Reduce Driveline Trauma Through Stabilization and Exit Site Management: 30 Days Feasibility Results from the Multicenter RESIST Study

Marcia Stahovich,* Kartik S. Sundareswaran,† Sarah Fox,‡ William Hallinan,§ Peggy Blood,¶ Leway Chen,‖ Salpy V. Pamboukian,¶ Raymond Chinn,* David J. Farrar,† Francis D. Pagani,‡ and Laura Blue#

The percutaneous lead management kit (PLMK) was developed for the HeartMate 2 (HM2) left ventricular assist device (LVAD) to reduce trauma at the exit site and to maintain a clean environment. REduce Driveline Trauma through StabIlization and Exit Site ManagemenT (RESIST) was a multicenter, prospective, nonrandomized study designed to evaluate the feasibility of the PLMK for managing the HM2 driveline exit site. Fifty patients were enrolled at five sites at a median of 495 days post-HM2 implant; 92% (46 of 50) of patients used the PLMK for a minimum of 30 days. At 30 days, more patients found the PLMK to be extremely comfortable (80% *vs.* 37%, $p < 0.001$) and extremely effective at stabilizing the driveline (82% *vs.* 40%, $p < 0.001$) compared with each center's standard of care. Frequency of dressing changes was 6–7 days or higher for 85% of the patients with PLMK. Three patients developed driveline infection while on PLMK (6%, 0.15 events per patient year), and 35 patients continued to use the PLMK after 6 months. The PLMK is easy to use, increases patient comfort, and increases driveline stability with a dressing change frequency of 6–7 days. *ASAIO Journal* 2016; 62:240–245.

Key Words: driveline infection, exit site trauma, driveline stabilization, percutaneous lead

Durable circulatory support with a continuous-flow left ventricular assist device (LVAD) provides survival and quality-of-life benefits for patients with advanced heart failure. During the past decade, clinical studies have demonstrated progressive improvement in outcomes for patients supported by continuous-flow LVADs partially because of a decline in adverse events.[1–3] However, infection, bleeding, and stroke are potentially lethal complications that continue to limit the overall effectiveness of the therapy. In LVAD patients, preoperative debilitation, extensive surgery for device implantation, and frequent hospitalizations are features that predispose to complications, particularly infection. The risk of infection is highest in the early postoperative time; but the risk continues throughout the course of support because of the presence of the percutaneous driveline that powers the LVAD pump.[4] Continued improvements in survival and quality-of-life outcomes for LVAD-supported patients necessitate further reduction in device-related infections.

The driveline exit site is the most susceptible to infection and is the most often precipitated by trauma to the tissue surrounding the site.[5] For outpatients, suboptimal self-care or trauma at the driveline exit site commonly results in an infection that requires rehospitalization for diagnostic studies, intensive antibiotic therapy, or, in some case, the need for surgical intervention. Driveline stabilization and exit site management are paramount in the prevention of driveline infections. Many centers have devised custom techniques to protect and to keep the exit site clean. However, driveline infections continue to be a major source of morbidity and mortality in both destination therapy (DT)[3,6] and bridge-to-transplantation patients.[7–9]

The goal of developing the percutaneous lead management kit (PLMK) was to minimize movement of the driveline and to maintain a clean environment at the exit site, that is comfortable and easy to use. This feasibility study was conducted to evaluate the comfort and ease of use of the PLMK in a group of patients undergoing long-term LVAD support. Long-term effects on driveline infection were not the goal of this study and have to be evaluated in a separate study.

Materials and Methods

Percutaneous Lead Management Kit

The PLMK was intended to be convenient, comfortable, and easy to use for driveline stabilization and infection mitigation for the HeartMate 2 (HM2; Thoratec Corporation, Pleasanton, CA) LVAD. Each patient was provided with sufficient kits (free of cost) to last the entire study duration (6 months). Ventricular assist device (VAD) coordinators instructed patients and their caregivers on the procedures for driveline care and the use of the PLMK. The kit is composed of commercially available products that are packaged together to be used by the patient or their caregivers for driveline exit site management in the

From the *Mechanical Circulatory Support Department, Sharp Memorial Hospital, San Diego, California; †Research and Scientific Affairs, Thoratec Corporation, Pleasanton, California; ‡Center for Circulatory Support, Department of Cardiac Surgery, University of Michigan Hospital and Health Systems, Ann Arbor, Michigan; §Division of Cardiac Surgery, University of Rochester Medical Center, Rochester, New York; ¶Division of Cardiovascular Disease, University of Alabama at Birmingham, Birmingham, Alabama; ‖Department of Cardiology, University of Rochester Medical Center, Rochester, New York; and #Duke Surgery, Duke University School of Medicine, Durham, North Carolina.

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Correspondence: Kartik S. Sundareswaran, PhD, Research and Scientific Affairs, Thoratec Corporation, 6035 Stoneridge Drive, Pleasanton, CA. Email: KSundareswaran@thoratec.com.

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Table 1. Percutaneous Lead Management Kit Components

Item Name	Manufacturer	Purpose/Use
Kendall Webcol swab (70% isopropyl alcohol)	Covidien, Mansfield, MA	Remove adhesive of driveline exit site dressings
Chlorascrub Maxi Swabstick and Swab	Professional Disposables International, Inc., Orangeburg, NY	Skin preparation; 3.15% chlorhexidine gluconate and 70% isopropyl alcohol
3M Cavilon No Sting Barrier Film	3M Critical & Chronic Care Solutions, St. Paul, MN	Prevent skin irritation in areas where the driveline dressing and anchor adhesives contact the skin
Silverlon Wound Pad Dressing 1.5×1.5 inch	Argentum Medical, LLC, Geneva, IL	Reduces bacterial colonization around exit site
SorbaView Ultimate dressing	Centurion Medical Products, Williamston, MI	Stabilize the driveline
Foley anchor	Centurion Medical Products, Williamston, MI	Strain relief
Sterile nonlatex gloves	Standard hospital supplies	
Hair cover		
Face mask		
Sterile saline		
Styrofoam tray		

outpatient environment. **Table 1** provides a list and description of the kit components (**Figure 1**).

The primary goal for developing this kit was to provide all the components required by the patient for performing a dressing change in a single kit that could simplify the dressing change procedure. Additionally, training was provided by the VAD coordinators to ensure that all patients were performing the dressing change the same way. The components of the kit include the following: Kendall Webcol swab (Covidien, Mansfield, MA) (70% isopropyl alcohol), hair cover, mask, nonlatex gloves, wrap, Chlorascrub Maxi Swabstick (Professional Disposables International, Inc, Orangeburg, NY), and Swab for site preparation; 3M Cavilon No Sting Barrier Film (3M Critical & Chronic Care Solutions, St. Paul, MN) to reduce skin irritation; a 1.5×1.5 inch Silverlon Wound Pad Dressing (Argentum Medical, LLC, Geneva, IL), sterile saline, and Styrofoam tray for infection mitigation; SorbaView Ultimate dressing (Centurion Medical Products, Williamston, MI) with securement tape for stabilizing the driveline; and a Foley anchor (Centurion Medical Products, Williamston, MI) for additional strain relief support. All components of the PLMK were recommended to be changed every 7 days.

Study Design

REduce Driveline Trauma through **S**tab**I**lization and Exit **S**ite Managemen**T** (RESIST) was a multicenter, prospective, self-controlled study that was designed to evaluate the feasibility of the PLMK. Fifty patients were enrolled from five participating medical centers located in different climates in the United States. The primary objective was to evaluate the use of the PLMK for 30 days. The patient or caregiver recorded the patient's subjective assessments after using the PLMK. Secondary objectives evaluated the incidence of infection, adverse reaction to any PLMK components, the efficacy of the antiseptic sponge (Silverlon), and the stabilization system (SorbaView Ultimate with securement tape). The follow-up period was 30 days for patient stabilization and for comfort assessment. Patients were followed for an additional 2–6 months from enrollment for infection assessment. Infections were determined by physical examination and cultures of the drainage from the site when indicated. After the 30 days follow-up period, patients had the option to continue using the PLMK or resume their original protocol. Patients were allowed to shower as part of the study. If the patient showered, he/she was instructed to contact the VAD coordinator after their first shower to assess the integrity of

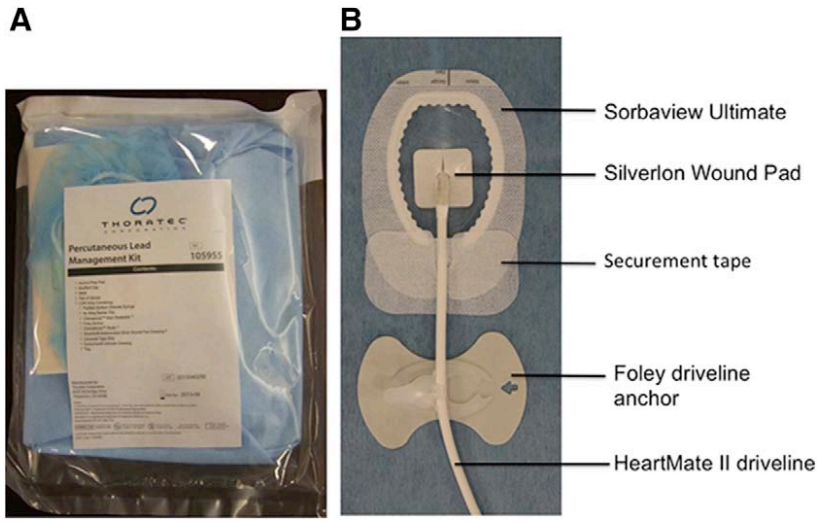

Figure 1. The packaged percutaneous lead management kit (PLMK) (**A**) and the components of the PLMK (**B**). full color online

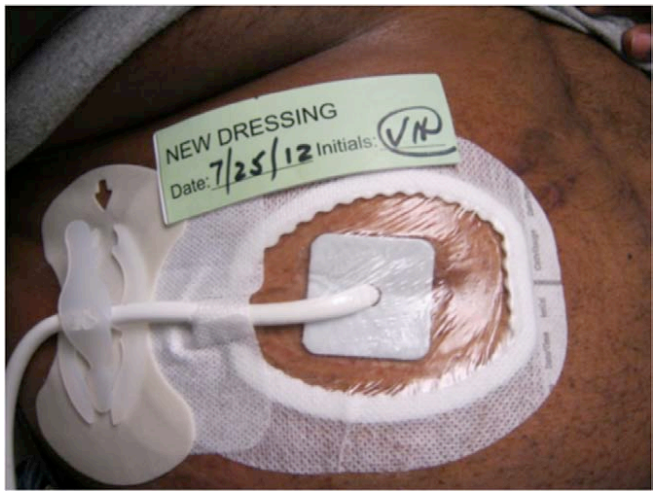

Figure 2. Representative photograph of the percutaneous lead management kit (PLMK) after patient completed their driveline exit site care. full color online

the dressing. A role of Press'n Seal (Glad Product Company, Oakland, CA) and 3M Transpore adhesive tape were provided to the patient as an additional measure to keep the exit site dry while showering.

Patients

The study included 50 patients who were older than 16 years, with ongoing HM2 (Thoratec Corporation) support, who had been discharged from the hospital with no signs or symptoms of driveline exit site infection at the time of enrollment, and who had no known allergies to products used in the PLMK. The patient or caregivers were instructed to change the dressing every 7 days for the 30 days study period. Patients completed questionnaires before and after the PLMK 30 days trial period to assess ease of use, comfort, and compliance with using the kit. Patients took photos of the exit site care in stages to verify proper application and completed case report forms at the time of the dressing change (**Figure 2**). The study protocol was approved by the Institutional Review Board of each participating center, and signed informed consent was obtained from all participants.

Statistical Analysis

Continuous variables were presented as mean ± SD. Discrete variables and adverse events were presented as percentages. Freedom from driveline infection was calculated with the Kaplan–Meier method with patients censored for transplantation, death, or withdrawal. Differences in categorical variables were evaluated with the Fisher exact test. Each patient served has his/her own control for all the comparisons. *p* values and percentages were calculated using both the as-treated (AT) and the intention-to-treat (ITT) principles. The ITT analysis utilized the 50 patients who were enrolled into the study as the denominator, whereas the AT analysis utilized only the patients who utilized the kit for 30 days (N = 46). All statistical comparisons were two sided with a significance level at a *p* value of less than 0.05. All statistical analyses were done with SAS software (SAS Institute, Inc., Cary, NC).

Results

The 50 patients enrolled in the study had a mean age of 62 ± 11 years, and 46 (92%) were men (**Table 1**). Patients were on LVAD support for a median of 496 days (range, 179–1,583 days) at the time of enrollment. Four patients (8%) had prior driveline infections, but they were resolved at the time of enrollment. Forty patients (80%) had the driveline placed with a silicone–skin interface with the velour completely below the skin, and the remainder had a velour–skin interface placement (i.e., the velour is exposed). **Table 2** shows the driveline exit site management approaches for the five institutions before incorporating the PLMK as part of the RESIST study. Dressing change frequency before PLMK was daily or every 2–3 days for all patients.

Of the 50 patients enrolled in this study, 46 (92%) used the PLMK for greater than 30 days and 35 (70%) for greater than 6 months. Out of the 15 patients who were no longer on PLMK at 6 months, 7 can be attributed to the kit itself (skin irritation: 4 patients, 3 patients driveline infection [1 < 30 days, 2 > 30 days]), 3 were attributed to non–kit-related reasons where the subject did not adhere to the VAD coordinator's instructions, and 5 were attributed to the patient outcome (3 were transplanted and 2 expired). Four patients used the PLMK for less than 30 days; of those, three stopped because

Table 2. Driveline Exit Site Management Approaches at the Five Institutions Before Initiating Using the PLMK

Protocol Aspect	Institution 1	Institution 2	Institution 3	Institution 4	Institution 5
Frequency of dressing change	2–3 days	2–3 days	Daily	2–3 days	Daily
Stabilization approach	Hollister tube attachment, dressing and tape to secure	Dale Abdominal Binder	Thoratec Stabilization Binder/Belt, Dale Abdominal Binder	Hollister tube attachment, Centurion Foley anchor	Thoratec Stabilization Binder/Belt,
Dressing method	Sterile gauze	Occlusive dressing	Sterile gauze	Sterile gauze, occlusive dressing, other	Sterile gauze
Cleaning method	H_2O_2	• Chlorhexidine (solution, swabs, sponges) • Silver	Chlorhexidine (solution, swabs, sponges)	Chlorhexidine (solution, swabs, sponges)	Chlorhexidine (solution, swabs, sponges)
Frequency of exit site trauma	Occasionally (50% of patients)	Occasionally (50% of the patients)	Rarely (25% of the patients)	Occasionally (50% of the patients)	Rarely (25% of the patients)

PLMK = percutaneous lead management kit.

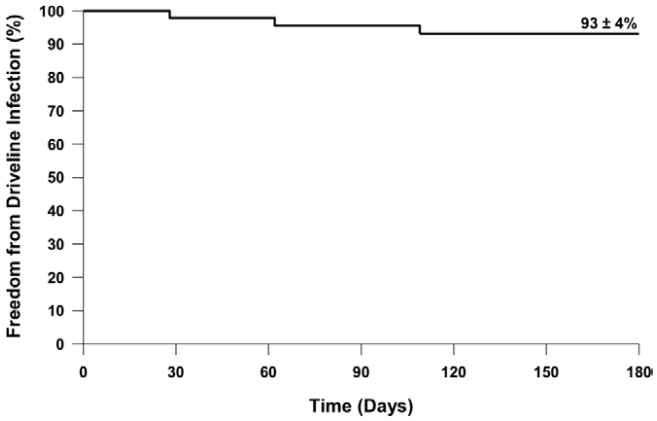

Figure 3. The freedom from driveline infection out to 180 days for the 50 patients enrolled in the study.

of skin irritation and one stopped because of a driveline infection. For the entire group of 50 patients, 3 (6%) developed driveline infections, and the overall freedom from the event at 180 days was 93% ± 4% (**Figure 3**), with an event rate of 0.15 events per patient year.

Of the 46 patients who completed the 30 days study requirements, 37 patients (74% [ITT], 80%[AT]) found the PLMK to be extremely comfortable compared with 17 patients (34%[ITT], 37%[AT]) using the prior standard of care dressing ($p < 0.001$ [ITT and AT]) (**Figure 4A**). Twenty-four (48% [ITT], 52% [AT]) experienced at least one level of improvement in *comfort* with PLMK use, and 18 (35% [ITT], 39%[AT]) reported no change when compared with their previous technique. With respect to ease of use, 33 patients (66% [ITT], 72% [AT]) found the PLMK to be extremely easy to use compared with 26 patients (52% [ITT], 57% [AT]) using their prior standard of care dressing ($p = 0.222$ [ITT], $p = 0.192$ [AT]) (**Figure 4B**). Eleven patients (22% [ITT], 24% [AT]) improved by at least one level in *ease of use* with the PLMK, and 30 (60% [ITT], 65% [AT]) reported no change.

For the PLMK *stabilization technique*, 41 patients (82% [ITT], 89% [AT]) were extremely satisfied with the PLMK compared with only 20 patients (40% [ITT], 43% [AT]) with the prior standard of care dressing ($p < 0.001$ [ITT and AT]) (**Figure 5A**). Twenty-four patients (48% [ITT], 52% [AT]) reported at least one level of satisfaction improvement, and 18 (36% [ITT], 39% [AT]) reported that there was no change when compared with their prior technique. Six patients (12% [ITT], 13% [AT]) reported improved *cleanliness* of the exit site with use of the PLMK, and 35 (70% [ITT], 76% [AT]) said that there was no difference between the techniques in the degree of cleanliness of the exit site ($p = 1.00$ [ITT and AT]) (**Figure 5B**). Patients changed their dressing less frequently with the PLMK compared with their prior dressing with 85% of doing the dressing change only every 6–7 days or more than 7 days. With the prior standard of care dressing, 100% of the patients were recommended to change the dressing either daily or once every 2–3 days.

The VAD coordinators overwhelmingly (98%) rated the PLMK superior to the prior techniques with regard to stabilization, cleanliness, ability to avoid infection, and ease of use. Out

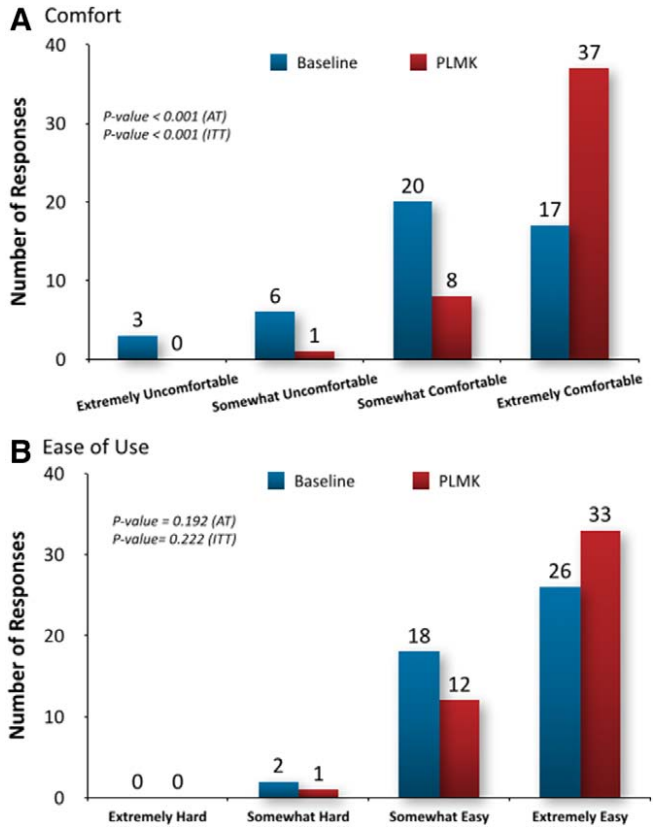

Figure 4. Results from patient assessment of comfort (**A**) and ease of use (**B**) after 30 days of percutaneous lead management kit (PLMK) use. full color online

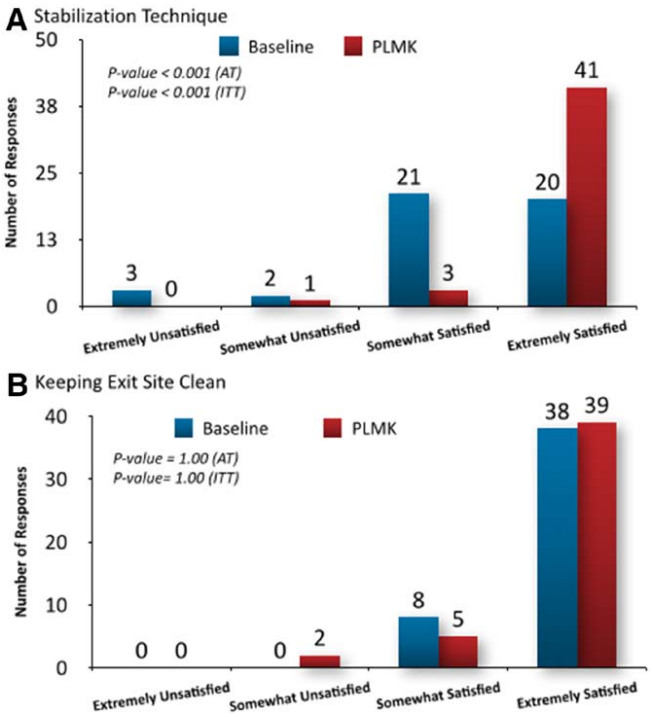

Figure 5. Results from patient assessment of stabilization technique (**A**) and keeping the exit site clean (**B**) after 30 days of percutaneous lead management kit (PLMK) use. full color online

of the five primary VAD coordinators, two indicated that they would recommend the PLMK to 100% of their patients, two said that they would recommend the PLMK to 75–99% of the patients, and one said that she would recommend to 50–74% of the patients. The VAD coordinator who selected the 50–74% of the option claimed that the other 25–50% may have issues with their driveline exit site and would require more frequent dressing changes. The VAD coordinators who felt that they would recommend the kit to 100% of their patients found the kit to be very effective and provided more freedom to patients without having to use a binder.

Discussion

Since the initial implants of durable LVADs 25 years ago, device-related infections have been a serious complication in numerous patients.[10–12] Infectious complications have declined considerably since the inception of continuous-flow LVADs, but driveline infection occurs in approximately 20% of patients in the first year of LVAD support, and the cumulative risk is continuous during support.[13] Effective care and management of the driveline exit site is essential to optimizing the outcomes of LVAD therapy, and the PLMK may be an additional step toward that end. The primary goal for developing this kit was to provide all the components required by the patient for performing a dressing change in a single kit that would 1) simplify the dressing change procedure and 2) reduce the frequency of dressing changes. The RESIST study was a 30 days feasibility study of utilizing the PLMK for HM2 driveline exit site management, with patients followed-up to 6 months in order to evaluate the infection rate.

The PLMK improved comfort and stability in at least 50% of patients when compared with previous infection management systems. Additionally, the PLMK dressing changes were only performed once a week. As more and more patients receive these devices for DT, patient compliance becomes an important variable in reducing variability and the subsequent risk of driveline infection. Simplifying and improving the dressing change technique may further reduce the risk of driveline infection, in addition to reduce the risk of infection surgically by internalizing the velour portion of the driveline at the time of VAD implant. A recent multicenter study by Dean *et al.*[14] demonstrated a 50% reduction in driveline infection rate at 1 year when the velour portion of the driveline was internalized, when compared with the HM2 clinical trial where the velour portion was externalized. Majority of the centers have now adopted this technique, including the patients in our study where 80% of the patients had the velour portion internalized.

Trauma at the skin exit site of the driveline is an event that precipitates most driveline infections. Avoiding trauma is difficult because of the relative rigidity of the driveline to the flexible abdominal wall.[15–17] The most common method for driveline immobilization and site protection has been with the use of an abdominal binder. These binders can be effective in preventing pulling of the driveline, but since some patients consider them uncomfortable, they are less likely to use them on a regular basis. The stabilization approach comprising of the Sorbaview Ultimate Dressing and the Foley anchor does increase the comfort associated with the dressing change, which increases the likelihood of patient compliance with the dressing change protocol.

Silverlon Wound Pad Dressing is a commercially available dressing used in a wide variety of infection mitigation applications.[18,19] Silver is known for its antimicrobial properties and has been used recently for reducing bacterial colonization near surgical wounds and catheter insertion sites. The Silverlon Wound Pad Dressing has been shown to be effective against *Staphylococcus aureus*, *Staphylococcus epidermis*, *Pseudomonas aeruginosa*, and *Enterococcus faecium*, which are common pathogens associated with LVAD driveline infections. Furthermore, Silverlon has a unique technology, which releases silver ions continuously during a period of 7 days in order to protect the exit site from bacterial colonization for the entire duration of use.[20,21]

Limitations

This was a nonrandomized study, which may result in enrollment bias, and hence results should be viewed within the context of a feasibility, pilot study. Larger prospective randomized studies are needed in order to conclusively determine the clinical impact of the PLMK. Another limitation is that the study utilized subjective assessments by patients in order to evaluate study endpoints. Patient compliance with detailed instruction on the site care is variable and cannot be controlled in a study such as this. Studies with longer follow-up durations (minimum 1 year) are required before impact on driveline infection can be determined.

Conclusions

A PLMK that is easy to use, increases patient comfort, and increases driveline stability with a decreased dressing change frequency of 6–7 days from daily to 3–4 days was developed and evaluated as part of this feasibility study. The kit may help reduce variability and simplify the process of driveline exit site management and increase patient compliance. When used in combination with other infection control and prevention modalities, exit site infections may be better prevented; however long-term studies are needed before the impact of the PLMK can be conclusively determined.

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