Serial Sterilization of Silicone Breast Implant Sizers Contributes to a Change in Volume as Compared to Permanent Breast Implants

Presenter: Katherine H. Carruthers, MD

Co-Authors: Julian Fazi, BS; Vidas Dumasius, MD

Affiliation: West Virginia University, Morgantown, WV

BACKGROUND: Breast implant sizers are commonly employed as an aid for permanent implant selection during both reconstruction after mastectomy and cosmetic augmentation. Because implant size is one of the most important factors influencing implant selection, the ability of sizer devices to accurately reflect their permanent counterparts is essential. In most facilities, silicone breast implant sizers are reused for multiple surgeries, in accordance with manufacturer recommendations, which allow multiple resterilizations before disposal. However, the sterilization process was observed to introduce air pockets into the silicone sizers which are trapped and retained after repeated sterilization. We hypothesized that introduction of air volume inside sizers contributes to mismatch in permanent implant selection. Therefore, the goal of this study was to determine how serial sterilization changes the volume of breast implant sizers and whether this change results in a clinically significant difference in permanent implant size selection.

MATERIALS AND METHODS: We selected representative devices across a range of volumes (200 to 600 ml moderate profile smooth round silicone breast implant sizers [Mentor Worldwide, LLC., Irvine, Calif.]) and measured their volumes after 10 serial sterilizations. All devices were processed according to the manufacturer recommendations for sterilization. After each resterilization, the device was inspected for the presence of sequestered air and the sizer volume was measured using a water displacement technique. The volume after each resterilization was recorded and the difference between the new volume and the original volume was calculated to show each interval increase in implant volume over the device’s lifetime. T test analyses were used to determine if there was a statistically significant change in sizer volume.

RESULTS: After 10 sterilizations, a similar absolute increase in volume was found in each device, ranging from 23.88 to 26.54 ml. Interestingly, as a percent, this increase was much greater for the 200 ml sizer (12.85%) than the 600 ml sizer (3.98%). Although the volume did gradually increase with each subsequent sterilization, the largest single increase in volume across all devices and sterilizations was 12.04 ml which occurred as a result of the third sterilization of the 250 ml device. Overall, the change in sizer volume became statistically significant after the fifth sterilization (P = 0.04).

CONCLUSION: The manufacturer standard for serial sterilization of breast implant sizers results in an approximately 25 ml increase in volume over the lifetime of the device, regardless of the initial volume of the sizer. As such, sterilization has a much greater impact on smaller volume sizers than on larger volume sizers. Furthermore, a statistically significant change in volume is seen after only 5 rounds of sterilization. This increase in volume may result in the selection of a permanent implant that is actually a size smaller than what was trialed intraoperatively. Therefore, accurate documentation protocols should be introduced to keep precise record of the number of sterilizations that each device has undergone from the time of manufacturing. Additionally, surgeons should adjust their permanent implant selection to account for a possible increase in sizer volume and exercise caution when resterilizing smaller volume silicone sizers.