Archives of Health Science
Research Article

A Novel Wound and Soft Tissue Flap Negative Pressure Drain System - a Pilot Study

Steven D. Jones Jr MD*[1], Parker J. Prusick MD[1], Bennie G. Lindeque MD PhD[1]

[1]Department of Orthopedic Surgery, University of Colorado Denver, 12631 E 17th Ave, Aurora, CO 80045, USA

***Corresponding Author**: Steven D. Jones Jr MD, Department of Orthopedic Surgery, University of Colorado Denver, 12631 E 17th Ave, Aurora, CO 80045, USA

Abstract

Background: Negative-pressure wound-therapy (NPWT) has become a mainstay of treatment for high-risk surgical wounds. In closed wounds, traditional NPWT utilizes surface level sponges alone to provide negative pressure. A technique that allows for deep dead-space management, while maintaining superficial negative pressure over a closed wound, may prove beneficial inhigh-risk patients.

Purpose: A novel technique and prospective case series are described which incorporate deep hemovac drain tubings into a traditional NPWT device (Deep Inside-Out Vac; DIOV). Pilot data is needed to begin evaluating the efficacy of this technique.

Methods: Fourteen patients were stratified by initial indication for DIOV placement. Group 1 patients underwent wide tumor resection, while Group 2 patients underwent extensive debridement for infection. Demographic, surgical, and microbiological data were recorded.

Results: Eight patients were identified in Group 1. Six were identified in Group 2. Both demonstrated 50% positive culture rates at time of drain removal. Most common organisms were coagulase negative staphylococcus species. At final follow-up, all wounds were clinically healed.

Conclusions: NPWT is an established augment in post-operative wound care. The DIOV may provide added benefit in wounds at high-risk for dead-space related complications. Contamination remains unfavorable, and further research is needed to determine this device's efficacy.

Level of Evidence: Level IV

Introduction

Background

Negative-pressure wound-therapy (NPWT) has become a mainstay of treatment for complex and high-risk surgical wounds over the last three decades. Orthopedic and General Surgical subspecialties alike have utilized these systems to improve wound healing and decrease morbidity in select patients. A recent 2020 Cochrane meta-analysis of over 40 randomized controlled trials (RCTs) demonstrated with moderate-certainty evidence that NPWT results in fewer surgical site infections compared to treatment with standard surgical dressings (8.8% vs 13.0% in the standard dressing group; relative risk 0.66) [18]. Surgical site infections are a common complication and are known to increase patient morbidity and substantially increase health care related costs. A 2009 systematic review found that surgical site infections often double healthcare costs, primarily due to increased lengths of stay [4]. Techniques to reduce these complications have been studied extensively and numerous modalities have been explored over recent years.

Traditional NPWT was first utilized in the early to mid-1990s. The first indications for these devices included open fractures and chronic, high-risk, lower extremity wounds [9, 2]. As techniques and technology have advanced, NPWT has become a safe and established method for improving surgical site related outcomes in select patients [1, 14, 15]. The cost effectiveness of NPWT remains controversial, though many studies have found it to be cost-neutral, if not cost saving, in a majority of applications [12, 16, 28]. NPWT has become a fundamental component of high-risk surgical wound management at numerous academic institutions.

Rationale

In orthopedic oncology, dead-space management is a critical component of success for wound healing. Wide-resections for tumor removal often create soft tissue cavities that are prone to seroma and hematoma formation. This concept also rings true in infectious cases requiring extensive debridement. Significant tissue loss for any reason(whether surgical, infectious, or traumatic) can create a negative pressure void prone to adverse fluid accumulation.

Literature dating back to the 1940s established that dead-space management is a crucial component of post-operative wound success [21]. Post-operative seroma and/or hematoma formation can place unyielding pressure on overlying tissues and may increase the risk of wound dehiscence [19]. NPWT has been proven to be beneficial for dead-space management in both human and animal models [23, 24]. For superficial tissues, incisional NPWT devices alone are often adequate to prevent post-operative, fluid-related complications. However, in deeper areas of dead-space (particularly in the thigh, groin, or in morbidly obese patients), superficial NPWT alone may not be sufficient to mitigate the risks associated with deep space fluid accumulation. A technique that allows for deep dead-space management, whilst simultaneously maintaining negative pressure over a closed wound, may provide added benefit in select patients at high-risk for dead-space related complications.

In this case series, we describe a novel technique for incorporating deep drain hemovac tubing into traditional NPWT over a closed surgical wound. The construct was termed the Deep Inside-Out Vac (DIOV) and was designed to further the depth of dead-space management while preserving the benefits of negative pressure over a closed wound. Pilot data from culture results at time of DIOV removal was assessed to determine if this technique maintains the device as a closed, aseptic, sealed system.

Methods

Approval from the University of Colorado School of Medicine Institutional Review Board was obtained for this prospective case series. The cases and subsequent microbiological analyses were conducted at a single institution. All surgical procedures were performed by a single, board-certified, fellowship-trained orthopedic oncologic surgeon (author BL). This author also serves as a bone sepsis and musculoskeletal infection specialist at the manuscript's host institution.

Device Components and Terminology

The NPWT system used included a V.A.C.™ device (Vacuum Assisted Closure; K.C.I. Licensing, Inc., San Antonio, TX) with black polyurethane ether sponges. The hemovac tubing was taken from standard 1/4th inch DAVOL drum-style drains (Medivida Corp. International, Causeway Bay, HK), which were packaged and opened sterilely at time of placement. The term "hemovac," when used in this manuscript represents any blub- or drum-style closed suction drain that relies on stored potential energy to maintain negative pressure across its system. While there is colloquial use of this term, it should be known that the term HEMOVAC® is a registered trademark of Zimmer Biomet Holdings, Inc. (Warsaw, IN), and would represent one specific brand of "hemovac" drain device. The preliminary design for the DIOV comes from Christopher J. Kleck MD at the University of Colorado School of Medicine. The device's initial use was for complex wound management following spinal surgery.

Patients and Indications

Fourteen patients were identified and prospectively enrolled in this pilot analysis. Patients were included if they

received a DIOV drainage system following an orthopedic oncologic or infectious debridement procedure. Patients were stratified into two groups based on their procedure at time of DIOV placement: primary oncologic patients were placed in Group 1, while infection debridement patients were placed in Group 2. While Group 2 patients were known to have some form of initial infection, all underwent serial debridements, and data gathered was from the DIOVs placed at time of final debridement. This presumes aseptic DIOV placement even in Group 2,as final debridement was determined after consecutive cultures were pan-negative, wounds were free of necrotic/ nonviable/ purulent material, and inflammatory markers (i.e. c-reactive protein, white blood cell count) were normalized or near normal. The determination of final debridement was made by a single-surgeon (BL) in all cases.

Data Collected

Demographic data obtained included patient age, gender, and body mass index (BMI). Clinical data obtained included diagnosis, procedure performed, estimated blood loss, and presence of acute post-operative complication (defined as within 6 weeks post-operative). Follow-up in this pilot series was limited to 3 months, as the immediate post-operative course is most critical for the DIOV system. Moderate -term to long-term follow-up will be included in future analyses, but was deemed unnecessary for this pilot description.

The length of time (days) with the DIOV system in place was recorded and considered the duration of therapy. The decision to remove a DIOV was made by a single surgeon (BL) during early-acute (within 7 days) post-operative wound inspections. Wounds that demonstrated complete epithelialization, minimal tenderness, and scant drainage were eligible for DIOV removal. Little to no wound care was needed after removal, as wounds were typically dry and amenable to open air exposure. DIOV output (mL) was also recorded, but was limited to inpatient data, as outpatient recordings were patient dependent and widely incomplete. Output data was therefore excluded from the analysis.

Microbiological data included pre-DIOV culture results (for Group 2 only) and post-DIOV culture results for both groups at time removal. Specimen fluid was obtained from the deep portions of hemovac tubing at time of removal via flush injection of 3cc of sterile saline. Care was taken to ensure sterile techniques were used while specimens were gathered to minimize iatrogenic contamination. Aerobic, anaerobic, mycobacterial, and fungal agars were used in the microbiologic analyses. Microbiologic analyses were performed at a single institution (University of Colorado Hospital - Anschutz Medical Campus) with all cultures being held for at least 14 days.

Regarding antibiotic use, all patients in Group 1 received pre-incisional antibiotics per the standard orthopaedic guidelines (typically a 1st generation cephalosporin or lincomycin/ amino glycoside administered within 1 hour of incision). Group 2 patients expectedly received a variety of antibiotic therapies. Details on antibiotic therapy were not included, as all therapies were felt to be similarly effective given the empiric-to-narrow therapeutic model used at the host institution.

Statistical Analysis

This series consists of prospective pilot data from a small sample size of patients at a single institution. There were no control groups. Extensive statistical analyses were thus deferred, as the utility was felt to be low. Simple two-tailed t-tests were performed amongst the groups to evaluate for statistical significance using a p value of <0.05. However, the inherent statistical limitations in this series are implicit, and all conclusions should be drawn as preliminary given the presence of confounders.

DIOV Technique

The DIOV drainage system was applied sterilely at the conclusion of all operations. The following steps describe the preparation and placement of the drain system:

1) After adequate hemostasis and preparation of the wound bed, two quarter-inch hemovac drain tubes are cut to a length approximately twice the length of the wound.

2) A synovial rongeur is used to create additional holes in the tubing sections that do not already contain fenestration.

3) The hemovac tubings are then percutaneously placed through the skin approximately 4-5cm from the most inferior aspect of the wound using the accompanying harpoon (the inferior aspect of the wound is typically chosen to mitigate the effects of gravity, but other sites may be more favorable in certain scenarios).

4) Approximately half of the length of tubing should then be placed at the maximal depth of the wound, with care to not wrap or tether the tubes to deep structures (tubes must remain free to allow for eventual removal).

5) The other half of the tubing is left outside of the skin during closure.

6) Once the tubings are at the desired depth, the wound can then be closed in a standard, layered fashion, with care not to capture the tubing with suture passes.

7) Once the wound is fully closed, there should be an approximate incision-length amount of tubing extending from the percutaneous hole at the inferior aspect of the incision.

8) Slightly withdraw and advance the tubing at this time to ensure it is mobile and not tethered in the closing suture. A few centimeters of smooth excursion is all that is needed to confirm mobility.

9) The skin should now be thoroughly cleansed and dried to allow for eventual sponge and adhesive drape placement (the authors prefer to use benzoin spray around the incision to improve adhesive properties). The adhesive drapes may be cut into strips for easier placement.

10) Two black polyurethane sponges should then be cut to the length of the incision at a width of 3-4cm and depth of 2-3cm.

11) One of the black sponges should then be incised longitudinally approximately 75% in depth to make a canal for the drain tubings to rest (Figure 1).

Figure 1: Preparation of the black polyurethane ether sponge with a longitudinal canal.

12) Because black polyurethane sponges are course and can have debridement-like properties, direct placement onto the skin should be avoided when planning for use under prolonged negative pressure. A petroleum-impregnated gauze (e.g. Xero form™or Adaptic™) should first be placed over the length of the incision at a width wider than the overlying sponge to protect healthy surrounding skin.

13) Once the petroleum-impregnated gauze is in position over the incision, the longitudinally incised black sponge can then be placed over the top with the prepared canal facing up.

14) The hemovac tubings are then brought from the inferior aspect of the incision up to the sponge and are laid in the previously prepared sponge canal (Figure 2).

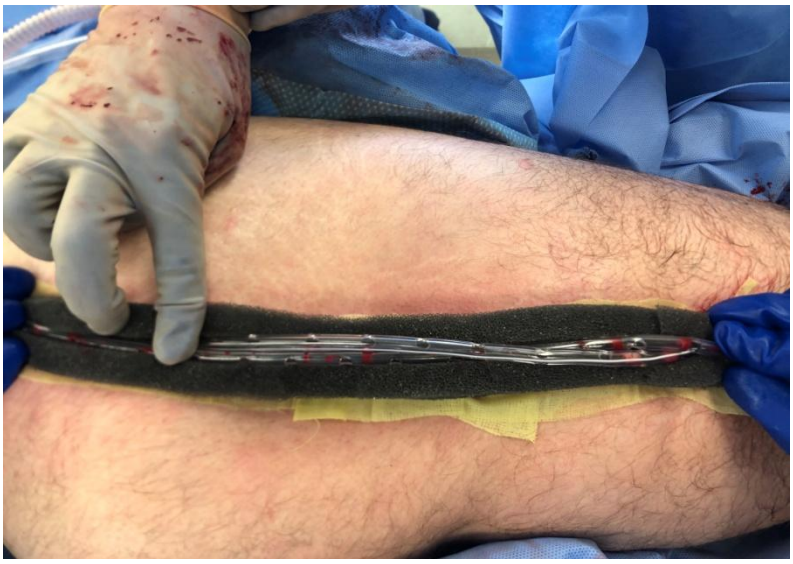

Figure 2: Placement of the deep hemovac tubings into the prepared sponge.

15) The sponge is then pinched to close the canal (Figure 3) and the second (non-incised sponge) is then placed over the top to create a closed sponge-drain construct (Figure 4).

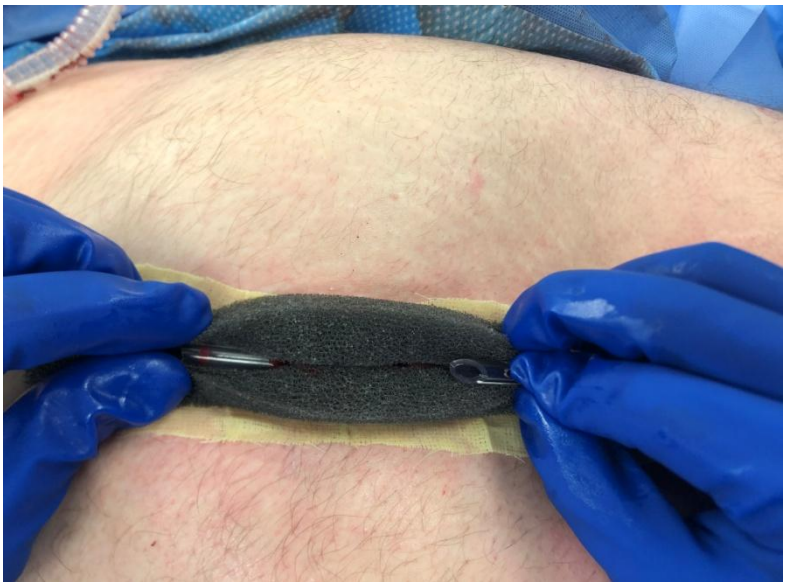

Figure 3: Pinching the sponge to allow for canal closure.

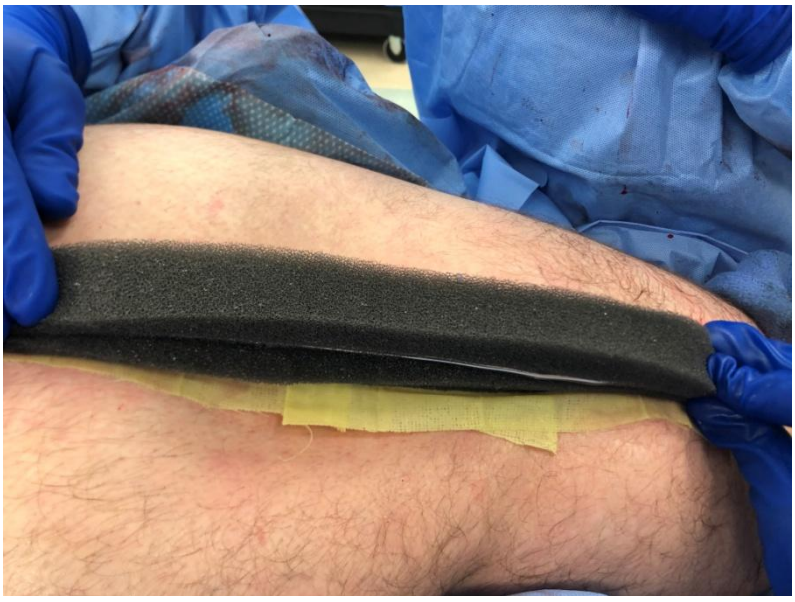

Figure 4: Placement of second sponge to complete canal closure.

16) Adhesive strips are then sequentially placed over the sponge with care not to dislodge the drain tubings from the sponges (Figure 5).

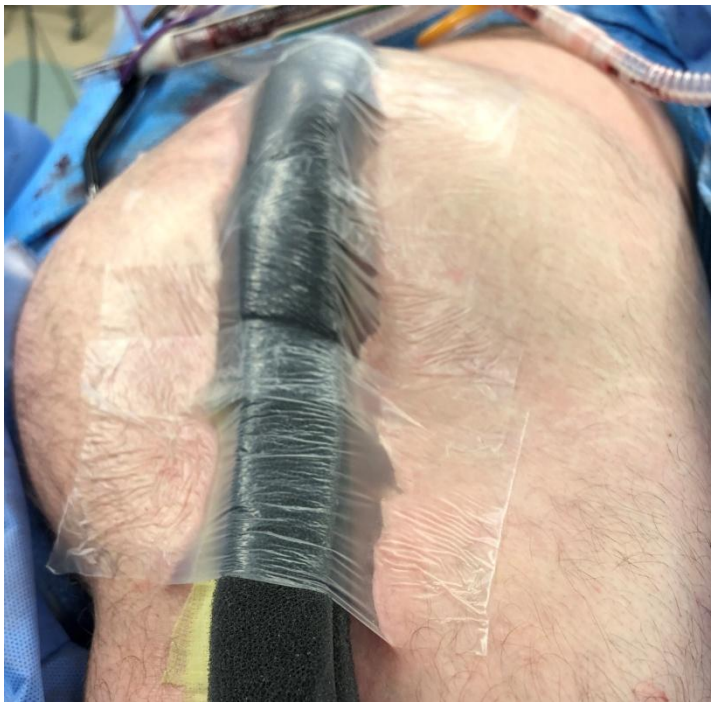

Figure 5: Placement of adhesive sealing strips in anticipation of final lily pad placement.

17) Once the sponges are adequately sealed with adhesive strips, the lily pad and external tubing can then be assembled in the standard fashion per the device being used.

18) The device may then be powered on, and a seal check should be performed. If the seal is intact, the sponge will compress. An example of the final construct is shown in Figure 6.

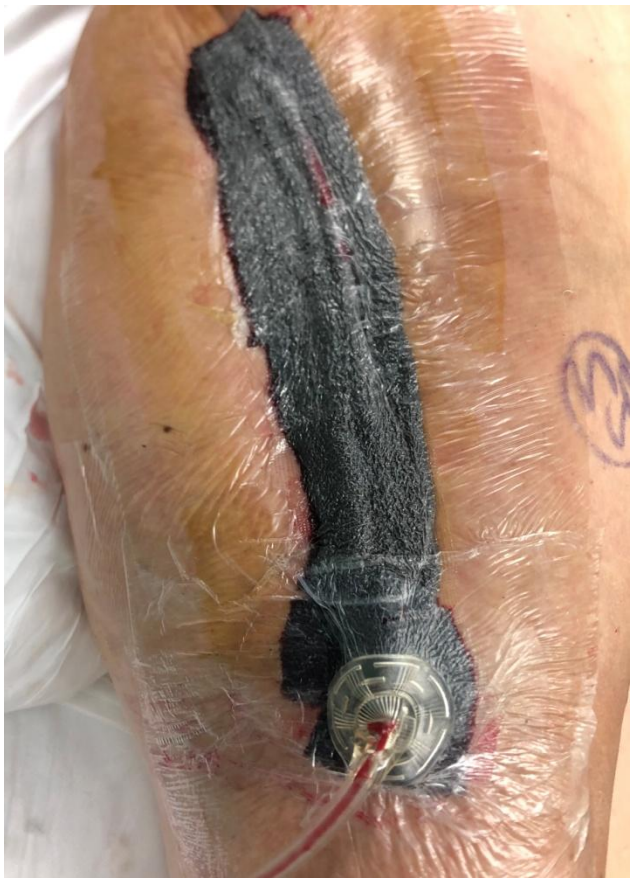

Figure 6: Completed DIOV system sealed and functioning.

Results

There were 8 patients stratified to Group 1 and 6 patients stratified to Group 2. Culture rates were found to be positive in 50% of patients in both groups at time of DIOV removal. The following sub-sections evaluate culture positive rates in relation to demographic, surgical, and microbiological data.

Demographic Data

Demographic data is summarized in Table 1. Average age of patients in Group 1 was 65.8years. Average age of patients in Group 2 was 61.6years. Group 1 included 4 males and 4 females. Group 2 included 2 males and 4 females. Average BMI in Group 1 was 26.2, while average BMI in Group 2 was 32.4. There were no statistically significant differences in culture rates by age or BMI.

Table1: Demographic data including age, gender, and BMI.

	Group I	Group II
Age	65.8	61.6
Male	4	2
Female	4	6
BMI	26.2	32.4

Surgical Data

Of the patients in Group 1, 6 of 8 underwent wide surgical resection for soft tissue sarcoma. These sarcomas included undifferentiated pleomorphic sarcoma, liposarcoma, myxofibrosarcoma, and intimal sarcoma. The other two procedures in Group 1 included a large lipoma resection and neurofibroma resection. Of the patients in Group 2, all underwent surgical debridement for complex musculoskeletal infections related to septic prosthetic joints. Data regarding estimated blood loss and duration of therapy can be found in Table 2. There were no statistically significant differences in culture rates in either group when compared with estimated blood loss at time of surgery. Average duration of therapy was 11.0 days in Group 1 and 9.3 days in Group 2. Increased duration of therapy was suggestive of increased rates of culture positive results, but did not reach statistical significance. The Group 1 positive culture patients had a DIOV in place for an average of 14.5 days, while the Group 1 negative culture patients had an average of 7.5 days ($p = 0.058$). This was similar to the Group 2 culture positive patients who had a DIOV in place for an average of 11.0 days, while the culture negative patients an average of 7.6 days ($p = 0.063$). Complications in the acute post-operative period were also recorded. Two patients in Group 1 were found to have incisional seromas after DIOV removal, but these were managed conservatively without need for repeat surgical intervention. There were no acute post-operative complications noted in Group 2. All patients went on to have full wound healing at the 3-month follow-up mark.

Table 2: Surgical data including estimated blood loss (mL) and duration of therapy (days).

	Group I (+Culture)	Group I (-Culture)	Group II (+Culture)	Group II (-Culture)
Blood loss (mL)	140	262.5	466.6	233.3
VAC time (days)	14.5	7.5	11.0	7.6

Microbiologic Data

Microbial data was obtained from all specimens. Positive culture rates at time of DIOV removal were 50% in both groups. Specific microorganisms cultured are listed in Tables 3 and4. Of all positive DIOV cultures, 4 of 7 revealed coagulase negative staphylococcus species (CoNS). Only one patient in Group 2 grew the same organism pre-DIOV and at time of DIOV removal, which was CoNS. One patient in Group 2 grew two different organisms - CoNS followed by proteus mirabilis. Half of positive culture patients in Group I grew CoNS.

Table 3: Microorganisms grown in Group I cultures.

	Group I + culture microbes
Microbes	Coagulase Negative Staphylococcus Sp.
	Klebsiella Aerogenes, TrueperellaBernardiae
	Coagulase Negative Staphylococcus Sp.
	Methicillin-Susceptible Staphylococcus Aureus

Table 4: Microorganisms grown in Group II cultures.

	Group II pre-DIOV microbes	Group II post-DIOV microbes
Microbes	Klebsiella Pneumonia, Candida Albicans, Coagulase Negative Staphylococcus Sp., Enterococcus Faecalis	Negative
	Klebsiella Aerogenes, TrueperellaBernardiae	Negative
	Coagulase Negative Staphylococcus Sp.	Proteus Mirabilis
	Methicillin-Susceptible Staphylococcus Aureus	Negative
	Coagulase Negative Staphylococcus Sp.	Coagulase Negative Staphylococcus Sp.
	Negative	Coagulase Negative Staphylococcus Sp.

Discussion

Wide tumor resections and extensive debridement for musculoskeletal infection create significant dead-space. As a result, underlying fluid accumulation can occur which may have detrimental effects on overlying skin and superficial tissues. Figure 7 demonstrates an example of this phenomenon in which a patient underwent wide resection for liposarcoma8 days prior (did not have a DIOV placed) and developeda large sub-incisional collection. It is known that underlying seroma and hematoma formation lead to unfavorable tension and providea nidus for bacterial colonization [3, 5]. Numerous techniques and modalities have been developed to aid with the treatment of post-operative fluid accumulation. A common technique involves intra-operative placement of a bulb- or drum-style closed suction drain device [7]. These are colloquially referred to as hemovac drains.

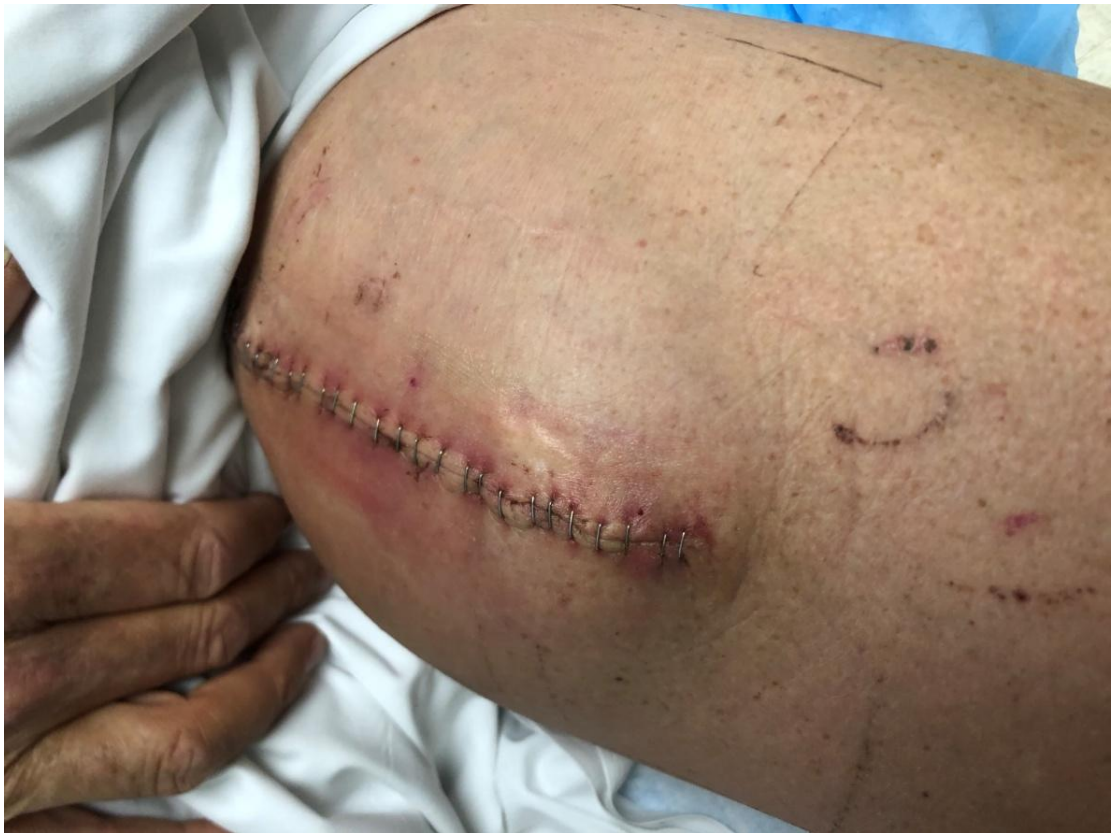

Figure 7: A post-operative, sub-incisional fluid collection seen in a liposarcoma patient that underwent wide resection 8 days prior. This patient did not receive DIOV therapy and required an unplanned return to the OR for management of this collection.

The use of hemovac drains for post-operative fluid management has been commonplace in a variety of surgical subspecialties for over 50 years [8, 25]. In the mid-late 20th century, closed suction drains were routinely used following primary hip and knee arthroplasty [8]. In recent years, routine drain use has fallen out of favor, as meta-analyses have shown questionable benefits in wound healing, and at times, increased rates of contamination and infection [20, 22]. Recent arthroplasty literature has also shown increased rates of hospital length-of-stay with routine drain use when compared to no drain [17, 27]. While wide tumor resection and extensive debridement for infection differ greatly from primary arthroplasty, the repercussions of drain use should still be considered highly before placement in any patient. Conceptually, select patients at high risk for post-operative wound complications related to fluid accumulation should benefit from a deep drain system that maintains sterility, transitions to use in the outpatient setting, and has a low impact on healthcare-related costs when compared to standard dressings. Here, a novel system is described to theoretically achieve the benefits of deep drain placement while simultaneously maintaining a negative pressure environment over a closed surgical wound.

Modern bulb- and drum-style drain systems have excellent designs and are rigorously tested to ensure aseptic packaging when manufactured. The high rates of bacterial colonization, and at times high rates of post-operative infection, seen with routine drain use warrants further investigation into the microbiological processes occurring at the body-drain interface. The fundamental assumption behind contamination is that the closed system becomes breached, allowing microorganisms to access deep tissues previously protected by a closed seal. While the most common mechanisms and locations for these breaches are unknown, most drain devices contain separate components requiring hand-assembly, affording potential sites for failure when placed under the stresses of routine post-operative patient activity. In addition, the skin-tubing interface at the drain site is not a perfect seal, again allowing access for microorganisms.

At the authors' institution, it is not uncommon for hemovac drains to become damaged or dislodged while patients are recovering on inpatient post-operative units. These events not only create a lapse in the drain's primary function (i.e. dead-space management), but also open the system to potential contamination from pathogenic microorganisms. To prevent this issue, a system was conceptualized to eliminate the vulnerable connections of standard hemovac drains while simultaneously preserving deep-space access and a negative pressure environment over closed surgical incisions. The premise of this involved incorporating deep hemovac drains into a more robust external drain system. The device components of traditional NPWT were found to be quite suitable for this role, as they are typically more durable, widely sealing, and stouter when compared to standard hemovac drains alone. These concepts led to the preliminary design of the DIOV, which now utilizes 1/4th inch DAVOL hemovac drain tubings with K.C.I. V.A.C.™ device components.

The K.C.I. V.A.C.™ device is one of the most commonly utilized NPWT systems in the United States [10]. It is estimated that the market size of NPWT will reach $2.74 billion by 2026, which is a 48% increase compared to its $1.85 billion market size in 2018 [10]. K.C.I. Licensing, Inc. (now owned by 3M, Maplewood, MN) and Smith & Nephew have been the industry leaders in NPWT over the last few years, with both companies producing high-quality, safe medical equipment. The transparent adhesive drapes, sturdy lily pad, and twist-locking tube connectors of the K.C.I. V.A.C.™ provide excellent external protections to the closed system of the DIOV. These protections allow the black polyurethane sponge to provide an even amount of negative pressure to the incision while preserving deep drainage from the incorporated hemovac tubings. The ability to maintain prolonged negative pressure over a closed surgical wound is key for the DIOV system, as recent meta-analyses have shown benefit from NPWT on closed surgical wounds when compared to standard dressings [11, 18, 26].

In a 2020 *Journal of Orthopaedic Trauma* meta-analysis, 9 studies including RCTs, prospective nonrandomized trials, and retrospective observational studies were compared assessing the rate of deep infection with NPWT versus conventional dressing (CD) alone for treatment of open fractures. The authors found that 8.9% of NPWT (55 of 614) patients compared to 17.4% of CD (84 of 481) patients developed deep infection, which was highly statistically significant and produced an odds-ratio of 0.43 ($p < 0.0001$) [11]. A 2019 Cochrane meta-analysis of 25 RCTs concluded that NPWT versus standard dressings alone may reduce the rate of surgical site infections (relative risk 0.67), but this was with low-certainty evidence due to serious risk of bias [26]. This meta-analysis was updated in 2020 with 14 new RCTs and found a reduced risk of bias, which increased the quality of evidence to moderate-certainty at a similar relative risk of surgical site infection of 0.66 [18].

While the benefits of NPWT remain controversial [6], expert panels have advocated for their use in complex wound management for over a decade [13]. The financial component of NPWT is complex, and studies have shown both increased [16] and decreased [6] healthcare related expenditures when NPWT is used. Because the DIOV systems used in this series were on average in place for >1 week, the healthcare related costs were felt to be comparable with standard dressings, as costly wound supplies and additional provider man-hours for dressing changes were avoided.

The pilot data from this series suggest that there are improvements to be made in the DIOV's ability to maintain a closed, aseptic system. Half of the patients in this series demonstrated positive cultures from the DIOV tubings at time of removal. Many of these cultures grew CoNS, an organism known to be a common contaminant at the host institution. While none of the positive culture patients went on to have true clinical infections, the exact clinical relevance of this finding remains unknown. Certainly prevention of contamination is preferred, however the risk of contamination compared to the theoretical benefit of dead-space management creates a challenge when deciding on DIOV use. A much larger sample size is needed to further identify the risks and benefits associated with the DIOV system.

The small (non-controlled) sample size and widely variable indications for DIOV placement are likely the greatest limitations in this series. Wide tumor resections and extensive musculoskeletal debridement procedures are uncommon, even in a full-time academic practice, which limits the available sample size from which to gather data. Additionally, only patients deemed high risk for dead-space related complications receive DIOV therapy, further limiting available subjects. A lack of cost analysis is also a limitation, as expenditure reports are needed to better understand the value of this type of system. Additional microbiologic data would have also been beneficial, as CoNS cultures were unable to be verified as valid versus lab contamination. While conceptually appealing, the DIOV system requires further study and refinement before being advocated for more wide use.

Dead-space management following tumor resection or extensive debridement poses a challenge to orthopaedic oncologists and infectious specialists alike. The ability to have a deep drain system in place, while maintaining negative pressure over a closed wound, theoretically provides simultaneous benefit to both deep and superficial tissues during use in the acute post-operative setting. The novel technique described here incorporates deep hemovac drain tubings into a superficial wound vac sponge to provide deep dead-space management while preserving the incisional benefits of NPWT.

High contamination rates of the closed system continue to be problematic, particularly with prolonged duration of therapy, which is similar to previous findings in routine hemovac drain use. While contamination rates in this series were high (50%), no patients went on to develop true clinical infections, questioning the clinical relevance of this type of finding. Currently, the DIOV system is felt to be a safe adjunct for dead-space management in select patients at high-risk for complications related to adverse deep space

fluid accumulation. Further studies are needed to better elucidate the safety and efficacy of the DIOV system.

Acknowledgments

- We thank Christopher J. Kleck MD for the preliminary design of the DIOV.
- We thank Jodi McConnell PA-C for contributions with specimen and data collection.

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Citation: Steven D. Jones Jr MD et al., (2021), "A Novel Wound and Soft Tissue Flap Negative Pressure Drain System - a Pilot Study", Arch Health Sci; 5(1): 1-12.

DOI: 10.31829/2641-7456/ahs2021-5(1)-002