**A simple device to secure ventricular assist device driveline and prevent exit-site infection**

# A simple device to secure ventricular assist device driveline and prevent exit-site infection

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## Abstract

**OBJECTIVES** Driveline infections are one of the most common and important complications in patients with left ventricular assist device (LVAD). One of the causes favouring the development of this complication is the traumatism of the exit site, which occurs in response to movement of the driveline. In this work, we present a simple and feasible method to immobilize the driveline at the level of the exit site.

**METHODS** From April 2013 until November 2013, 6 patients underwent implantation of HeartWare LVAD (HVAD) for an end-stage heart failure. When the patient has begun to mobilize after the implantation of the device, we have combined the use of two components with the aim of securing the driveline to the patient's skin: a StatLock system and a silicone suture.

**RESULTS** No case of local traumatism and no case of local infection at the driveline were observed during the follow-up. No patient reported pain or swelling at the driveline exit site. All patients were satisfied with their quality-of-life and they do not report any limitations in their daily activities.

**CONCLUSIONS** One of the major long-term complications in patients with LVAD is the development of infections of the exit site of the driveline. The trauma of this skin region promotes the onset and maintenance of an inflammatory process and local infectious. Avoiding excessive mobilization of the driveline is likely to reduce the incidence of infections of the exit site and improve the quality-of-life.

## INTRODUCTION

Driveline infections are one of the most common and important complications in patients with left ventricular assist device (LVAD) [1–3]. Currently there are not any new systems for energy transmission which do not involve the presence of a percutaneous cable, exposing the patient to a risk of exit-site infection. Some studies on the use of alternative supply for LVAD are currently underway, such as transcutaneous energy transmission, but their clinical application is still far [4]. One of the causes favouring the development of exit-site infections is the traumatism of the exit site, which occurs in response to movement of the driveline. Several authors have described the role of local trauma in the subsequent development of infection [1, 3]. In this work, we present a simple and feasible method of immobilizing the driveline at the level of the exit site using a non-traumatic device (StatLock, Bard Limited Forest House, Crawley, West Sussex, UK) and a silicone suture wing, part from a central venous catheter set (Arrow International, Inc., PA, USA). We used this method in 6 patients supported by HeartWare (HeartWare International, Inc., MA, USA) LVAD as bridge to decision.

## MATERIALS AND METHODS

From April 2013 until November 2013, 6 patients underwent implantation of HeartWare LVAD (HVAD) for an end-stage heart failure. All patients were in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level III. The mean age was 57.5 years (39–65 years). All patients were male. In all patients, the implantation was done through a median longitudinal sternotomy and the driveline was tunnellized on the right side of the abdominal wall just a few centimetres under the umbilicus. To immobilize the driveline, we have combined the use of two components: a StatLock system adhering to the skin at the point chosen for attachment and a silicone suture wing taken from a central venous catheter (CVC) set (7 or 8.5 French, but the second is better), routinely used for fixing the catheter at the skin.

The StatLock device was placed on the skin ~4–7 cm from the exit site (also depending on the need and comfort of the patient) (Fig. 1). The driveline was ensured at the level of the StatLock using the silicon suture wing. The driveline was locked into the suture wings using a silk thread (it is possible to use a silicone tape in contact with the driveline, to avoid a traumatism of the suture on the cable) (Fig. 2). The suture wing was connected to the StatLock using two plastic closures.

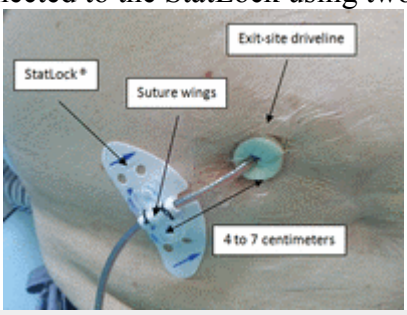


**Figure 1:**
Correct positioning of the device.

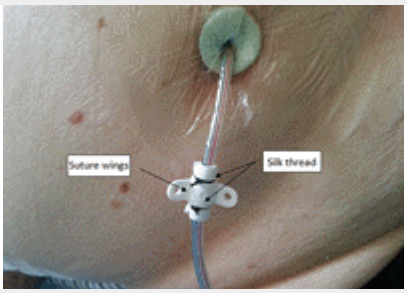


**Figure 2:**
Positioning of the suture wing on the cable. A strip of soft material is interposed appropriately to prevent decubitus of the silk thread on the driveline.

It is possible to mobilize the driveline from the StatLock allowing an easy mobilization and disinfection of the exit site, opening the plastic closures (Fig. 3); routinely, the medication was carried out using chlorine-based disinfectants and placing a protective-disk chlorhexidine based.

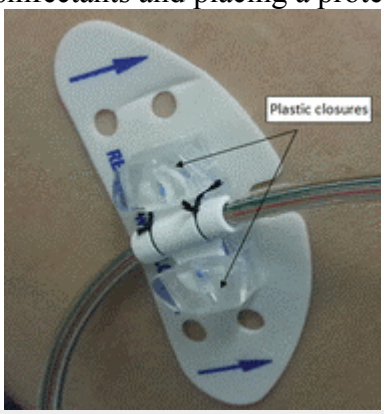


**Figure 3:**

Fixing system of the suture wing to StatLock.

## RESULTS

All patients survived after the LVAD implantation and they were discharged from the hospital. The mean follow-up was 120 days (23–224 days). Before using this device, which began in April 2013, we recorded 2 cases of driveline infections out of 11 patients supported by HVAD (November 2010 to April 2013) with an incidence of 18.2%. From April 2013 until now we did not record driveline infection events. Both prior to the introduction and after, the disinfection protocol of the wound and the exit site dressing were the same. The exit site is disinfected with chlorine-based products and is covered with a protective disk chlorhexidine based. The exit site is further protected by applying a transparent film dressing such as Tegaderm.

The StatLock device has been used in all cases in order to fix the driveline after a complete mobilization of the patient. The movement of the bag containing the controller and batteries leverages at the exit site. Basically, this device has the task of moving the fulcrum of the lever a few inches away from the exit site. No case of local traumatism and no case of local infection at the driveline were observed during the follow-up. No patient reported pain or swelling at the driveline exit site. Being a device adhering to the skin, StatLock does not cause pain to the patient in case of excessive traction with detachment. The StatLock device was changed every 7–10 days. We did not detect damage to the driveline. All patients were satisfied with their quality-of-life; the amplitude of motion of the driveline is reduced to a few centimetres without causing particular limitations in normal daily activities such as driving, showering, etc. Patients who have tried our device reported no particular limitations in their daily activities, contrary to patients implanted before April 2013. In some cases, the patients reported that they did not remember having a percutaneous cable, because the immobilization of the driveline at the level of the exit site did not cause traction resulting in redness and inflammation.

## DISCUSSION

Although there are commercial LVAD with alternative locations of the driveline, such as a skull-mounted pedestal in Jarvik *et al.* [5], the majority of devices present a percutaneous driveline localized at the abdominal level.
The importance of a stabilization of the driveline to avoid excessive trauma of the exit site [1–3] is described in the literature. Zierer *et al*. [1] in their multivariate analysis recognize in the exit-site trauma an independent factor favouring the development of infection. Goldstein *et al.*[2], in their subanalysis of the INTERMACS registry, showed that the freedom of exit-site infection event is 81% at 1 year after implant, according to the last INTERMACS report. Their study reported that age is the only multivariate predictor of percutaneous site infection; for every decrease in 10 years of age, the risk of infection rose by 20%. Our cohort of patients is within the first two groups identified by Goldstein (<50 years and 50–70 years) with an increased risk of developing exit-site infections. This is probably due to more physical activity in young patients than in elderly, resulting in greater exit-site driveline trauma. Choi *et al*. [6] recognized the importance of the immobility of the driveline to promote healing of the exit site, even assuming the use of antimicrobial substances on the surface of the driveline to prevent early infections and facilitate ingrowth of tissue.
There is, therefore, the need to avoid excessive movements of the driveline, in order to prevent skin lesions with risk of bacterial overinfection.

Currently, there are no commercially specific devices for locking the driveline to the skin in patients supported by HeartWare; our simple and feasible method may help to reduce the risk of local trauma and improve the quality-of-life of the patient. No difficulty has been experienced with the management of the exit-site's medications or from the home nurse who has the task of dressings patients after discharge home.

This fixing method has a very low cost. The price of the CVC set is ~18 dollars (in our case, the suture wing is not routinely used by our anaesthesiologists and was recovered from sterile sets) and StatLock is available to us at the cost of ~5 dollars. The use of these components in our method is off-label, not on the data sheet of the products.

## CONCLUSION

Currently, one of the most important limitations of the ventricular assist device is the energy supply of the device that requires a percutaneous drive-line. While waiting for new forms of energy transmission such as transcutaneous energy transmission systems, our method is configured as a valuable aid for the prevention of traumatism of the exit site, favouring a lower incidence of infections and promoting a better quality-of-life of the patient.

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