CorMatrix® Pediatric Performance
Summary of 809 Published Procedures
CorMatrix Pediatric Performance

SIS-Extracellular Matrix (ECM) has been extensively studied and implanted in over 1,000,000 patients. CorMatrix ECM has been used for cardiac tissue repair since 2007. The unique properties of ECM (resistance to calcification and infection, the ability to remodel into site-specific tissue and the potential to grow in the young patient) make its use popular with pediatric heart surgeons. Dacron, BP or other synthetic or cross-linked materials do not possess these characteristics and will likely require repeat surgeries for the pediatric patient.

Several long-term patient series have been published on the use of CorMatrix in the pediatric/congenital population. The data from 5 recent publications show a success rate of 96% when CorMatrix was used in 809 procedures. Failure was defined as any patient who required intervention (surgical or catheter based). The most common type of failure was stenosis of small-branched pulmonary followed by valve regurgitation after using CorMatrix for MV/AV repair [PA (13) and MV (4), AV (7), and TV (1)]. This document provides more details on these 5 publications.

Of the 809 procedures reported, 4% (32 procedures) required surgical or catheter-based intervention related to ECM. Intervention details are shown in Figure 2.

*Failure in this summary is defined as any patient who required surgical or catheter based intervention.

FIGURE 1: CorMatrix ECM Procedures in the Pediatric/Congenital Population

FIGURE 2: Intervention Type & Quantity

<table>
<thead>
<tr>
<th>Condition</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Artery Stenosis</td>
<td>13</td>
</tr>
<tr>
<td>Aortic Valve</td>
<td>7</td>
</tr>
<tr>
<td>Mitral Valve</td>
<td>4</td>
</tr>
<tr>
<td>Tricuspid Valve Stenosis</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
</tr>
</tbody>
</table>
Select Key Literature

   - N= 37 Patients (48 repairs with CorMatrix); Mean follow-up= 411 days; 2 cases that required intervention (95% success rate).
   - Repair locations include: ASD= 11; PA= 12; superior cavo-pulmonary anastomosis=7; RVOT=6; supravalvular aorta=3; pulmonary root=3; VSD=2; pulmonary valve=2; SVC=1; LVOT=1.
   - 2 cases of CorMatrix failures (95% success rate).
   - RVOT stenosis
   - PA stenosis (treated with balloon dilation and stent placement). In this case, CorMatrix was used to reconstruct the majority of the circumference of the PA. The authors suggest that using CorMatrix as a full conduit should be avoided.
   - All patients were followed by echo post-procedure at varying intervals.
   - There were no cases of thrombosis, aneurysm, calcification or patch tearing.

   - N= 103 patients; 132 procedures; Median follow-up= 23.3 months; 14 cases that required re-intervention (89% success rate).
   - Repair locations include: Valve=38; septal repairs=16; arterioplasties= 71; other= 7.
   - No complications or deaths related to ECM.
   - There were 6 re-operations that were required due to ECM failure. 5 of these failures were after leaflet extension in Aortic Valve and 1 was after a leaflet extension of anterior leaflet of MV.
   - Intervventional procedures were required in 8 patients due to PA stenosis. 4 patients required balloon dilation and 4 required stenting.
   - This series also evaluated functional failure (valve regurgitation after free edge extension was the most common mode of functional failure).

   - N= 532 patients; mean follow-up= 518 days; Histology was performed on a total of 12 specimens taken from 11 patients. There were 6 cases (5 patients) where the graft demonstrated failure before surgery.
   - 99% of the cases did not require intervention.
   - Cases that required intervention include:
     - 1 MV failure due to infection.
     - 2 AV regurgitation
     - 1 patch thickening when used as a pulmonary venous baffle.
     - 2 RVOT failures

   - N=54 patients (67 repairs with CorMatrix); 8 cases that required intervention in 7 patients (88% success rate).
   - The most common use of CorMatrix was for RVOT and MPA repair (N=33); Septal repair (N=7) and Small Branch Pulmonary artery repair (N=12). There were no failures in either septal repairs or RVOT/MPA repairs.
   - There were 3 cases of small branch pulmonary stenosis, and 1 failure each of an interpositional tubularized graft and a composite graft hood; each required stent placement. There were 2 MV failures (in same patient) and 1 failure after closure of a ventriculotomy.

   - N=30 patients; 2 cases that required intervention. These included 1 PA stenosis that was treated with balloon dilation and 1 TV stenosis, (93% success rate).

This paper highlights the importance of implanting CorMatrix to healthy, viable tissue vs. dysplastic tissue as well as performing patch augmentation for valve repair vs. a free edge extension.
Product Guidelines:

» Soak CorMatrix in room temperature saline for 1-2 minutes.
» Make sure that CorMatrix is sewn to healthy, viable tissue. Prolene suture is recommended.
» Limit the use of glues, sealants and hemostatic agents.
» Do not oversize or undersize the material. Remodeling depends not only on cellular cues, but also the physical environment.

Key Messages

» The data in these papers show that CorMatrix has been used in 809 total procedures with a success rate of 96%. The majority of the failures were stenosis after small branched PA repair that were amenable to balloon or stent intervention.

» When using CorMatrix for valve repair, perform a repair where the ECM is surrounded by viable tissue vs. a leaflet extension which exposes a ‘free edge’. A majority of the valve repair failures are valve repairs (mitral and aortic) where a free edge repair was performed.

» Do not oversize the material. Proper ECM remodeling is dependent on not only the chemical but also the physical microenvironment.

» As cells infiltrate the ECM and lay down their own ECM, there will be a transient thickening of the material. For this reason, do not use the 4 ply CorMatrix for small vessel reconstruction. TYKE (2-ply) should be considered for these repairs. Keep in mind that even though the papers classify PA stenosis following use of the 4-ply material as failures, most were amenable to balloon and/or stent intervention and did not require repeat surgery in the OR.

» ECM relies on M2 inflammation for remodeling. This is different from the traditional M1 foreign body response. In most cases, macrophages were not phenotyped in the literature.

» Sew to viable tissue. In situations where the CorMatrix did not perform as expected, inflammation was seen. Outside of lack of macrophage phenotype, it could indicate that native tissue at time of implant was not viable (scar, etc.)

To see the natural difference of CorMatrix, visit cormatrix.com

ORDERING INFORMATION

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