, as well as the quality of, reprocessed shaver blades. **Methods:** We assessed 7 new shaver blades and 27 shaver blades that had been reprocessed with mechanical cleaning, functional testing, and sterilization with ethylene oxide. A spectrophotometer measured the amount of nucleic acid and protein. The blade quality was assessed by photographing the blades with magnification and determining the percentage of damage present on each blade. A subset of shaver blades were then used to cut meniscal tissue, and the cut surface was measured for smoothness by image processing and automated laser scanning cytometry. In evaluation of the meniscus, for the subset of shavers, an image processing value of 1 indicates a smooth, straight line, and values lower than 1 reflect deviations in the cut surface (the closer the value is to 1, the smoother the surface). Laser scanning cytometry values indicate the percentage of irregularities in the cut surface (the lower the value is, the smoother the surface). **Results:** Of the 27 reprocessed shaver blades, 13 (48%) had detectable levels of protein and 17 (63%) had detectable levels of nucleic acid. On the reprocessed shaver blades, protein levels ranged from 2.43  $\mu\text{g}$  to 60  $\mu\text{g}$  and nucleic acid levels ranged from 0.40  $\mu\text{g}$  to 3.5  $\mu\text{g}$ . No new shaver blade had contaminants. Twenty reprocessed shaver blades had been manufactured with teeth and could be evaluated for visible damage. Of these, 10 had 1% to 25% damage, 5 had 26% to 50% damage, 3 had 51% to 75% damage, and 2 had 76% to 100% damage. The new blades had no visible damage. Image processing revealed smoothness of the surface cut with new shaver blades, yielding values of  $1 \pm 0.12$ , whereas the values for reprocessed shaver blades ranged from  $0.62 \pm 0.02$  to  $1 \pm 0.07$ . Laser scanning cytometry values ranged from 3.3% to 7.1% for the new blades as compared with 5.8% to 20.0% for the reprocessed blades. **Conclusions:** Of the reprocessed shaver blades, 48% had detectable levels of protein and 63% had detectable levels of nucleic acid. All of the reprocessed blades visually evaluated showed some level of damage or wear, whereas no new blade had such damage. In addition, menisci cut with reprocessed shavers showed rougher edges than did menisci cut with new shavers. **Clinical Relevance:** To make an informed decision regarding the use of reprocessed shaver blades, surgeons will want to know the level of contamination on, and the quality of, reprocessed shaver blades. **Key Words:** Shavers—Nucleic acid—Laser scanning cytometry.

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**T**he modern era of managed care has brought about many changes in medicine. In response to economic pressure to lower costs, medical device repro-

cessing companies have developed a nationwide market for reprocessing and resale of single-use surgical instruments. A wide spectrum of devices are currently being reprocessed. They include orthopaedic shaver blades, burs, saw blades, and drill bits, as well as instruments used in cardiovascular surgery, laparoscopy, endoscopy, and ophthalmology. The average surgical center would save 25% each year on arthroscopic shaver blades if each blade were used twice.

These companies adhere to Food and Drug Administration (FDA) standards of reesterilization and quality control and assert that they are able to provide shaver blades that are as safe and effective as new blades. As of 2002, the reprocessing companies are considered

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manufacturers and must submit their protocols for reprocessing to the FDA. The FDA has the authority to inspect the procedures and the reprocessed equipment. The protocols for reprocessing are varied. Many include mechanical cleaning, functional testing, and ethylene oxide sterilization.<sup>1</sup>

There has been no previous study published in the orthopaedic literature evaluating the level of contamination or quality of reprocessed blades. The presence of contaminants would certainly raise concerns about the transmission of microorganisms. The purpose of this study was to describe the level of residual contaminating nucleic acid and protein and the quality of reprocessed shaver blades. Further study would be required to determine whether the presence of such material poses any clinically significant risk of infection to patients.

## METHODS

Dyonics (Smith & Nephew, Andover, MA) provided 7 new shaver blades and 16 reprocessed Dyonics shaver blades for use in this study, which comprised set 1. They were of different models and were obtained from 4 different reprocessing companies. All sterile wrapping was intact, with no obvious breaches of quality. In addition, we purchased 11 reprocessed shavers from local hospitals to be used as an additional set to test for contaminants and blade quality, which comprised set 2. All shaver blades were reported by the reproprocessors to have been mechanically cleaned, functionally tested, and then sterilized with ethylene oxide. Because of the lack of a tracking system, there is no way to determine the type of tissue or the time period for which the shaver blades were used. Nor could it be determined how many times the blades had been reprocessed. All shaver blades were assigned a random number to prevent the data collection from being biased toward the new blades. Each sterile blade was unwrapped in a sterile laminar flow hood and separated into the outer and inner blades.

### Contaminants

For this portion of the study, we used 27 reprocessed shaver blades, 3 new shaver blades, and 1 used but not reprocessed blade. The 27 reprocessed blades and 2 of the new shaver blades (negative controls) were sequentially dipped for 1 hour each at room temperature (22°C) in a sterile tube containing 500  $\mu$ L of wash buffer (10-mmol/L Tris, 100-mmol/L sodium

**TABLE 1.** Residual Nucleic Acid and Protein Detected on Shaver Blades

|       | Reprocessed Shaver Blades        |                             | New Shaver Blades                |                             |
|-------|----------------------------------|-----------------------------|----------------------------------|-----------------------------|
|       | Nucleic Acid*<br>(Total $\mu$ g) | Protein†<br>(Total $\mu$ g) | Nucleic Acid*<br>(Total $\mu$ g) | Protein†<br>(Total $\mu$ g) |
| Set 1 | ND                               | ND                          | ND                               | ND                          |
|       | ND                               | ND                          | ND                               | ND                          |
|       | 0.40                             | ND                          |                                  |                             |
|       | 0.134                            | ND                          |                                  |                             |
|       | 0.19                             | 6.8                         |                                  |                             |
|       | 0.43                             | 114                         |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | 0.21                             | 46.4                        |                                  |                             |
|       | 0.38                             | 39.8                        |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | 0.16                             | ND                          |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | 0.2                              | ND                          |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
| Set 2 | 1.39                             | 8.6                         |                                  |                             |
|       | 1.20                             | 7.8                         |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | 0.76                             | 2.43                        |                                  |                             |
|       | 0.89                             | 4.36                        |                                  |                             |
|       | 1.11                             | 10.3                        |                                  |                             |
|       | 1.38                             | 9.8                         |                                  |                             |
|       | 1.14                             | 6.1                         |                                  |                             |
|       | 1.36                             | 8.9                         |                                  |                             |
|       | ND                               | ND                          |                                  |                             |
|       | 1.19                             | 4.75                        |                                  |                             |

Abbreviation: ND, none detected.

\*Total micrograms of nucleic acid detected on blade surface (calculated from optical density measurement).

†Total micrograms of protein detected on blade surface (calculated from optical density measurement).

chloride, and 0.1% Tween-20 in distilled water). The optical density at  $A_{260}$ ,  $A_{280}$ , and  $A_{320}$ -nm wavelengths of the resulting solution were measured on a Beckman DU 640 spectrophotometer (Beckman Coulter, Fullerton, CA).

The third new shaver blade was used as a positive control by placement in a solution of 1  $\mu$ g/mL salmon sperm deoxyribonucleic acid and 1 mg/mL bovine serum albumin (as a source of protein) for 1 hour at room temperature. One shaver that was used but not reprocessed was obtained from the surgical suite. After use, the shaver was rinsed in sterile saline solution, wiped dry, and placed in a plastic bag, and it was used as an additional positive control. The positive control shaver blades were allowed to dry for 1 hour and were

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