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A Comparative Study Between the Stryker EZout Powered Acetabular Revision System and the Zimmer Explant Acetabular Cup Removal Systems

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Summary: The conservation of bone stock and the decrease of intraoperative acetabular fracture risk associated with revision surgery is a primary goal to improve the outcome of the procedure. The objective of this study was to evaluate and compare the performance of the Explant Acetabular Cup Removal System and the EZout Powered Acetabular Revision System in an in vitro model. Acetabular components were implanted into instrumented composite hemipelvises and divided into 2 groups, EZout System and Explant System. One experienced orthopedic surgeon and 1 orthopedic resident physician performed the removal procedures. The strains at various points in the periacetabular bone, the temperature at the implant-bone interface, the total time to removal, the torque applied to the implant and the amount of acetabular foam on each cup after extraction, as a surrogate for cavitary acetabular bone stock loss, were calculated for each test. Statistical analysis was conducted using 2-way multivariate analysis of variance followed by Tukey honestly significant difference multiple comparisons. The EZout System required an overall lower force and torque (P < 0.0001, both)during removal, producing lower strains in the surrounding composite bone. The procedure was faster (P < 0.0001) and less energy demanding with the EZout compared with the Explant. The amount of foam on the cup was on average less for the EZout than for the Explant (P < 0.05).

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We found that the EZout System is effective in achieving safe removal of a well-fixed acetabular component in an in vitro model of cementless fixation. This system should be considered as a reasonable alternative to manual removal techniques.

Key Words: hip-revision-revision arthroplasty-arthroplasty-EZout-Explant—acetabular cup—bone conservation—osteotome.

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he removal of well-fixed components during revision arthroplasty can be very demanding, time-consuming, and potentially damaging to the surrounding host bone.^{1,2} The complexity of revision of the acetabular reconstruction is directly proportional to the extent of cavitary and segmental acetabular bone loss present following explantation.³ Iatrogenic damage to the pelvis may increase the complexity of the reconstruction and potentially compromise the longevity of the revision construct. Preservation of bone stock is particularly important in younger patients. The existence of many different techniques reported in the literature is an indication of the complexity associated with removal of acetabular components with the concurrent goal of inducing the least amount of damage to the host bone. 1,4-8 Described removal methods mostly included the use of various types of curved osteotomes. These techniques have not sufficiently addressed the issue related to iatrogenic damage to the acetabular host bone. The introduction of the Explant Acetabular



FIGURE 1. The Zimmer Explant System. (1) The short and (2) the long blades match the curvature of the implant to precisely disrupt the implant/bone interface. (3) The procedure starts with the short blade at the periphery/mouth of acetabulum followed by the long blade to reach the polar region of the implant. Rotation of the pivoting osteotome is applied to disrupt the implant-bone interface about the entire circumference.

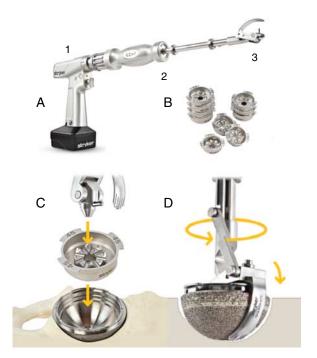


FIGURE 2. The Stryker EZout System. A, 1 handpiece, 2 attachment, 3 blade. B, Centering plugs. C, Plug and cup assembly. D, While the handpiece is rotated about its axis to translate the blade around the periphery of the cup (without the need for any inclination from the center axis of the cup), the blade is advanced into the implant-bone interface by sliding the handle of the EZout System attachment along the shaft axis.

Cup Removal System (Zimmer, Warsaw, IN) has eased the ability to achieve removal of conventional modular acetabular shells. However, conservation of the bone stock and the decrease of intraoperative acetabular fracture associated with revision surgery has remained a concern.

The Explant System has helped to achieve the removal of cementless acetabular shells and has been the system of choice for many surgeons during hip revision surgery. This pivoting osteotome system (Fig. 1) consists of a handle connected to an acetabular liner-centering device which drives a curved cutting blade around the periphery of the acetabular shell at the implant-bone interface. Two blades are used sequentially. The first, a short blade penetrates the dense peripheral bone at the mouth of the prosthesis creating a channel. A second, long, full-radius blade is intended to disrupt the interface circumferentially to the dome or polar region of the implant. Both blades are ~2 mm thick and are of a tapered, double-edged design.

The EZout Powered Acetabular Revision System (Stryker, Kalamazoo, MI) (Fig. 2) is a powered tool system comprising a unique and original powered handpiece, a set of centering plugs, and 2 serrated blades (short and long). The centering plug allows fitting of the EZout System to both Stryker and non-Stryker acetabular cups once the liner is removed. The centering plugs are sized to match the appropriate patient acetabular cup size. Tabs on the centering plug rest on the rim of the cup to prevent rocking. In use, the blade undergoes powered oscillation ± 5 degrees. The surgeon is free to manually rotate the attachment infinitely in either the clockwise or counterclockwise direction to facilitate cutting around the cup. The surgeon can also manually slide the handpiece handle forward to advance the blade forward, deeper into the pelvis, along the periphery of the cup at the implant-bone interface. Blades of 2

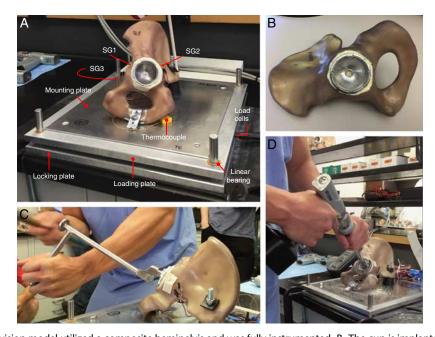


FIGURE 3. A, The revision model utilized a composite hemipelvis and was fully instrumented. B, The cup is implanted into the hemipelvis during foam curing. The layer of foam around the cup has mechanical properties similar to those of cancellous bone. C, The Explant System requires the use of a mallet and striking force from the surgeon to disrupt the interface. D, The Stryker EZout System requires less physical effort from the surgeon and incorporates powered disruption of the interface. SG1 indicates strain gauge placed on the posterior wall; SG2, strain gauge placed on the anterior wall; SG3, strain gauge placed on the internal ischium in proximity to the Haversian Notch.

different lengths, short and long, used in sequence, allow for the removal of the acetabular component from the surrounding pelvic bone.

The scope of the present study was to evaluate the performance of the Stryker EZout System to the Zimmer Explant System in a randomized, comparative, in vitro investigation. The primary objectives were to assess the force and strains transferred to the periacetabular bone, the amount of foam left on the cup, and the ease of use of the 2 systems. The study provides information for surgeons to consider when performing revision hip surgery.

MATERIALS AND METHODS

Acetabulae of composite hemipelvises (Sawbones Inc., Vashon Island, WA) with a foam density of 0.48 g/cm³ were reamed and filled with polyurethane foam. The geometry and composition of the hemipelvis assured a very close replication of the in vivo conditions where the periacetabular bone also serves as a heat sink, therefore contributing to the dissipation of heat generated during cup removal.

A 54-mm Stryker Trident Hemispherical Acetabular Shell was inserted into the foam of each specimen during the curing process to emulate a well-fixed cementless construct. The hemipelvis was mounted on a supporting plate system (Fig. 3A). Three load cells (FX1901; Measurement Specialties, Fremont, CA) were

positioned between a free-to-move loading plate and locking plate (Fig. 3A), and then calibrated by applying known forces through the polar region parallel to the vertical axis of the mounted cup. Three strain gauges (SG) were placed on the posterior wall (SG1), on the anterior wall (SG2), and on the internal ischium in proximity to the Haversian Notch (SG3), and calibrated as above. Last, a thermocouple (T) was fixed with adhesive onto the outer surface of the cup in the polar region, at the interface of the cup and foam, by drilling a hole (0.5 mm diameter) into the hemipelvis. The thermocouple function was validated and calibrated using hot water poured into the cup, at 3 different calibration temperatures. Forces, strains, and temperature were recorded using a DAQ system (cDAQ-9174; National Instrument, Austin, TX) and processed using a custom Matlab routine (MathWorks, Natick, MA). An experienced orthopedic surgeon and an orthopedic resident were asked to perform the procedure using both systems (Figs. 2C, D). The implant removal procedure was repeated 6 times per surgeon and per instrument (total of 24 specimens). Applied forces during removal (F1, F2, F3), strains in periacetabular bone (R1, R2, R3), interface temperature (T), and total removal time were recorded during each test. The cancellous bone left on a cup is a reflection of iatrogenic cavitary bone loss induced from the cutting blades and due to any avulsion of bone by the implant. The amount of foam (simulated cancellous bone) was estimated by comparing the weight of each cup before insertion and after the test (average of 4 measurements each). The

TABLE 1.	Values for Recorded	d and Calculated	Parameters

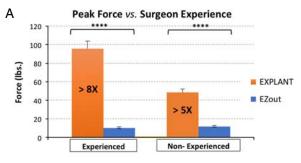
	Peak Force (kgf)	Peak R1	Peak R2	Peak R3	Peak Torque (Nm)	Time (min)	Temperature (°C)	Weight (g)
Experienced surgeon								-
Explant								
Average	96	808	10,055	23,852	480	5.8	26.5	1.04
SD	20	113	19,661	24,150	69	0.9	1.6	0.70
SE	8	46	8027	9859	28	0.4	0.8	0.18
Minimum	66	679	1531	2052	385	5.0	25.2	0.45
Maximum	123	939	50,169	51,654	541	7.4	28.6	1.74
Δ (maximum-minimum)	57	260	48,637	49,602	156	2.4	3.4	1.3
EZout								
Average	12	184	1190	1302	67	1.7	38.4	0.39
SD	2	53	551	564	9	0.4	5.6	0.19
SE	1	22	225	230	3	0.2	2.8	0.07
Minimum	7	132	756	675	59	1.1	32.6	0.15
Maximum	14	275	2158	2326	83	2.4	45.7	0.67
Δ (maximum-minimum)	7	143	1402	1651	24	1.3	13.1	0.52
Ratio (EX/EZ)	8.1	4.4	8.4	18.3	7.2	3.5	0.7	2.6
Nonexperienced surgeon								
Explant								
Average	48	816	2464	2838	223	8.2	32.0	0.87
SD	9	177	1182	1523	31	2.2	2.4	0.47
SE	4	72	482	622	13	0.9	1.2	0.20
Minimum	39	681	1148	1113	187	4.2	28.9	0.59
Maximum	59	1127	3633	4737	272	11.0	34.1	1.56
Δ (maximum-minimum)	20	445	2485	3625	85	6.8	5.2	0.98
EZout								
Average	10	216	1128	1069	65	2.7	34.7	0.34
SD	2	77	523	505	15	0.4	3.4	0.08
SE	1	32	213	206	6	0.2	1.7	0.03
Minimum	7	137	554	485	47	2.2	30.7	0.24
Maximum	347	347	1791	1784	88	38.9	38.9	0.46
Δ (maximum-minimum)	339	209	1236	1299	41	36.7	8.2	0.21
Ratio (EX/EZ)	4.8	3.8	2.2	2.7	3.4	3.0	0.9	2.6

EX indicates Explant; EZ, EZout.

torque (τ) generated during the removal process was calculated by estimating the radial distance (r) to each force sensor from the center of the hip socket as $\tau = r \times F$. Torque was calculated for each time point, and the resulting torques were vectorially added and presented on scatter plots.

RESULTS

The values for the recorded and derived parameters are summarized in Table 1. During the acetabular component removal procedures, the maximum force transferred to the implant was > 4 times lower with the EZout System regardless the surgeon experience (Fig. 4). Overall, recorded strains were lower for the EZout System than the Explant System with the higher decrease in strain (5x) observed at the posterior wall region, R1 (Figs. 5A, B). The temperature at the interface was higher for the EZout System but close to physiological body temperature (Fig. 6). The total removal time was decreased on average by one third with the EZout System compared with the Explant System (Fig. 7). The calculated torque was lower for the EZout System and dependent on the surgeon's experience. The difference in average peak torque was higher for the experienced surgeon $(7\times)$ than the resident $(3.5\times)$ when using the Explant System (Fig. 8). Plotting all values recorded for



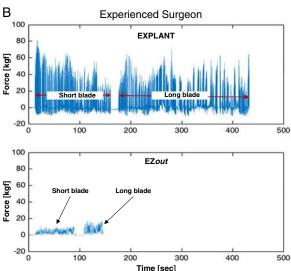


FIGURE 4. A, The average peak force was 8 and 5 times higher for the Explant System for the experienced and nonexperienced surgeon, respectively. B, Extraction force recorded during a typical test. Note the 2 distinct phases for the extraction using first the short blade and then the long one. ****0.001 < P < 0.0001.

force and the calculated values of torque demonstrated significant differences between the EZout System and Explant System (Fig. 9), with much higher values of torque exerted during the extraction with the Explant System. The amount of foam left on the cup after removal was higher on average for the Explant System than the EZout System (Fig. 10). Values ranged on average up to 2.5 times higher for the Explant System with most of the foam concentrated in the polar region. For the implants removed with the EZout System, the foam was more evenly distributed on the outer surface of the prosthesis. Last, it was observed that the polar region of each implant was reached by rotating the EZout System handpiece within a very narrow cylinder of space centered along the axis of the acetabular component compared with the Explant System, which required movement of the pivoting osteotomes within a large coneshaped operating envelope.

Statistical analysis was conducted using 2-way multivariate analysis of variance followed by Tukey honestly significant difference multiple comparisons. There was a statistically significant interaction effect between the type of acetabular cup removal system and surgeon's experience on the combined dependent variables (F = 6.466, P = 0.005; Wilks $\Lambda = 0.205$, observed power = 0.954).

DISCUSSION

A technical goal for the successful removal of a well-fixed acetabular component during revision surgery involves minimizing damage to the surrounding host bone to maximize preservation of bone stock, as well as reducing the risk of intraoperative iatrogenic fracture of the pelvis. Forceful removal of well-fixed cementless acetabular components using curved gouges and osteotomes may lead to significant bone loss and subsequently result in a higher incidence of early failure due to aseptic component loosening. ¹⁰ The importance of using a more bone-conserving technique has been emphasized in the literature, 1,9,11-13 and several have been described to address the difficulty of achieving this goal. 14-17

The implant industry has responded to the need for more effective revision instrumentation to overcome these issues. The Explant System was designed to minimize acetabular bone loss at the implant-bone interface and to ease the overall performance of the procedure. With the Explant System, the interface is disrupted by compression failure of the surrounding bone as the curved pivoting blade is advanced. The needed force may generate significant bone strains that may lead to acetabular fracture secondary to tension failure of the bone. In fact, wellfixed, medialized sockets must be approached very cautiously to avoid damage to the medial wall. 14 Moreover, use of the Explant System requires a sufficiently large operating cone of space around the surgical site. The Explant technique requires the surgeon to leverage and pivot the handle of the tool with a sufficient arc of motion within that operating envelope to reach the polar region throughout the 360-degree circumference of the implant. Furthermore, the procedure is physically demanding and may require significant energy expenditure at the beginning of a surgical procedure that can be long and challenging. Stryker Surgical has recently developed an alternative to the Explant System that utilizes powered, self-clearing oscillating blades guided via a handpiece and centering plug (Fig. 2). The system is intended to be less physically demanding to use and can potentially provide more accurate and complete interface disruption while offering better conservation of surrounding bone stock with a lower risk of iatrogenic fracture. The operating envelope for the EZout System is smaller in size

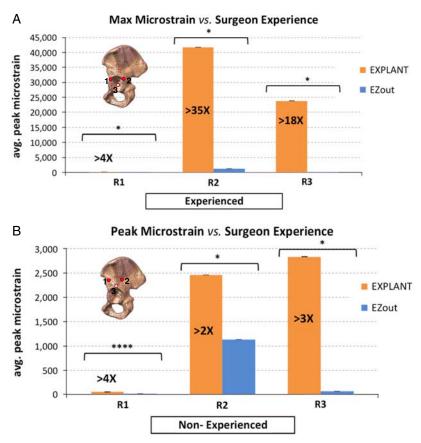


FIGURE 5. Recorded average peak microstrains for the experienced surgeon (A) and nonexperienced surgeon (B). $^*P < 0.05$ and $^{****}0.001 < P < 0.0001$.

(cylindrically-shaped) than that of the Explant System (coneshaped). Therefore, there is a potential benefit regarding a reduced amount of surgical exposure and dissection required to access the prosthesis and to mobilize the proximal femur to disrupt the acetabular implant-bone interface.

The 2 systems were evaluated side by side in a controlled and reproducible in vitro composite hemipelvis model (Fig. 3). Each test pelvis was unconstrained along the axis perpendicular to the mounting plate to replicate more closely the in vivo conditions and to allow for the measurement of the force generated during the removal procedure. The in vitro test conditions favored the Explant System, as there was no simulation of a potentially obstructing

proximal femur, the femoral component, the surrounding soft tissues, or the wound margin. During in vivo use, the presence of the femur restricts the potential size of the operating cone. Therefore, complete interface disruption is limited in the anterior one third of the acetabulum, resulting in an increased risk of cavitary and/or segmental acetabular bone stock loss as well as potential damage to the proximal femur due to instrument impingement with the use of the Explant System.

The average peak force recorded during the test (Fig. 4A) was higher for the Explant System especially for the experienced surgeon (8×). By plotting the force data recorded during the procedure (Fig. 4B) the difference between the Explant System

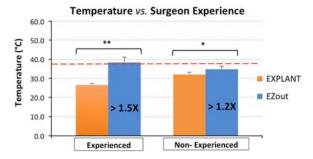


FIGURE 6. The recorded temperature at the interface was higher for the EZ*out* System but was very close to or lower than the physiological body temperature (dotted line). *P<0.05 and * * 0.05 < P<0.01.

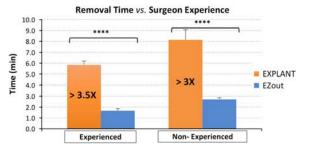


FIGURE 7. On average, removing the cup with the Explant System required more time than the EZout System. ****0.001 < P < 0.0001.

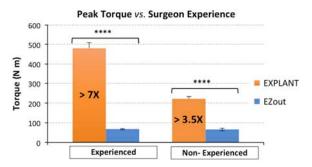


FIGURE 8. Peak values for the torque are higher during the removal with the Explant. Note how the difference is even higher for the experienced surgeon. ****0.001 < P < 0.0001.

and the EZout System is even more dramatic. The difference in average peak force is attributable to the impaction of the mallet against the strike face of the Explant System handle used to advance the blade. This strike force is absent when the implant removal procedure is executed with the EZout System.

As a result of higher applied forces, recorded microstrains with the use of the Explant System were also higher as shown by the graph in Figure 5. The maximum increase in microstrain was observed on the internal ischium in proximity to the Haversian Notch (R3). The floor of the Haversian Notch is the medial most extent to which the acetabular component can be seated and is also where the thickness of the periacetabular bone is often the least. Because of the paucity of bone in this

area, there exists a risk of iatrogenic fracture or avulsion fracture of the acetabulum due to tension failure resulting in the generation of a possible medial wall defect. Figure 5 shows a dramatic increase of microstrain in this region for the Explant System—18 times greater than EZout System for the experienced surgeon. The other region where microstrains were observed to be high was on the anterior wall. In this case, the Explant System trials showed 8 times greater values of average peak microstrain compared with the EZout System. This region was also the one where the highest microstrain was observed for the EZ*out* System.

The temperature at the interface was higher for the powered EZout System (Fig. 6). Such an increase was likely produced by the mechanical friction of the powered oscillating blade. However, the temperature remained within physiological limits of the body and fell far below values that could compromise bone viability due to thermal necrosis. 18,19

The time to perform the procedure was significantly reduced using the EZout System by more than one third (Fig. 7). On average, phase 2 cutting time (with long blade) was shorter with the EZout System whereas phase 1 cutting time (with short blade) was shorter with the Explant System. The shorter time may be due to a more efficient interface disruption with the oscillating blade in phase 2, as well as lower force and torque demand with the EZout System compared with the Explant System. The shorter time in phase 1 cutting with the Explant System may reflect the shorter blade length compared with the EZout System, and the more limited extent of interface disruption and time spent with that short Explant System blade relative to the short EZout System blade. Assessment of the

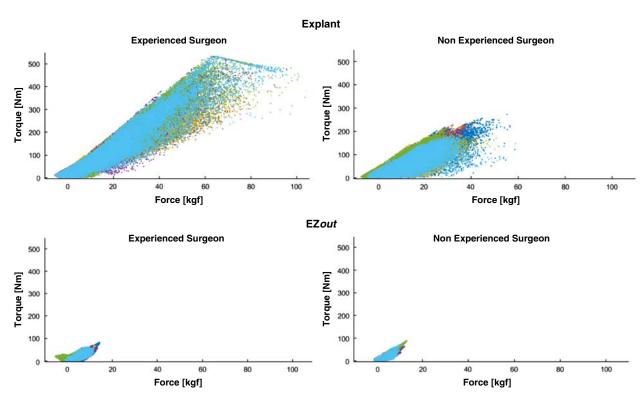


FIGURE 9. Torque versus force recorded for a typical test. Note that the plot shows every value that has been recorded and therefore represents all the values of force and torque transmitted through the hemipelvis. The spread is much larger for the Explant System, particularly for the experienced surgeon, top left. Moreover, the torque values are much higher for the Explant System than for the EZout System, top graphs.

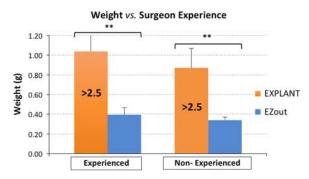


FIGURE 10. Weight loss versus surgeon's experience. The difference in cup weight before and after removal was greater for the Explant System than the EZout System independently of the surgeon's experience. **0.05 < P < 0.01.

time data demonstrates that the Experienced surgeon was faster than the nonexperienced surgeon when each was using the same System. However, the nonexperienced surgeon was able to remove an implant faster with the EZout System, than the Experienced surgeon was able to remove it with the Explant System. The more rapid removal may be of potentially significant benefit to the occasional revision surgeon in reducing operative time while providing potentially greater ease of implant removal.

The estimated torque was higher for the Explant System (Fig. 8), particularly for the experienced surgeon (8x). Scatter plots (Fig. 9) indicate significant differences in resultant torque both in terms of surgeon experience and the specific system used for implant removal. The differences may be explainable by taking into account the different manners in which each of the 2 systems disrupts the implant-bone interface. The blade of the Explant System is forced into the interface by malleting of the handle to drive the curved blade about the surface periphery of the prosthesis by pivoting the handle away from

the axis of the cup/acetabulum. The distance from the cup axis creates a leverage that produces high torque. The intrusion of the blade of the Explant System into the implant-bone interface acts as a space-occupying mass, creating a bony channel as a result of compression failure of the bone at the cutting edge. In contrast, the EZout System functions by rotation of the powered cutting blades about the axis of the acetabular component. The EZout System disrupts the implant-bone interface by cutting and clearing bone, creating a channel for passage of the blade, and minimizing bone strains as well as torque. The powered removal requires less physical exertion by the surgeon and less force application which may contribute to lower surgeon fatigue as well as lower bone strains in the pelvis as previously noted. Moreover, a narrower operative space and smaller wound channel are required around the surgical site to use the EZout System as compared with the Explant System.

The amount of foam left on the cup implant after prosthesis removal is a gross estimate of cavitary acetabular bone loss as it does not take into account the amount of bone removed by the advancing blade. Overall, the foam on the cup after removal with the EZout System was 2.5 times lower than the Explant System suggesting a higher precision in following the interface contour and greater effectiveness at disrupting the interface (a reduction of bone avulsed from the surrounding acetabulum due to tension failure). Although vibration of the blade may have contributed to the separation of the foam from the cup, larger sections of foam remained attached to the acetabular components removed with the Explant System (Fig. 11), while no large pieces of foam were found on the implants removed with the EZout System. As a model for the creation of iatrogenic cavitary defects that result from avulsed periacetabular bone attached to the surface of the implant, the surgeon intervention for management of this bone loss would appear to be greater with the Explant System. The contained iatrogenic cavitary defects would have to be managed intraoperatively by the surgeon by either reaming deeper to optimize implant-bone interface contact or for larger cavitary defects, by

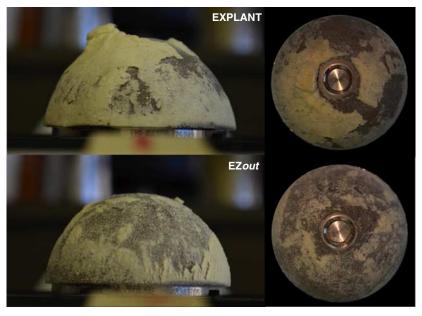


FIGURE 11. Foam residues on the cups after removal. Note the different amount of foam that remained attached to the cup for the Explant System and the EZout System.

preparing morselized graft material or use synthetic bone void fillers to address the bone loss.

The learning curve for the nonexperienced surgeon was also much shorter with the EZout System as shown by the close values of the recorded parameters between the experienced and nonexperienced surgeon (Table 1). This shorter learning curve may be advantageous for surgeons who perform hip revision arthroplasty less frequently.

Like any powered instrument, cutting bone of increasing density typically translates into longer duration of use and higher temperature. This in vitro model was intended to represent the maximum scenario of biological fixation and interface strength, and therefore, the worst case for time to implant removal and heat generation. The patient specific variations in bone density are easily addressed by this powered system whether bone quality and quantity are poor, or whether the interface bone is dense and sclerotic. There are, therefore, no contraindications to the use of this system based on bone density, and the EZout System is indicated for use in the removal of any hemispherical acetabular component that is well-fixed—independent of periacetabular bone quality.

CONCLUSION

The EZout Powered Acetabular Removal System is effective in achieving safe removal of a well-fixed acetabular component in an in vitro model of cementless fixation. This system should be considered as a reasonable alternative to manual removal techniques.

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