Mechanical Characterization of Anchoring Devices for the Prevention of Driveline Infection in Left Ventricular Assist Device Patients

Johanna Schachl,* Martin Stoiber,†‡ Martina Socha,* Daniel Zimpfer,* Dominik Wiedemann,* Heinrich Schima,*†‡ and Thomas Schlöglhofer*†‡

Driveline infection (DLI) is associated with increased mortality and morbidity in left ventricular assist device (LVAD) patients. Because trauma to the driveline exit-site (DLES) is a risk factor for DLI, adhesive anchoring devices are used to immobilize the DL. In this study, commonly used products (identified through literature review and contact with nine international VAD implantation centers) were mechanically characterized to evaluate their effectiveness in preventing DLES trauma. Eight devices were tested in an *in vitro* abdominal model of the DLES, where a tensile force (10 N) was applied to a HeartMate 3 DL, whereas the resulting force (F_{Total}) on the DLES was recorded using a three-axis load cell. Four devices (CathGrip: F_{Total} = 2.1 ± 0.4 N, Secutape: F_{Total} = 2.6 ± 0.3 N, Hollister: F_{Total} = 2.7 ± 0.5 N, Tubimed: F_{Total} = 2.9 ± 0.2 N) were significantly ($p < 0.05$) better at preventing tensile forces at the DLES compared to the other four devices (Main-Lock: F_{Total} = 3.7 [0.7] N, Secutape sensitive: F_{Total} = 3.9 ± 0.4 N, Foley Anchor: F_{Total} = 4.3 ± 0.5 N, Grip-Lok: F_{Total} = 5.4 ± 0.8 N). Immobilization of the DL with each anchoring device resulted in lower tensile force on the DLES than without an anchor (F_{Total} = 8.2 ± 0.3 N). In conclusion, the appropriate selection of anchoring devices plays a critical role in reducing the risk of DLI, whereas the CathGrip, Secutape, Hollister, or Tubimed were superior in preventing trauma to the DLES in this study. *ASAIO Journal* 2023; XX:XX–XX

Supplemental Visual Abstract; http://links.lww.com/ASAIO/B168.

Key Words: left ventricular assist device, mechanical circulatory support, driveline infection, driveline exit-site wound dressing, driveline immobilization, driveline anchoring

Mechanical circulatory support (MCS) has become an established treatment option for patients with end-stage heart failure (HF),[1] with 1 and 5 years survival rates of 83.0% and 51.9%, respectively.[2] However, adverse events still provide a serious challenge for left ventricular assist device (LVAD) patients.[3] Especially major infection, including driveline infection (DLI), remains among the most frequent adverse events in all phases of LVAD support[3] and can lead to serious complications and increased mortality rates.[4] Consequently, DLI is a leading cause of hospital readmissions in LVAD patients.[5,6] Preventing DLI is essential to ensure the long-term success and safety of LVAD therapy.

Driveline infection is primarily caused by bacterial and sometimes fungal colonization along the external parts of the DL.[7,8] The DL exit-site (DLES) creates a potential entry point for microorganisms, which may lead to infection.[8] Disruption of the interface between the DL and skin tissue exacerbates this problem.[9] This disruption often occurs due to trauma to the DLES during everyday activities, such as dropping controllers and batteries or the DL being caught in passing objects.[9]

The risk for developing DLI is influenced by many different factors, such as age, history of diabetes, BMI, DLES dressing protocol, or the device type.[7,10,11] The variation in DLI rates for different LVAD devices can be explained by their DL features. Kranzl *et al*.[10] examined the relationship between DLI rates and mechanical DL features, and found that the HeartMate 3 LVAD (HM3) (Abbott Laboratories, North Chicago, IL) has unfavorable mechanical DL characteristics, such as large diameter, high stiffness, and low flexibility, which may lead to an increased risk for trauma to the DLES and thus higher DLI rates. In particular, the modular connector, which allows for easy replacement of the modular DL cable, increases the DLs rigidity and may result in a higher risk of DLI.[7,10]

Because the HM3 is currently the only commercially available LVAD on the market, new dressing techniques are needed to compensate for its unfavorable mechanical features and to prevent trauma at the DLES.[7,10,11] To date, there is little evidence as to which dressing technique is most effective, and no consensus on a best practice dressing procedure has been established.[11,12] This lack of best practice is reflected in the wide variability in DL infection rates between VAD centers.[13] The most beneficial care protocols appear to

From the *Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria; †Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Vienna, Austria; and ‡Ludwig Boltzmann Institute for Cardiovascular Research, Vienna, Austria.

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Correspondence: Thomas Schlöglhofer, Department of Cardiac Surgery, Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Waehringer Guertel 18-20, Leitstelle 4L, 1090 Vienna, Austria. Email: thomas.schloeglhofer@meduniwien.ac.at.

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be those that include chlorhexidine, a silver-based dressing, and an adhesive anchoring device to immobilize the DL.[12] The use of an anchoring device to immobilize the DL is also recommended by the International Society for Heart and Lung Transplantation[8,14] and serves the dual purpose of securing the DL and reducing tension and trauma to the DLES. However, because there is no product recommendation or evidence of superiority of one anchoring device over another,[12] this *in vitro* study aims to mechanically evaluate the effectiveness of different commonly used DL anchoring devices.

Materials and Methods

Search Strategy for Anchoring Devices

Commonly used anchoring devices were identified through a literature review and by contacting international VAD implanting centers in April 2023. All selected devices consisted of a self-adhesive anchoring plate and a tie for DL fixation. Alternative immobilization techniques such as binders or sutures were not included.

The literature review was conducted according to the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) statement[15] using the database "PubMed" (Figure 1). The search terms used were "driveline infection," "driveline exit site care," "driveline anchoring," "driveline fixation," "driveline immobilization," "driveline infection and anchoring," and "driveline infection and fixation." Only original articles and reviews providing the full name or an image of at least one anchoring device were included. The following nine international VAD implanting centers were contacted as additional sources: Medical University of Vienna, Vienna, Austria; Hannover Medical School, Hannover, Germany; University Medical Center Utrecht, Utrecht, the Netherlands; The Alfred Hospital, Melbourne, Australia; St Vincent's Hospital, Sydney, Australia; Mayo Clinic Rochester, Rochester, NY; University of Chicago Medicine, Chicago, IL; Bryan Heart, Lincoln, NE; and Advocate Christ Medical Center, Oak Lawn, IL.

Mechanical Measurement

For mechanical characterization of the anchoring devices, an *in vitro* model of the DLES and abdomen was constructed (see Figure 2) in which a tensile force could be applied from an adjustable angle to a HM3 LVAD DL (Abbott Laboratories, North Chicago, IL) and the resulting force on the artificial DLES recorded.

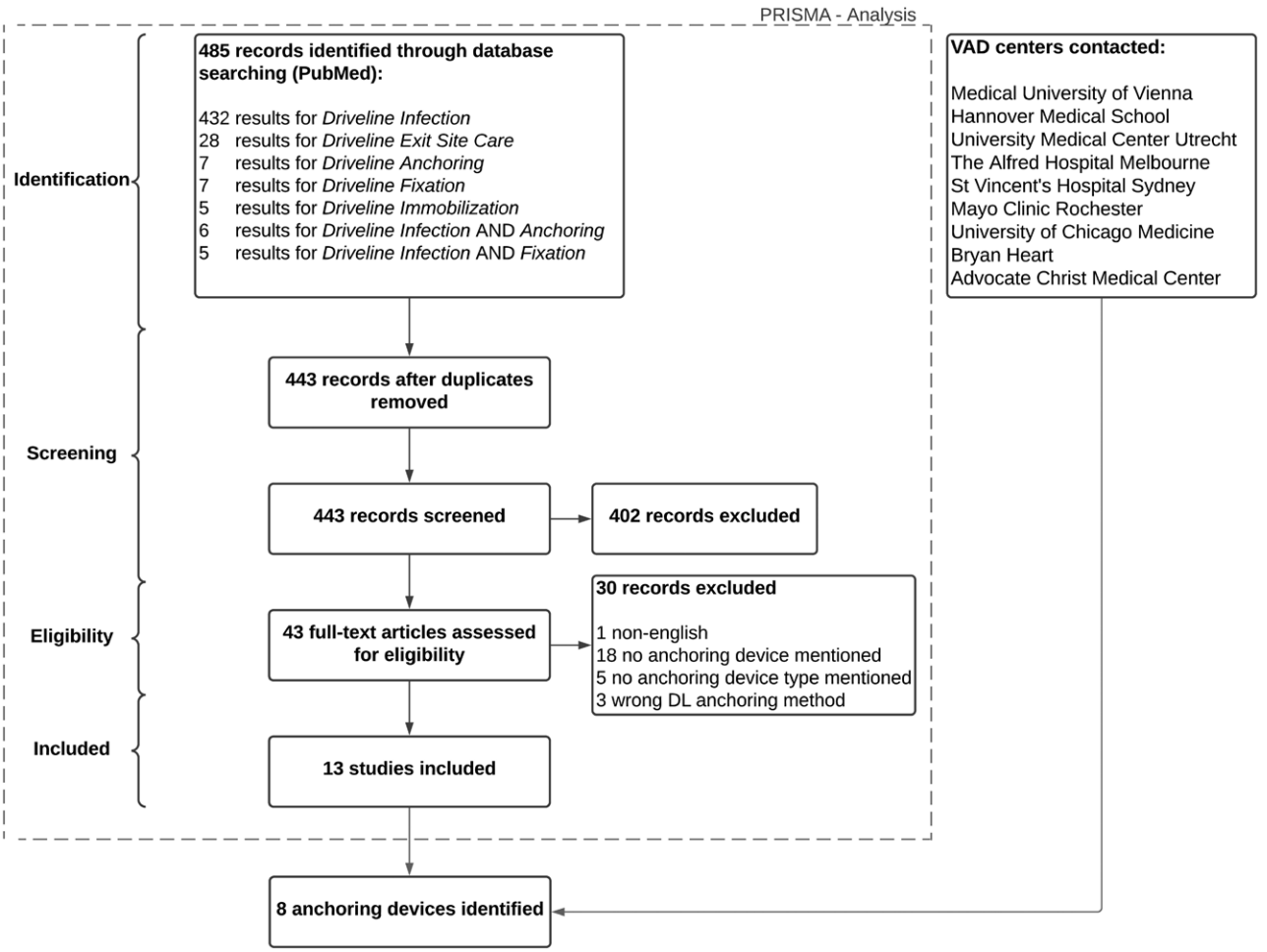

Figure 1. Search strategy for identifying anchoring devices after the PRISMA statement. DL, driveline; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta Analysis; VAD, ventricular assist device.

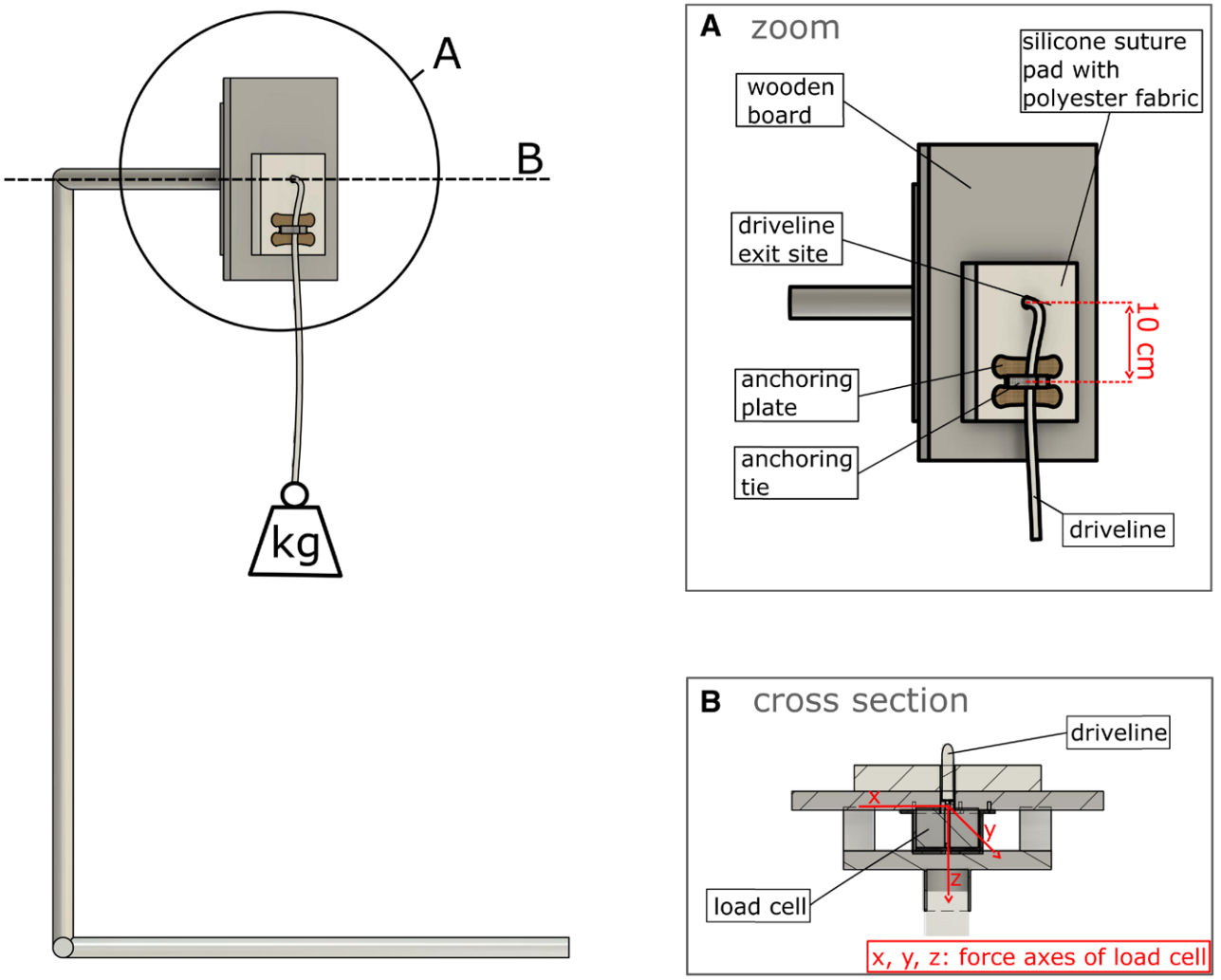

Figure 2. Setup for tensile force measurement; the abdomen model A is mounted routable on a stand. **A**: Zoom of abdomen model with driveline and anchoring device attached. **B**: Cross section of abdomen model showing the position of the load cells and its axis alignment.

The artificial abdomen consisted of a silicone suture training pad (Skin Stitchtraining Module; Blue Butterfly Medical Model Co. Ltd., Guangdong, China) covered with a knitted polyester fabric. To identify a suitable material with adhesion properties similar to human skin, seven different materials were evaluated in a 90° peel-adhesion test according to ÖNORM ISO 29862:2018[16] to assess the maximum peeling force and the slope of the peeling force by calculating the time constant at which 63.2% of the maximum peeling force was reached (see Supplementary Material 1, Supplemental Digital Content, http://links.lww.com/ASAIO/B169).

To mimic the DLES, the end of the DL was guided through an opening in the artificial abdomen and then connected to a 3-axis loadcell (±50 N, F233 Multi-Axis Loadcell; Novatech Measurements Limited, St. Leonards on Sea, England). Tensile force was applied by attaching a 1 kg weight to the distal end of the DL and suspending it freely in the air. The setup was rotatably mounted on a stand to simulate tensile forces from different directions.

Each anchoring device type and a reference measurement without fixation were measured five times. For the anchoring devices, the anchoring plate was removed from its packaging, warmed with a heat gun for 1 min to simulate skin temperature, as temperature affects the adhesion properties of some adhesives,[17] applied to the artificial abdomen and heated again for 1 min. The DL was then immobilized with the securement strap and the weight was applied. Subsequently, the setup was rotated manually and a 10 sec measurement was taken every 10° from 0° to 90°. Over these 10 sec, the mean force was calculated for each axis to account for the periodic oscillation of the weight, and forces measured on all axes were combined into a total tensile force (F_{Total}). The F_{Total} for each angle and anchoring device was plotted in a 90° polar plot and classified into four force categories (high protection: 0–25%, medium protection: 25–50%, low protection: 50–75%, and no protection: 75–100% of the applied tensile force). In addition, the angle at which each anchoring device tore off the abdominal model was documented as tear-off point.

Statistical Analysis

Statistical analysis was performed in SPSS (IBM SPSS Statistics, Version 28.0, SPSS Inc, Chicago, IL). Statistical significance was set at p value of less than or equal to 0.05 for all

statistical tests. Descriptive statistics are stated as mean ± standard deviation for normally distributed continuous variables and as median (interquartile range [IQR]) for non-normally distributed continuous variables. The Shapiro–Wilk test was used to test for normal distribution. Categorical variables (data points per force category) are reported as percentages (%). One-way analysis of variance (ANOVA) or Kruskal–Wallis test was used to test continuous variables (F_{Total}, depending on the lowest tear-off point) between groups (anchoring device types), followed by Bonferroni-corrected post-hoc test for multiple comparisons.

Results

Anchoring Devices Identified

After screening 485 articles, 13 studies were included in the literature review.[7,18–29] Details on the screening process are summarized in Figure 1. This process identified three anchoring devices—Secutape (SECUTAPE Velcro binder set big nonwoven; TechniMed AG, Rorschach, Switzerland), Foley Anchor (Foley Anchor, UrineCatheter/Drainage Line/Driveline Securemen; Centurion Medical Products Corp., Williamston, MI), and Hollister (Horizontal Tube Attachment Device; Hollister Incorporated, Libertyville, IL). The VAD centers contacted provided these three anchoring devices, as well as five others (Secutape sensitive: SECUTAPE fixing set for big lumina hydrocolloid; TechniMed AG; Main-Lock: Main-Lock 14; Novo Klinik-Service GmbH, Bergheim, Germany; Grip-Lok: GRIP-LOK (PICC and CVC Securement Device) medium, TIDI Products; LLC, Neenah, WI; Tubimed: Drainagen Fixierung Gr. 3; Tubimed GmbH, Memmingen, Germany; CathGrip: Securement CathGrip large double strap; BioDerm Inc., Largo, FL). A more detailed list and images of all anchoring devices, including sources for the literature review[7,18–29] and specifics regarding use in the contacted VAD centers, are provided in Supplementary Material 2, Supplemental Digital Content, http://links.lww.com/ASAIO/B170.

Mechanical Measurement

In the 90° peel-adhesion tests (Supplementary Material 1, Supplemental Digital Content, http://links.lww.com/ASAIO/B169), knitted polyester fabric was found to have the most comparable adhesion properties to human skin: maximum peeling force (0.38 ± 0.04 N *vs.* 0.57 ± 0.10 N, $p = 1.0$) and peeling force slope (1.08 ± 0.04 sec *vs.* 1.33 ± 0.12 sec, $p = 0.20$). The results of the mechanical tensile force measurements are shown in the polar plot in Figure 3. Their percentage distribution in the previously defined F_{Total} protection zones are depicted in Figure 4. With a maximum tensile force of 2.3 ± 0.3 N at 0°, the CathGrip anchoring device was continuously (100%) in the "high protection" zone. Secutape and Tubimed also had the majority of data points (70% and 60%) in the "high protection" zone, with maximum forces at 10° of 2.8 ± 0.3 N and 3.0 ± 0.2 N, respectively. Secutape sensitive (max. force: 4.0 ± 0.4 N at 10°), Main-Lock (max. force: 3.7 ± 0.6 N at 10°), Hollister (max. force: 2.6 ± 0.5 N at 10°), and Foley Anchor (max. force: 4.5 ± 0.4 N at 10°) were mainly in the "medium protection" zone (up to 80%) with the remaining data points in the "high protection" zone. The Grip-Lok device was the only device with data points in the "low protection" zone (55%) with a maximum tensile force at 5.6 ± 0.9 N (at 20°). When no anchoring device was used, 100% of data points were in the "no protection" zone between 7.9 ± 0.4 N (at 0°) and 8.5 ± 0.1 N (at 60°). The Hollister device had the lowest tear-off point at 30–40°, CathGrip at 60°, Grip-Lok at 80°, and all other anchoring devices at 90°.

Statistical analysis of the tensile forces of the anchoring devices over 0–30° ($F_{Total,0–30°}$) showed that the degree of protection against trauma can be divided into two groups, with means that differ significantly from each other (Figure 4): CathGrip ($F_{Total,0–30°}$ = 2.1 ± 0.4 N), Secutape ($F_{Total,0-30°}$ = 2.6 ± 0.3 N), Tubimed ($F_{Total,0-30°}$ = 2.9 ± 0.2 N) and Hollister ($F_{Total,0–30°}$ = 2.7 ± 0.5 N) had significantly lower tensile forces ($p < 0.05$) at all angles than Secutape sensitive ($F_{Total,0–30°}$ = 3.9 ± 0.4 N), Main-Lock ($F_{Total,0–30°}$ = 3.7[0.7] N), Grip-Lok ($F_{Total,0–30°}$ = 5.4 ± 0.8 N), and Foley Anchor ($F_{Total,0–30°}$ = 4.3 ± 0.5 N). Within the two groups, no significant differences ($p > 0.20$) were found (see Figure 5).

Discussion

Different adhesive anchoring devices are used to secure the LVAD DL to provide stability and minimize tension on the DLES.[8,11,12,14] The selection of an appropriate anchoring device plays a critical role in reducing DLI, as trauma to the DLES caused by movement and manipulation of the DL during everyday activities is a major risk factor for DLI.[9,30] This study, which provided evidence based on *in vitro* tensile force measurement, supports the clinical recommendations[8,14] for the use of an anchoring device by clearly demonstrating that each of the eight anchoring devices tested provides some protection against tensile forces compared to no anchoring device (Figure 3). Therefore, this DL immobilization technique is effective in preventing trauma to the DLES, which may reduce the risk of DLI.

The literature research and consultation of nine international VAD implanting centers revealed that a great number of different adhesive anchoring devices are used in clinical practice, potentially reflecting the center variability[13] in DLI rates. In addition, VAD centers often use multiple products in their clinical practice (Supplementary Material 2, Supplemental Digital Content, http://links.lww.com/ASAIO/B170). However, there was a clear preference toward the Foley Anchor and Hollister devices, which were used in five and six of the centers contacted, respectively, and are frequently cited in literature.[18–25,27–29] With no universally accepted product recommendation for an anchoring device currently available,[11,12] the main finding of this study was that the selection of an appropriate anchoring device plays a critical role in reducing the risk of DLIs and that the use of the CathGrip, Secutape, Tubimed, and Hollister devices resulted in significantly lower tensile forces in a range of 0–30° at the DLES compared to other anchoring devices tested. Therefore, these four devices appear to be significantly more effective in preventing trauma to the DLES than other commonly used devices. The use of any of these four products in clinical practice may therefore be beneficial for the diminishment of the risk of DLI.

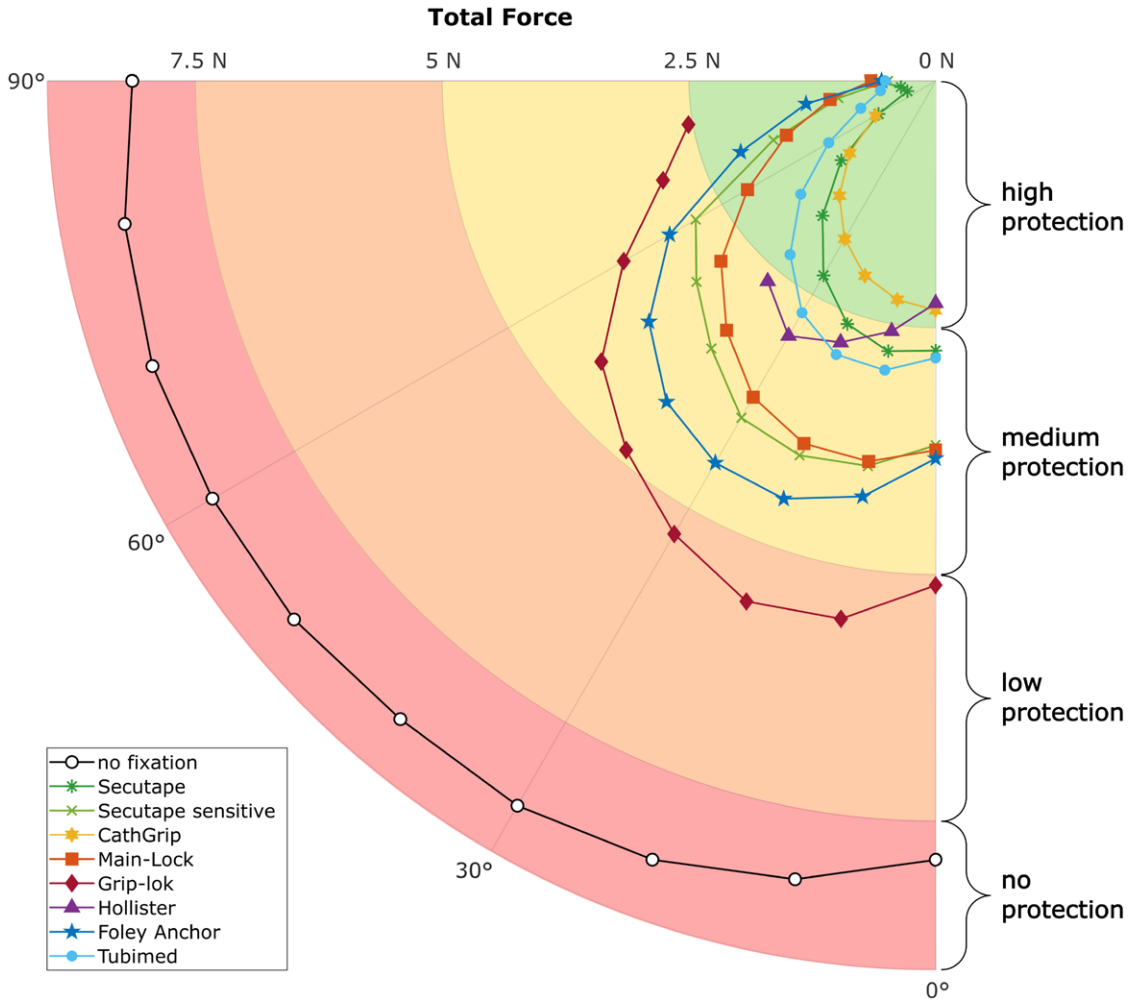

Figure 3. Mean tensile force to the DLES, 90° polar plot, stratified by seven types of anchoring device types and no fixation (protection zone categories: green: high protection [0–25%], yellow: medium protection [25–50%], orange: low protection [50–75%], red: no protection [75–100%] of the applied tensile force). DLES, driveline exit-site.

Figure 4. Bar plot visualizing the distribution of the mean tensile forces to the DLES for each angle and anchoring device stratified by protection zone (green: high protection [0–25%], yellow: medium protection [25–50%], orange: low protection [50–75%], red: no protection [75–100%] of the applied tensile force). DLES, driveline exit-site.

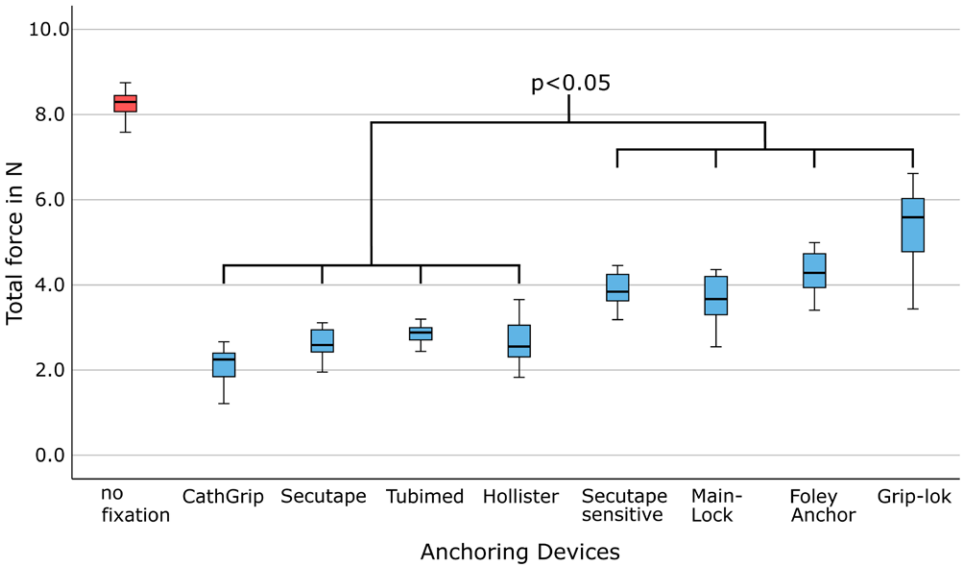

Figure 5. Statistical analysis of the tensile forces (0–30° force application) stratified by anchoring devices (only significant *p* values are presented, all other *p* values were not statistically significant at $p < 0.05$). "no fixation" representing the resulting tensile force without anchoring device as a reference.

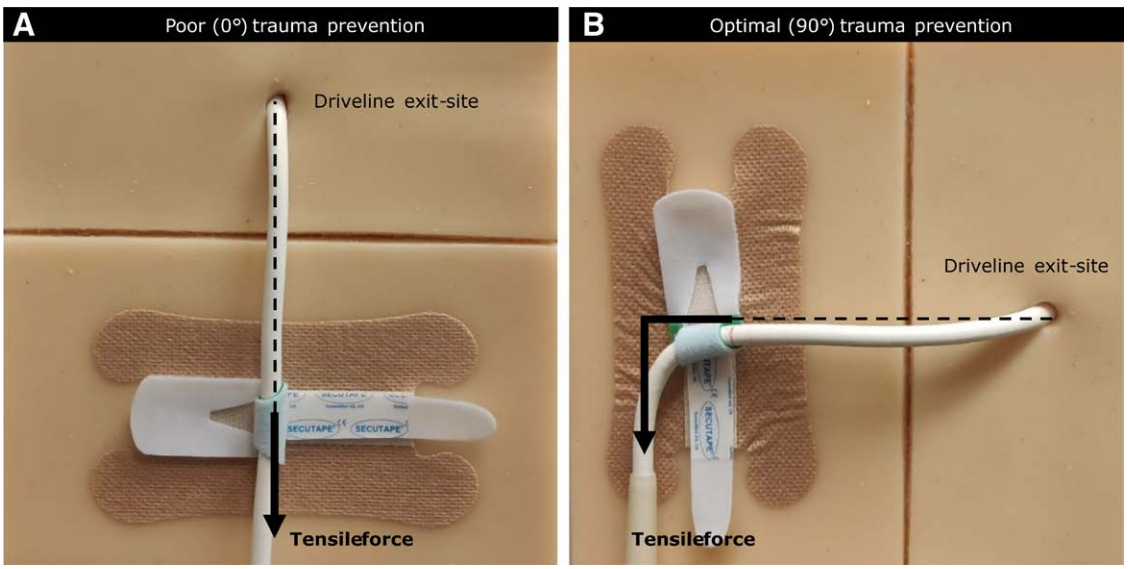

Figure 6. Clinical recommendation of poor 0° (**A**) and optimal 90° (**B**) placement of an adhesive anchoring device for driveline exit-site trauma prevention when the carry bag is dropped.

In addition to effective tensile force absorption, there may be other factors to consider when selecting an adhesive anchoring device. For example, the patient's skin integrity and allergies may influence the decision to prevent skin irritations and medical adhesive-related skin injury.[17,31] Furthermore, the patient's environment and product availability (both locally and financially in terms of health care costs) may also influence choice.[17,31]

Another clinical implication of this study was that, regardless of the anchoring device used, the highest tensile forces were measured when the applied force and the DL were at 0° to the anchoring device and DLES (Figure 6A), whereas less tensile force was applied to the DLES when the applied force (*eg*, in the worst case, by dropping the carry bag) and the fixation point were at 90° (Figure 3). In fact, the anchoring device with the highest total tensile forces (Foley Anchor) performed better at 90° than the best anchoring device with the highest protection (CathGrip) at 0°. This suggests that abdominal positioning is of even greater importance than device selection. Therefore, it may be recommended to apply dressing techniques close to 90° (see Figure 6B) for optimal trauma prevention to minimize the risk of DLI.

This study has several limitations. First, because the integrity of human skin is highly susceptible to change and the skin adhesion properties are influenced by patient-specific factors such as age, health, skincare routine, and environment,[17,31–33] the abdomen model used in this study is only simplified. It does not account for skin aging and hydration, whereas skin

temperature was only approximated. In addition, a substrate model can only simulate the first few minutes after adhesive tape application, as dwell time and external factors such as humidity and temperature affect adhesive properties.[16,17] Second, in the model, the DL exits the abdomen at an angle of 90°, whereas in reality the DL usually exits the body at an angle of approximately 42°.[34] Although this setup, which applied force in the x-y plane, allowed for the assessment of the resultant F_{Total} in three dimensions, further studies could explore actively "pulling" on the DL in the z-axis, simulating abdominal flexion. Third, it is possible that not all anchoring devices used in clinical practice were identified, as no broader international survey, including more VAD centers, has been conducted. Fourth, this study was limited to *in vitro* data, therefore, future research should aim to correlate clinical DLI and provide clinical evidence through a randomized clinical trial, assessing the effectiveness, patient satisfaction, and ease of use of the anchoring devices.

Conclusions

To conclude, the selection of an appropriate LVAD anchoring device plays a critical role in reducing the risk of DLIs. The use of the CathGrip, Secutape, Tubimed, and Hollister devices resulted in significantly lower tensile forces to the DLES compared to other anchoring devices tested. Regardless of the type of anchoring device used the angle of fixation can be a major factor in optimal trauma prevention to minimize DLIs.

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