The Standard Reusable Orthopaedic Depth Gauge: A Pilot Study of Residual Device Contamination Following Routine Cleaning

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Financial Disclosure: This study was funded by EDGe Surgical, Inc. Biochemical tests were provided by Healthmark Industries, Inc.

Introduction

Surgical Site Infection (SSI)

- SSIs are a serious issue in orthopaedic trauma surgery
- SSI occurs in approximately 4% of trauma procedures (Bachoura 2011, Thakore 2015)
- Contaminated medical devices can cause SSI – particularly those with rigid lumens and other design features (Azizi 2012)
- Devices that have not been adequately cleaned cannot be properly sterilized (FDA 2015)

Standard Orthopaedic Depth Gauge

- Resuable device designed to measure depth of pilot hole prior to choosing screw
- Shares several risky design features with other proven "difficult-to-clean" reusable medical devices: microscopic curves, long, rigid lumens, and multiple parts
- The device is used in a sterile space, where it routinely comes into contact with bone and soft tissue
- The effectiveness of cleaning orthopaedic depth gauges in practice has not been thoroughly investigated to date

Objective:

Evaluate the cleanliness of orthopaedic depth gauges following standard reprocessing

Hypothesis:

The standard, reusable orthopedic depth gauge will harbor debris and potentially bioburden following routine cleaning

	Testing Methods & Results					
		Multi-Channel Test			Single-Channel Tests	
Depth Gauge	Visual Test	Protein	Blood	Carbohydrate	Protein	Blood
1	Failed	Negative	Negative	Negative	Negative	Negative
2	Failed	Negative	Negative	Negative	Negative	Negative
3	Failed	Negative	Negative	Negative	Negative	Negative
4	Failed	Negative	Negative	Negative	Negative	Negative
5	Failed	Negative	Negative	Negative	Negative	Negative
6	Failed	Negative	Negative	Negative	Negative	Negative
7	Passed	Negative	Negative	Negative	Negative	Negative
8	Failed	Negative	Negative	Negative	Negative	Negative
9	Failed	Negative	Negative	Negative	Negative	Negative
10	Failed	Negative	Negative	Negative	Negative	Negative
11	Failed	Positive	Positive	Negative	Positive	Positive
12	Failed	Negative	Positive	Negative	Positive	Positive

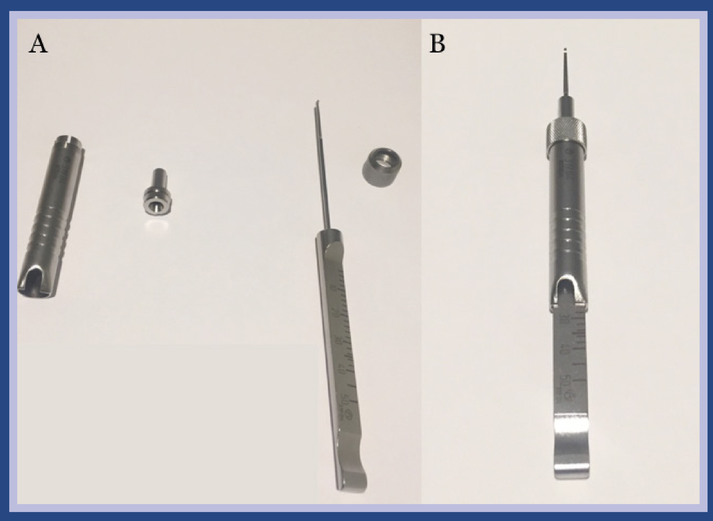

Figure 1: (A) The orthopaedic depth gauge disassembled. (B) An assembled depth gauge.

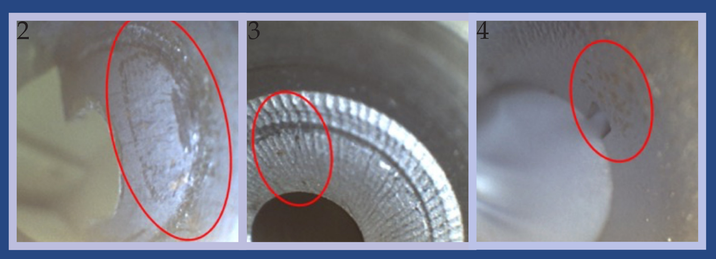

Figure 2: Debris within the large lumen of the device.

Figure 3: Debris near the connection between the probe and the ruler.

Figure 4: Soil in the small lumen, where the probe slides.

Methods

- Twelve depth gauges were randomly selected at an anonymous, highly-ranked level I Trauma Center
- Devices were removed from trauma trays after cleaning or cleaning and sterilization
- Visual inspection for soils – outside examined by naked eye, inside examined using a 3.3 mm borescope (Healthmark Industries, Fraser, MI)
- Tested for protein residue (ProCheck-IITM Detection; Healthmark)
- Tested for hemoglobin residue (Hemocheck™; Healthmark)
- Multi-channel test for carbohydrate, protein, and hemoglobin (ChannelCheck-TM; Healthmark)

Results/Discussion

- 11/12 devices (91.7%) failed visual inspection with eye, borescope
- 2/12 devices (16.7%) failed biochemical testing, esp. hemoglobin
- 10/11 devices (90.9%) that failed testing harbored soils within the device lumen
- Sterilization may "cake on" this debris
- This device is challenging, if not impossible, to clean correctly
- Residual debris after reprocessing could endanger patient safety

Conclusion:

Routine hospital reprocessing does not adequately clean orthopaedic depth gauges. Therefore, adequate sterility cannot be guaranteed consistently. Strategies should be developed to ensure that depth gauges do not endanger patient safety.