INCOR® INVASTOP

Reduction of Driveline Infection

Results of a Clinical Study
INCOR® Redesigned Driveline

Potential reduction of driveline infection rate due to redesigned driveline
- The length of the driveline velour was adapted to anatomical needs (shortened from 38 to 19 cm)
- Driveline silicone section is prevalently exposed at the percutaneous driveline exit site

Clinical intention
- Anti-adhesive silicone surface reduces attachment of pathogens
- Protective barrier against pathogens due to rapid-consolidation of epidermal integrity
- Classic driveline tunneling technique can be maintained

FIGURE 1 Driveline silicone section is exposed at the percutaneous driveline exit site
Courtesy of Prof. C. Schmid, Universitätsklinikum Regensburg, Germany

1 Merchel et al., J Heart Lung Transplant. 2012 Apr;31(4):S21
Driveline Infection Rate in Literature

Potential reduction of driveline infection rate due to driveline with only silicone section exposed

- Driveline velour is essential for fixation and ingrowth in subcutis
- Driveline exit site infections occur in more than 30% of LVAD patients¹
- Increased patient activity correlates with increase in driveline infection rate due to tension at exit site that leads to loss of driveline-intergument barrier¹
- Negatively affects long-term survival in VAD patients¹,²
- Increases the risk of ischemic and hemorrhagic strokes by up to eightfold¹,²

<table>
<thead>
<tr>
<th>Publication</th>
<th>Patients</th>
<th>Freedom from driveline infection Silicone-to-skin interface at exit site*</th>
<th>Freedom from driveline infection Velour-to-skin interface at exit site</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSI-registry</td>
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<tr>
<td>Dean et al., 2015</td>
<td>200 vs. 201 patients</td>
<td>at 1 year: 77 %</td>
<td>at 1 year: 91 %</td>
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<tr>
<td>J Heart Lung Transplant 2015;34:781–789</td>
<td>Time on support ≥ 10 months</td>
<td>at 2 years: 65 %</td>
<td>at 2 years: 83 %</td>
</tr>
<tr>
<td>Singh et al., 2014</td>
<td>80 vs. 45 patients</td>
<td>at 1 year: 80 %</td>
<td>at 1 year: 91 %</td>
</tr>
<tr>
<td>ASAIO Journal 2014; 60:613–616</td>
<td>Mean follow-up period 628 days</td>
<td>at 2 years: 63 %</td>
<td>at 2 years: 91 %</td>
</tr>
</tbody>
</table>

* Implementation of novel tunneling technique to keep the entire driveline velour portion in subcutaneous tunnel

¹ Goldstein et al., Driveline Infections in LVADs: Is it the Pump or the Patient?, JHLT, 2011
² Aggarwal et al., ASAIO J. 2012; 58: 509-513
**Prospective, observational, multi-center, non-invasive survey**

**Primary objective**
Evaluate infection rate at driveline exit site

**Definition driveline exit site infection**
Combination of pain, swap positive regarding infection, redness, induration & sanies

**Patient population**
22 patients

**Investigator sites**
Universitätsklinikum Erlangen, Germany
Universitätsklinikum Regensburg, Germany
### Preoperative demographic data

<table>
<thead>
<tr>
<th>Variable</th>
<th>INCOR® Patients (n=22)</th>
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<tbody>
<tr>
<td>Mean age in years (range)</td>
<td>56 (45-77)</td>
</tr>
<tr>
<td>Mean BMI in kg/m² (range)</td>
<td>27.4 (21-36)</td>
</tr>
<tr>
<td>Ratio male/female in %</td>
<td>96/ 4</td>
</tr>
<tr>
<td>Preoperative ECMO in %</td>
<td>23</td>
</tr>
<tr>
<td>Preoperative IABP in %</td>
<td>20</td>
</tr>
<tr>
<td>Preoperative Impella in %</td>
<td>5</td>
</tr>
<tr>
<td>Mean CI in l/min/m² (range)</td>
<td>1.7 (1.2-3.0)</td>
</tr>
<tr>
<td>Mean LVEF in % (range)</td>
<td>15 (5-25)</td>
</tr>
</tbody>
</table>

### Preoperative diagnosis

- **Acute myocardial infarction**: 9%
- **Ischemic CMP**: 55%
- **Idiopathic CMP**: 36%

### INTERMACS level

- **Level 1**: 36%
- **Level 2**: 36%
- **Level 3**: 18%
- **Level 4**: 5%
- **Level 5**: 5%

All patients were NYHA class IV. 72% of patients were either INTERMACS level 1 or 2. 91% of the patients were indicated for bridge to transplantation.

72% INTERMACS level 1 or 2
Competing outcome with 1-year survival (n = 22)

In this severely sick patient population, 1-year survival was 73 % (32 % transplanted, 41 % still on device). Mean time on device was 238 ± 135 days.
Freedom from driveline infection

Freedom from driveline infection at one year in patients with silicone-to-skin interface was 86 %.

Driveline infection rate in this cohort was 6 % (0.10 EPPY).

Isolated pathogen at driveline infection site was Methicillin-resistant Staphylococcus aureus (MRSA).

Velour was exposed at percutaneous exit side post-implantation in three patients. Migration of driveline from silicone-to-skin to velour-to-skin interface was observed in further two patients (e.g. significant weight loss). These patients were excluded from evaluation of freedom from driveline infection with silicone-to-skin interface.

Driveline infection rate (silicone-to-skin interface) 6 % (0.10 EPPY)
Reduction of driveline infections particularly important in long-term VAD therapy as it is associated with increased morbidity and mortality.

Reduced rate of driveline infections could be demonstrated in patients with INCOR® VAD with redesigned driveline (silicone-to-skin interface).

Driveline infection rate (silicone-to-skin interface)
6% (0.10 EPPY)