

USE OF THE SABER YANKAUER™ HANDHELD ILLUMINATOR IN ANTERIOR APPROACH TOTAL HIP ARTHROPLASTY SURGERY

A Survey of Leading Orthopedic Surgeons on the Benefits for Surgical Precision, Workflow Efficiency, & Patient Safety

Joel Matta, MD¹, John Masonis, MD², Anthony Carter, MD³, David Homesley, MD⁴, Tarun Bhargava, MD⁵, Cass K Nakasone, MD⁶, Hamid Redjal, MD⁷, Charles DeCook, MD⁸, Herrick Siegel, MD⁹, J. Dean Cole, MD¹⁰, Anthony Unger, MD¹¹

¹St. John's Medical Center, ²Carolina's Medical Center, ³Bon Secours Mary Immaculate Hospital, ⁴Novant Health Charlotte Orthopedic Hospital and Carolinas Medical Center-Mercy Main, ⁵University of Kansas School of Medicine-Wichita, ⁶Straub Clinic and Hospital, ⁷Spine and Orthopedic Center, Cottage Hospital, ⁸Northside Hospital, ⁹University of Alabama Birmingham, ¹⁰Florida Hospital Orlando, ¹¹Sibley Memorial Hospital

Abstract

BACKGROUND

Total hip arthroplasty (THA) is an established cost-effective treatment for arthritis of the hip joint. The anterior approach is becoming more popular among patients. The Saber Yankauer™ device (Invuity, San Francisco, CA) can be used to improve visualization during anterior approach THA. The study aim was to gain some initial survey data from leading surgeons on how the Saber Yankauer enables them to perform anterior approach THA more precisely, efficiently, and safely.

METHODS

A cross-sectional questionnaire survey was administered to 12 orthopedic surgeon thought-leaders performing a high volume of anterior approach THAs using the Saber Yankauer.

RESULTS

All 12 surgeons agreed that Saber Yankauer provides improved visualization of critical structures and anatomical landmarks during anterior approach THA. Eleven of 12 surgeons agreed that Saber Yankauer improves OR workflow and surgical efficiency. Eleven of 12 surgeons agreed that the Saber Yankauer improves the overall quality of patient care.

CONCLUSION

Saber Yankauer delivers volumetrically uniform, thermally cool, bright illumination inside the surgical cavity, thus enabling surgeons to better see what they are doing. By providing better visualization of critical anatomy, especially around the acetabulum, and potential bleeders, the Saber Yankauer improves surgical precision, workflow efficiency, and patient safety in anterior approach THA.

INTRODUCTION

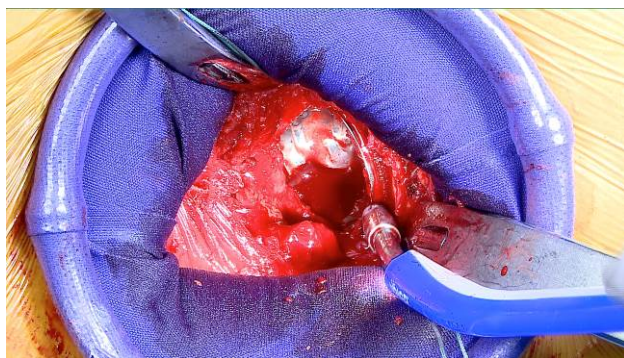
Arthritis of the hip joint is a painful and debilitating condition that affects many Americans as they age. Total hip arthroplasty (THA) is an established cost-effective treatment that enables most patients to resume their normal lives.[1,2] THA is most commonly performed through posterior or lateral approaches, but a few other approaches are also possible. The anterior approach to THA (hereafter referred to as anterior approach THA) has been steadily gaining interest in the past decade. By passing between the sartorius muscle and the tensor fascia latae, anterior approach THA is the only approach that utilizes a true intraneural and intramuscular plane, thereby minimizing damage to the muscles, compared to other approaches, and leading to faster patient recovery and return to normal activities.[2,3,4,5]

As with any new approach, anterior approach THA can be challenging to learn and perform. First, it is common during a surgeon's learning phase for anterior approach THA to observe an increase in

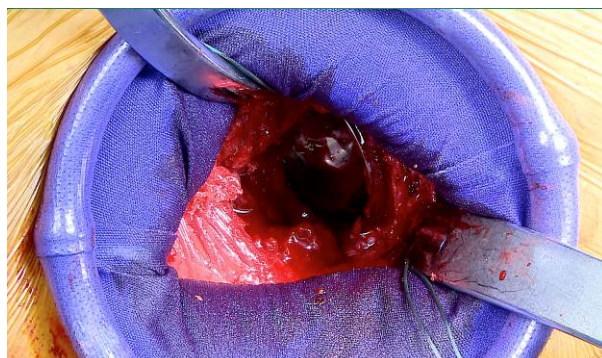
blood loss over their previous THA technique since identification and coagulation of bleeding points are initially unfamiliar to the learning surgeon. Second, small skin incisions (between 8-10cm) for anterior approach THA are routinely used by experienced surgeons, even for obese patients. Though there is no clear evidence that a small incision leads to a better recovery or outcome [6,7,8], there is an understandable desire by the patient for a small, cosmetic incision. Inevitably small skin incisions, particularly with obese or very muscular patients, challenge visualization. Therefore, as the incisions become smaller and deeper, there is a greater need to illuminate the surgical cavity from within so visualization is not impaired by incision size and depth. As such, intracavity visualization is crucial for maintaining hemostasis, anatomic precision and avoiding iatrogenic complications.

Invuity®, Inc (San Francisco, CA) is a medical technology company focused on pioneering the use of advanced photonics to illuminate the surgical cavity from within by providing optimal direct visualization, and thereby enabling enhanced precision, efficiency and safety. Invuity's patented Intelligent Photonics™ technology directs and shapes light into broad, uniform, volumetric, and thermally cool illumination throughout the entire surgical cavity.

The Saber Yankauer™ device (Invuity, Inc, San Francisco, CA) can be used to improve visualization during anterior approach THA. It is a unique handheld illuminator built on a Yankauer-style aspirator with integrated proprietary Intelligent Photonics that creates broad, uniform, volumetric, thermally cool illumination inside the surgical cavity. The Saber Yankauer uniformly and volumetrically lights up the entire surgical cavity, better than traditional overhead lighting, surgeon headlamps, or other basic, lighted instruments, thus enabling the surgeon to better see what he or she is doing during anterior approach THA (Figure 1). At the same time, the Saber Yankauer remains thermally cool, thus virtually eliminating the thermal hazard associated with traditional fiber optic lighting that may burn the patient's skin surface or tissues within the surgical cavity.[9]



Anterior Approach THA with Saber Yankauer



Anterior Approach THA without Saber Yankauer

Figure 1

The Saber Yankauer can be used in a variety of surgical approaches to THA to improve intracavity visualization. Since anterior approach THA is rapidly gaining in popularity, we wanted to better explore and quantify how the Saber Yankauer was helping surgeons with this procedure specifically. We chose to conduct a survey, because we wanted to understand surgeons' *experiences* with how the Saber Yankauer impacts the surgical procedure. The aim of the study was to gain some initial survey data from leading surgeons on how the Saber Yankauer enables them to perform anterior approach THA more precisely, efficiently, and safely.

METHODS

Development of the Survey

This study was designed as a cross-sectional (i.e. one-time) questionnaire survey. The questionnaire was developed by Invuity to explore the technical reasons surgeons use Saber Yankauer and its influence on workflow efficiency and patient safety. Its content was based both on the statements

Invuity heard informally from surgeon users and from a previous survey on the use of this device for breast surgery.

Data Collection and Analysis

The survey was administered either by telephone or WebEx by the study designers. Surveys were conducted between October 2014 and December 2015. Descriptive statistics were used to summarize the results. Missing data were very rare and are always reported here as such.

RESULTS

The Surgeons and Their Practices

Twelve surgeons completed the survey. All 12 surgeons are considered leaders in the field of total hip arthroplasty.

Eight of the 12 surgeons surveyed reported using the anterior approach for 100% of their total hip arthroplasty procedures, 3 surgeons used it for 90% or more, and 1 surgeon used it for 75% of procedures. Ten of the 12 surgeons reported performing over 200 cases of anterior approach THA per year. In response to the question, “Do you feel offering anterior hip arthroplasty provides you a competitive practice advantage?”, 11 of 12 surgeons replied “yes”.

The median time that the surgeons had been using the Saber Yankauer was 12 months, with a range of 3 to 20 months. Ten of 12 surgeons reported using Saber Yankauer for primary anterior approach THA, and 11 of 12 reported using it for revision anterior approach THA. None of these surgeons reported using headlights during anterior approach THA.

Technical Motivation for Use

Several survey questions explored the various reasons why surgeons adopted Saber Yankauer for anterior approach THA. Table 1 presents the challenges in performing anterior approach THA *without* using the Saber Yankauer.

Challenges of Anterior Approach THA <i>without</i> Saber Yankauer	Surgeons Agreeing
Locating and controlling bleeders or potential bleeders	11
Visualization of the acetabulum during exposure & preparation	10
Poor visualization	9
Increased surgical time	7
Appropriate seating of the acetabular shell and liner	6
Internal inspection of the femoral canal	5
Limited access through small incisions	3

Table 1: Number of surgeons who checked items on a list of responses to the question, “What are the biggest challenges in performing anterior hip arthroplasty without Saber Yankauer?”

Eleven of 12 surgeons agreed that Saber Yankauer overcomes the challenges they had cited.

To explore these challenges further, the survey first asked them to rate the importance of visualizing critical structures and anatomical landmarks during anterior approach THA, on a 5-point scale: 1 (not), 2 (slightly), 3 (somewhat), 4 (very), 5 (most). Ten surgeons replied “most”, 1 replied “very”, and 1 replied “somewhat”. All 12 surgeons agreed that Saber Yankauer provides improved visualization of critical structures and anatomical landmarks during anterior approach THA. The survey also asked the surgeons to “rate how much Saber Yankauer improves your visualization within the surgical cavity” on the same 5-point scale. Six surgeons responded “most”, 4 surgeons responded “very”, and 2 surgeons responded “somewhat”. The survey then asked them about the visualization of specific anatomic structures. First, it asked them to rate the level of difficulty in seeing release points and

visualizing the acetabulum during exposure, preparation, and seating of the liner within the acetabular shell. Five surgeons responded “most”, 2 surgeons responded “very”, 4 surgeons responded “somewhat”, and 1 surgeon responded “slightly”. All 12 surgeons agreed that Saber Yankauer increases their ability to see release points and visualize the acetabulum during exposure, preparation, and seating of the liner within the acetabular shell. Second, the survey asked the surgeons to rate the level of difficulty in visualizing, inspecting, and preparing the femoral canal. One surgeon responded “most”, 4 surgeons responded “very”, 4 surgeons responded “somewhat”, 2 surgeons responded “slightly”, and 1 responded “not”. Six of 12 surgeons agreed that Saber Yankauer increases their ability to visualize, inspect, and prepare the femoral canal, 4 surgeons disagreed, 1 surgeon was not sure, and 1 surgeon gave no answer.

The survey then asked the surgeons what benefits they felt the Saber Yankauer provides. Table 2 presents the reported benefits of using Saber Yankauer.

Benefits of using Saber Yankauer	Surgeons Agreeing
Improved visualization of critical anatomic structures	12
Improved visualization during preparation of the acetabulum	12
Improved surgical efficiency	11
Decreases surgical time	10
Decreases blood loss	10
Improves safety	10
Improved visualization during implant placement	9
Improves clinical outcomes	9
Improves visualization during preparation of the femoral canal	7

Table 2. Number of surgeons who checked items on a list of responses to the question, “What benefits do you feel that Saber Yankauer provides?”

Additionally, the survey asked the surgeons to rate the importance of intracavity illumination and visualization in improving training of residents and fellows on surgical approaches and techniques. Six surgeons replied “most”, 3 surgeons replied “very”, 2 surgeons replied “somewhat”, and 1 surgeon was missing data. Ten surgeons agreed that the intracavity illumination and visualization provided by Saber Yankauer improves the training of residents and fellows on surgical approaches and techniques, 1 surgeon was not sure, and 1 surgeon was missing data.

Workflow Efficiency

The survey also explored how much Saber Yankauer improves workflow efficiency during anterior approach THA. The survey first asked the surgeons to rate the importance of improving OR workflow (i.e. reduction in luminaire actions and adjustments), on a 5-point scale: 1 (not), 2 (slightly), 3 (somewhat), 4 (very), 5 (most). Six surgeons replied “most”, 3 replied “very”, and 3 replied “somewhat”. Eleven of 12 surgeons agreed that Saber Yankauer improves OR workflow.

Next, the survey asked the surgeons to rate the importance of increasing surgical efficiency (i.e. identifying tissue planes, critical structures, locating and controlling bleeders, etc.), again on the same 5-point scale. Eight surgeons replied “most”, 3 replied “very”, and 1 replied “somewhat”. Eleven of 12 surgeons agreed that Saber Yankauer increases surgical efficiency.

Then the survey asked the surgeons to rate the importance of reducing procedure time in the OR, using the same 5-point scale. Seven surgeons replied “most”, 3 replied “very”, and 2 replied “somewhat”. Ten of the 12 surgeons agreed that Saber Yankauer reduces procedure time for anterior approach THA. Finally, we asked the surgeons to estimate the average reduction of procedural time and blood loss for their anterior approach THAs with Saber Yankauer. The median estimated reduction of surgical time when using Saber Yankauer was 6.5 minutes, and the responses ranged from 0 to 20 minutes. The

median estimated reduction of blood loss when using Saber Yankauer was 75 mL, and the responses ranged from 50 to 200 mL, (with missing data for two surgeons).

Patient Safety

Last but not least, the survey addressed several aspects of patient safety. First, it asked the surgeons to rate the importance of minimizing the need to make adjustments to the overhead lights during anterior approach THA, in order to minimize the potential risk of contamination, on a 5-point scale: 1 (not), 2 (slightly), 3 (somewhat), 4 (very), 5 (most). Seven surgeons replied “most”, 3 surgeons replied “very”, and 2 surgeons replied “slightly”. Eleven of 12 surgeons agreed that Saber Yankauer minimizes the need to make adjustments to overhead lights, thereby minimizing a potential risk of contamination.

Next, the survey included two questions about traditional fiber optic lighted retractors for the 9 surgeons who had used them. The survey asked the surgeons to rate the importance of reducing thermal hazards associated with the use of fiber optic lighted retractors, using the same 5-point scale. Five of the 9 surgeons responded “most”, 1 responded “very”, 1 replied “somewhat”, 1 replied “not”, and 1 had missing data. Eight of the 9 surgeons agreed that the thermally cool illumination emitted from the Saber Yankauer prevents or reduces thermal hazards in the OR, and 1 surgeon disagreed.

Then the survey asked the surgeons to rate the importance of preventing unintended retained foreign objects (URFOs), using the same 5-point scale. Eight surgeons replied “most”, 2 replied “very”, 1 replied “not”, and 1 had missing data. The survey also asked if Saber Yankauer serves as an “assistive technology” (as recommended by the Joint Commission) to facilitate improved visual inspection of the surgical cavity during surgery and prior to closing to help prevent URFOs. Ten of the 12 surgeons responded “yes”; (one surgeon was not asked this question).

Finally, the survey posed the question: “Does Saber Yankauer improve overall quality of patient care?” Eleven surgeons replied “yes” and 1 replied “no”.

DISCUSSION

Total hip arthroplasty (THA) is an established, cost-effective treatment for arthritis of the hip joint. Demand for the procedure will continue increasing as the population ages. One well-conducted forecast modeling study estimated that the demand for primary THAs will grow by 174% [from 2005 levels] to 572,000 cases annually by 2030.[10] It is estimated that anterior approach THAs comprise 25% of the THA market today, and this percentage is expected to grow. Several literature reviews have concluded that there is no difference in the long-term patient outcomes and safety between posterior, lateral, and anterior approaches, and these literature reviews have recommended that the surgeon should just use whichever approach he or she feels most comfortable with.[1,2] However, a preponderance of evidence does suggest that anterior approach THA leads to earlier hospital discharge, faster patient recovery and return to activities, and perhaps lower rates of revision surgery.[1,2] Anterior approach THA avoids muscles dissection, and only such avoidance of muscle dissection makes a difference in how quickly the patient recovers from the operation,[2,4,6] (while the length of the incision itself remains virtually irrelevant [7,8]). Moreover, patients perceive anterior approach THA as having these advantages. Thus, for example, a small but interesting qualitative study from California showed that patients often decide to have anterior approach THA (*before* they even start looking for a surgeon to do the operation), because they want to have a faster recovery, often because they cannot afford to take six months off from work.[11] “Participants acknowledge that their choice of surgeon, type of procedure and implants were largely based on their desire to choose a technique that minimized disruption to their muscles and led to a quick recovery.”[11] Indeed, that survey seemed to even suggest that many patients only decided to have THA at all, because anterior approach THA promised to get them back to work quickly. Both the fact that the patient alone is choosing which surgical approach to use (without asking the doctor's opinion), and also the reasoning they use to choose anterior approach THA (faster recovery = most important consideration) are emerging healthcare trends that will only continue growing in the

coming years. Thus altogether, it can be anticipated that there will be a growing demand for THAs for the next few decades as the population ages, and that an ever-increasing portion of all THA patients will seek out surgeons who can perform their procedure from an anterior approach. So, the question naturally arises, “Who is going to meet this rising healthcare demand for anterior approach THAs?”

As with any new approach, anterior approach THA can be a challenging procedure to learn and perform since identification and coagulation of bleeding points are initially unfamiliar to the learning surgeon, and since growing patient demand for small incisions presents visualization challenges especially in obese or very muscular patients. One key aspect of successful anterior approach THAs is good visualization, which in turn depends on high quality intracavity illumination, as it is difficult to perform anterior approach THA if the lighting is too poor to see critical anatomic structures. The Saber Yankauer is a unique handheld illuminator built on a Yankauer-style aspirator that has the advantage of proprietary Intelligent Photonics that creates broad, uniform, volumetric and thermally cool illumination inside the surgical cavity.

Before we discuss the actual results of this survey, we should briefly consider its methodological strengths and limitations. First and foremost, we must consider that the surgeons participating in this survey were all experienced, leading practitioners of anterior approach THA, which is both a strength and limitation of this survey. On the one hand, as leaders in the field of anterior approach THA, these surgeons may not be representative of all surgeons performing this procedure, and their survey responses may not always be generalizable to other surgeons. On the other hand, these surgeons can be viewed as “experts” for the “best practices” in anterior approach THA, so their responses may actually be more valuable than a survey sampled randomly from all THA surgeons. Second, all of the surgeons included in the survey were dedicated ongoing users of the Saber Yankauer device, and this may have skewed the results in a positive direction. However, since these surgeons are “experts” for the “best practices” in anterior approach THA, their responses should be applicable to any surgeon considering this technology for their THAs. Third, the sample size (n=12) is admittedly small, but it is still sufficient to gain an understanding of the topics addressed here, as it is unlikely the results would be much different with twice as many respondents. Fourth, an uncommon strength of this study is that it is perfectly transparent for any curious reader to see how the questions were formulated for data collection. Fifth, there was virtually complete data collection from all respondents (i.e. virtually no missing data), which helps ensure the reliability of the results. Sixth, one final limitation of the study is that the results on OR time, blood loss, and patient safety are not based on objective clinical data, but instead are only the surgeon’s subjective impression. However, each surgeon’s estimations of OR time and blood loss are based on their familiarity with the objective operating records, so their estimates are probably not far off the mark. Patient safety by contrast would require large patient registries (with thousands of cases) to obtain reliable objective data, which is obviously beyond the scope of this endeavor. Such research should be conducted by the manufacturers of the hip implants as part of their FDA post-marketing surveillance.

The present survey covered three topics: surgical precision, workplace efficiency, and patient safety. Saber Yankauer delivers broad, uniform, volumetric, thermally cool, bright illumination inside the surgical cavity, thus enabling surgeons with direct visualization of the surgical target. All 12 surgeons agreed that Saber Yankauer provides improved visualization of critical structures and anatomic landmarks during anterior approach THA, and all 12 surgeons agreed this is one of the benefits of using Saber Yankauer. All 12 surgeons also agreed that improved visualization during preparation of the acetabulum is one of the benefits of using Saber Yankauer. Ten of 12 surgeons agreed that visualization of the acetabulum during exposure and preparation is challenging without Saber Yankauer, and all of these 10 surgeons agreed that Saber Yankauer overcomes this challenge. Nine of 12 surgeons also agreed that improved visualization during implant placement is one of the benefits of using Saber Yankauer. Thus, Saber Yankauer improves the ease and precision of anterior approach THA by improving a surgeon's visualization.

This improved visualization and surgical precision leads to increased workplace efficiency. First, 11 of 12 surgeons agreed that improved surgical efficiency is a benefit of Saber Yankauer, and all 12 surgeons agreed that Saber Yankauer improves OR workflow. Second, 11 of 12 surgeons agreed that

locating and controlling bleeders is challenging without Saber Yankauer, and Saber Yankauer overcomes this challenge. Third, 10 of 12 surgeons agreed that Saber Yankauer reduces procedure time for anterior approach THA, and 10 of 12 surgeons felt that decreased surgical time was one of the benefits of using Saber Yankauer. The median estimated reduction of surgical time was 6.5 minutes. (This may not sound like much time, but the costs of surgery and the patient risk of infection rise with every minute of additional surgery time.) Ten of 12 surgeons also felt that decreased blood loss was one of the benefits of using Saber Yankauer. The median estimated reduction of blood loss was 75mL. These improvements to workplace efficiency in the OR trim the costs of the surgery and contribute subtly to better patient safety.

The improved visualization provided by Saber Yankauer should lead to better patient safety. Ten of 12 surgeons felt that improved safety was one of the benefits of using Saber Yankauer. Eleven of 12 surgeons agreed that Saber Yankauer minimizes the need to make adjustments to overhead lights, thereby minimizing risk of contamination. Although the risk of patient infections during surgery is generally low, it does happen, with potentially substantial impact on the patient's health and costs to the healthcare system. Insurance companies are actively fighting to lower surgical infection rates, so any measures that the OR team can take to lower infection risks are worth the effort. Additionally, 10 of 11 surgeons asked agreed that Saber Yankauer serves as an “assistive technology” (as recommended by the Joint Commission) to facilitate improved visual inspection of the surgical cavity during surgery and prior to closing, to help prevent unintended retained foreign objects (URFOs). URFOs are even far more rare than infections, but again, they do occur. Since URFOs are a highly embarrassing and dangerous liability that normally requires a return to the OR, it is prudent for surgical teams to take any possible measure to avoid such an event. The Joint Commission recently recognized Invuity’s proprietary photonics technology for improved patient safety by stating, “Another newer technology to consider is proprietary photonics technology [Invuity, Inc.]. This provides thermally cool intracavity illumination, which greatly improves visualization of the surgical cavity and allows a thorough visual inspection both during surgery and before closing.”[13]

The results of this survey suggest several ways in which the Saber Yankauer presumably enables hospitals to reduce their own costs and the costs to the healthcare system. First, the surgeons surveyed gave a median estimate that the Saber Yankauer reduces surgical time by 6.5 minutes. This would reduce both billable charges such as anesthesia time as well as costs borne by the hospital, such as staff and power.

Second, since none of the surgeons surveyed reported using headlights, Saber Yankauer can be assumed to decrease a surgeon’s dependence on their headlight if not eliminate the headlight (and thus the small capital expense) all together. Yet more important potential savings come about through avoidance of rare but very costly preventable errors and Never Events, such as infections, or reoperations.[12]

Third, by reducing the operating time by about 6.5 minutes and by eliminating the need to readjust overhead lighting and headlights, Saber Yankauer reduces the risk of infections, the treatment of which can be quite costly to the patient and healthcare system, and reflect poorly on a hospital.

Fourth, 10 of 11 surgeons asked agreed that Saber Yankauer serves as an assistive technology to reduce the risk of URFOs. URFOs are a very rare complication, but are also quite costly (necessitating reoperation) and are particularly damaging to a hospital’s reputation when they do occur.

Fifth, all 12 surgeons agreed that Saber Yankauer provides improved visualization of critical structures and anatomical landmarks during anterior approach THA. Although our survey did not explore this further, it can be assumed that this improved visualization leads to a lower chance of complications or revision surgery, especially if the surgeons is still coming up the learning curve.

In sum, the costs of complications arising from THA are potentially very high, so any measure that surgeons and hospitals can take to reduce such risks is prudent and worth the investment.

In conclusion, total hip arthroplasty is an established and cost-effective procedure for treatment of hip arthritis. The demand for anterior approach THA is projected to continue growing as the population ages and patient demand for this approach increases.[10] Therefore, surgeons and hospitals that offer anterior approach THA have higher surgical volumes. This is why the 11 surgeons who answered this

survey question (one surgeon left this question blank) stated that offering anterior approach THA creates a competitive advantage for their practice. Ten of the 12 surgeons agreed that the intracavity illumination and visualization provided by Saber Yankauer improves the training of residents and fellows on surgical approaches and techniques, and may expedite the potential learning curve. Finally, 11 of 12 surgeons agreed that the Saber Yankauer improves the overall quality of patient care. By providing better intracavity illumination and visualization, Saber Yankauer improves surgical precision, workflow efficiency, and patient safety in anterior approach THA.

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