ClipVac™ presurgical hair removal system

Value analysis committee request

This dossier provides Value Analysis Committee members the background and rationale for the trial and/or acquisition of the ClipVac™ system.
Executive summary

- Presurgical hair clipping is a common practice when hair interferes with the procedural field.\textsuperscript{1,2}

- Hair and airborne particles left behind from surgical clipping on the patient, linens and floor can contaminate the surgical environment, and the use of adhesive tape in the clean-up process may increase the risk of patient complications:
  - Clipped hair can carry microbial contamination leading to possible infection.\textsuperscript{3,4,8,10}
  - Adhesive tapes can damage skin, creating a portal for infection.\textsuperscript{16,17}
  - Patients can experience allergic reactions to tape adhesive.\textsuperscript{17}
  - The reuse of tape rolls is a cross-contamination risk.\textsuperscript{13-15}

- Surgical hair clean up using adhesive tape is time-consuming.\textsuperscript{7}

- The ClipVac system is a portable vacuum-assisted, hair-collection device that attaches exclusively to the market-leading surgical clippers distributed by Becton Dickinson (BD).

- The ClipVac system uses a disposable filter that captures an average 98.5\% of hair and airborne contaminants generated in the clipping process, down to 0.3 μm.\textsuperscript{7}

- This technology eliminates the cleanup process; saving time and avoiding the risks associated with adhesive tapes.\textsuperscript{7}
Introduction

Hair removal is commonly performed in preparation for surgery, and according to the Association of periOperative Registered Nurses (AORN) and Centers for Disease Control (CDC), it should be performed when hair interferes with the procedural field.\(^1\)\(^2\) Because surgical site hair (SSH) may contain pathogenic microorganisms such as *Staphylococcus aureus* and group A *Streptococcus*, \(^3\)\(^4\) its removal is also perceived as a critical step in a broader effort to reduce sources of contamination in the surgical field.

While advancements in perioperative hair removal have been made over the years, including the shift from razors to electric clippers and timing the removal of hair to as close proximity to surgery as possible, surgical clipping still has significant drawbacks. Most notable among these drawbacks are the dispersal of hair and particulate matter during clipping and the subsequent need to clean up the hair following clipping. Traditional methods for hair cleanup (i.e., adhesive tapes and sticky mitts) do not address dispersal during the clipping process and are largely ineffective and inefficient.\(^5\)\(^6\) It is not uncommon to observe loose hair being brushed from the patient or bed before the patient is prepped and draped.

Recently published research demonstrates the efficacy of surgical clippers fitted with the innovative, vacuum-assisted, hair-collection device ClipVac, thus reducing operative field contamination and eliminating the need for cleanup with adhesive tapes or sticky mitts.\(^7\)

The problem of surgical-clipping cleanup

Hair as a contaminant

Since the 1960s, research has demonstrated the pathogenic risk of hair. In their 1965 study, Summers et al isolated bacteria from hair in 72% of outpatients, 61% of inpatients, and 46% of medical and nursing staff in a general hospital, with *S aureus* the most common pathogen found (37%, 40.3%, and 27.4%, respectively).\(^8\) Other pathogens detected in significant numbers in hair were *Escherichia coli* and *Streptococcus viridans*, although *Proteus vulgaris*, *Pseudomonas*, and *B-haemolytic streptococci* were also identified.\(^8\) In another study, Noble found *S aureus* in the hair of people who had no hospital contact (10%) and on about 50% of patients with skin diseases.\(^9\)

More concerning is that postsurgical infection outbreaks have occasionally been traced to organisms isolated from the hair or scalp.\(^10\) Dineen and Drusin, for example, reported two outbreaks of surgical wound infections attributed to a surgeon with *S aureus* in his hair and a transplant ward nurse who had persistent Staphylococcal scalp lesions and *S aureus* in her hair.\(^3\) Similar results were reported by Mastro et al, who traced a prolonged outbreak of *Streptococcus pyogenes* at the surgical site to an operating room (OR) technician with chronic scalp lesions.\(^4\)

These findings underscore the role of hair as a potential contaminant, emphasizing the need for hair coverings by staff, surgical-clipping dispersion control, and effective cleanup (or avoidance) of patients’ surgical clippings.

Location of surgical hair-clipping dispersion

Because hair can be a source of microbial contamination, the location of perioperative hair removal has been a concern of operating room nurses and other healthcare professionals.\(^7\) In addition to clipped hair left behind on the patient, airborne dispersion of hair and particles can be found more than a foot away from the surgical site on linens and floors.\(^7\) This potential contamination of the surgical field, as well as a lengthy cleanup process, prompted AORN and the CDC to recommend that hair removal be performed outside of the OR.\(^1\)\(^2\) However, recent studies and observational data indicate that despite a serious infection risk, clipping is done inside operating rooms with great frequency.\(^5\)\(^11\) For example, data collected from 250 surgical personnel with at least two years of SSH removal experience revealed that patients are clipped 60% of the time within the OR.\(^5\) The top three reasons cited were surgeon/physician preference, patient safety/privacy, and insufficient clipping outside the OR (area or cleanliness).\(^5\) Similar results were found in another survey of surgical personnel who personally clip: 57% who work in inpatient settings and 44% in outpatient settings reported that they perform this task in the OR, primarily because of a lack of resources/understaffing, the substandard quality of clipping outside the OR and/or a preference to do clipping under anesthesia.\(^11\)
If surgical hair clipping is to be done inside the OR, as is a common practice according to these survey results, then a system must be in place to contain hair dispersion.

**Traditional cleanup methods: Problems with adhesive tape and sticky mitts**

Adhesive tape is used for a variety of reasons in healthcare facilities, including the cleanup of surgical hair clippings. Despite being readily available and easy to use, much research demonstrates that it has serious limitations.

**Limited effectiveness**

In the survey of AORN members, respondents indicated that removing the clipped, loose hair completely from patients and surgical tables was as important as the control and limit of OR traffic. Yet these surgical professionals estimated that, on average, only 71% of hair is collected using tape.

**Rolls of adhesive tape are a cross-contamination risk**

Redelmeier and Livesley describe adhesive tape as a unique piece of medical equipment because it is almost never washed or sterilized after initial opening of the package; furthermore, a roll is typically managed by multiple healthcare personnel using ungloved hands while treating several patients. In their study, they found that 74% of tape specimens collected in one hospital were colonized by pathogenic bacteria, most commonly coagulase-negative staphylococci. First and second specimens from each roll yielded similar results (identical in 90% of pairs), and the colonies were too numerous to count in 24 of 59 specimens.

These results corroborate findings from a recent survey in which 70% of nurses reported that they sometimes or always notice the contamination of the tape roll left in the drawer.

**Adhesives can damage the skin, creating a portal for infection**

Skin injury related to medical adhesive tape usage is a prevalent yet under-recognized complication that occurs across all care settings and age groups. Adhesives can cause tissue trauma, compromised skin barrier function, skin tears, and allergic contact dermatitis, as well as deeper tissue injuries. Edmiston et al found that complete removal of clipped hair with adhesive tape often required multiple passes, which altered skin barrier function. Similarly, surveyed AORN members reported that 28% of the time they sometimes, often, or always notice skin irritation, redness, scratches, or minor cuts in the OR when tape or sticky gloves are used.

**Surgical site hair cleanup is an extra step that takes time**

AORN members reported that, on average, the amount of time it takes to clean up clipped hair is 4.1 minutes per case. This figure does not include time associated with changing of bed sheets, which is frequently done following hair clipping. If clipping is performed in the OR, procedures must wait until the patient and surgical area are properly prepared. A 2005 study of 100 U.S. hospitals found that OR charges can go as high as $133 per minute. Over time, the cumulative cost is considerable.

Costs are also impacted when a 10-yard roll of tape that was previously shared between two or three patients is now designated to one patient and discarded after a single use. One study demonstrated that during a two-week observation period, average tape usage was only one yard of a 10-yard roll. Projecting this usage to the hospital’s annual activity would result in wastage of 11,310 rolls or 73 miles of tape. These data suggest that designating...
adhesive tape rolls as *single-use* to reduce cross-contamination risk is not a cost-effective solution, nor does it eliminate the time associated with hair cleanup, changing of bed sheets, or potential damage to the skin.

**The ClipVac presurgical hair removal system**

Use of standard surgical clippers (SSCs) is high (98%); however, what has been lacking is an efficient and effective hair cleanup system. AORN-recommended practices suggest that body hair should be removed when it may interfere with surgery and that hair removal should limit particle dispersion.19

A technology that meets this requirement and eliminates the hair cleanup process is now available—the ClipVac presurgical hair-removal clipping system. The ClipVac system is a portable vacuum-assisted, hair-collection device (SCVAD) that attaches exclusively to the market-leading surgical clippers distributed by BD. It is designed to improve the safety and efficiency of presurgical hair-removal practices. Its vacuum technology uses a single-use, surgery-grade filter that captures an average 98.5% of hair and airborne contaminants generated in the clipping process, down to 0.3 μm.

*This technology saves valuable time by eliminating the entire secondary step of cleanup and the need for adhesive-based cleanup products that can be bacteria-laden, damage skin layers, and potentially cause adverse reactions.*

Figure 4: Rechargeable lithium ion battery

The system is comprised of a lightweight, portable vacuum unit powered by a rechargeable lithium ion battery. The battery, when fully charged, provides approximately 75 minutes of continuous power. A fully discharged battery recharges in less than 4.5 hours.

The vacuum unit connects to a suction port fitted on the clipper by way of a surgery-grade disposable filter. After each use, the self-contained filter, suction port, and flexible hose are discarded of or recycled, significantly minimizing the risk of cross-contamination.

**Supporting data**

A pilot analysis was conducted to quantify the reduction in hair dispersal using the ClipVac system and microbial contamination in hair left behind by a standard clipper. With standard clippers, residual hair was collected using adhesive tape or a sticky glove. Results showed a significant reduction (*P<.001*) in microbial recovery and hair-particle dispersion following use of the ClipVac system; most impressive was that 98.5% of hair was captured with the ClipVac system.20

Building on these findings, Edmiston et al investigated key outcomes for standard surgical clippers and adhesive tape vs the ClipVac system: total time required to clip and clean up residual hair; quantity of hair dispersion and associated microbial burdens; and degree of skin abrasion/irritation. Additionally, nurses and study subjects were asked their opinions on efficacy and comfort associated with the use of SSC or SCVAD.7

Results revealed that the use of SSC required a significantly (*P<.001*) longer time for clipping and clean up of hair from chest and groin sites than the ClipVac system—SSC: average 5.3 minutes for chest, 4.2 minutes for groin, with a maximum of 8.5 minutes; the ClipVac system: average 3.2 minutes for chest, 2.7 minutes for groin, with a maximum of 4.9 minutes.7

The vacuum unit connects to a suction port fitted on the clipper by way of a surgery-grade disposable filter. After each use, the self-contained filter, suction port, and flexible hose are discarded of or recycled, significantly minimizing the risk of cross-contamination.
Supporting data (cont’d)

Significant reduction in total clipping and cleanup time with the ClipVac system

Recovered hair particulates and microbial contamination were significantly ($P < 0.003$) lower with the ClipVac system than with the SSC.  

![Time Savings Graphs](image)

Using the ClipVac system while clipping the chest resulted in 60% mean time savings vs tape cleanup.

Using the ClipVac system while clipping the groin resulted in 36% mean time savings vs tape cleanup.

Significant reduction of microbial-contaminated hair with the ClipVac system

Degree of skin irritation was also assessed. The use of SSC and subsequent hair removal with adhesive tape produced a significantly ($P < 0.001$) higher measured change in transepidermal water loss (TEWL) at chest sites compared to the the ClipVac system, suggesting structural changes occurred that compromised skin barrier function.  

![Microbial Contamination Graphs](image)

Using the ClipVac system while clipping the chest resulted in 85% mean reduction in microbial-contaminated hair vs tape cleanup.

Using the ClipVac system while clipping the groin resulted in 100% mean reduction in microbial-contaminated hair vs tape cleanup.

Study nurses reported that compared to SSC, the benefits of using the ClipVac system included an increase in speed of clipping and a significant increase in cleanliness following the clipping process; moreover, study subjects indicated that they experienced little-to-no discomfort during the clipping process.

BD surgical clippers and the ClipVac system

Working together to provide a complete presurgical hair-removal system, BD surgical clippers and the ClipVac system save valuable patient-prep time and may help reduce the risk of complications for patients (microbial contamination on hair left behind potentially leading to infection; skin damage, allergic reactions and cross-contamination risk associated with adhesive tape clean-up).  

3, 8, 10, 13-17
The ClipVac system features and benefits

- ClipVac captures an average 98.5 % of hair and airborne contaminants at the source, eliminating the need for cleanup with adhesive tape or mitts and minimizing the risk of associated complications for patients.
- The suction port is designed to promote proper clipping techniques and conveniently attaches to your existing BD surgical clippers.
- The surgery-grade disposable filter captures clipped hair and debris down to 0.3 μm.
- Weighing less than two pounds, the vacuum is easily portable and maneuverable
- The rechargeable battery maintains a constant 16,000 RPM throughout the 75 minutes of continuous run time and can be fully charged in four hours.
- The tubing and suction port are completely recyclable, and the filter can be placed in general waste after use.

Appropriate use of the ClipVac system

The ClipVac system does not need to be used on every patient or during every procedure—its purpose is to assist in prepping those procedures where hair may interfere with the surgical field. These surgeries typically include cardiothoracic, major orthopedic, obstetric, gynecologic, and neurological procedures.

Cost

The ClipVac portable vacuum unit and battery are provided to hospitals and ambulatory surgery centers (ASCs) at no capital cost, provided a minimum of 80 disposables [tubing, suction port, and filter cartridge (SKU# 5575)] is purchased annually for every vacuum unit provided.

The acquisition price for each disposable is driven by volume use and group-purchasing organization (GPO) agreement, but range from $8–9. Specific details should be discussed with an institution’s BD surgical representative.

Budget impact

It’s up to the hospital or ASC to consider the budget impact. With OR charges calculated as high as $133 per minute, acquisition costs of the ClipVac disposables may likely be offset by the reduction in staff time otherwise required to clean up surgical clippings, as well as possible reductions in linen changing time and laundry costs. Direct costs eliminated include rolls of adhesive tape and sticky gloves used in the cleanup process.

Finally, the financial impact of a patient complication was demonstrated in a study by de Lissovoy et al who showed, on average, HAI extended length of stay by 9.7 days while increasing cost by $20,842 per admission. So in practice, avoiding a single patient complication like this would more than counterbalance the incremental cost of ClipVac disposables.

Summary

The ClipVac system solves the unmet need for more efficient and effective surgical clipping cleanup. In addition to improving efficiency (i.e., less time devoted to cleaning the patient and surgical environment, thus achieving quicker turnover in the OR space), the ClipVac system encourages a consistent infection-prevention standardization strategy.
References