Clinical and Cost effectiveness of treating patients with bypass occlusions

Rotarex®S vs. Open surgery

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Disclosure

Bruno Migliara

I have the following potential conflicts of interest to report:

☑ Consulting:
  - AB Medica (Italy)
  - Abbott
  - BD Bard
  - Boston Scientific
  - Cook Medical
  - Philips
  - Straub Medical
Bypass failure is related with a high rate of limb loss.

**Limb salvage (2 y) = 23-46%**
Robinson KD, Lombardi JV, Henke PK

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**Limb salvage after infrainguinal bypass graft failure**
Zachary K. Baldwin, MD, Benjamin J. Pearce, MD, Michael A. Curi, MD, MPA, Tina R. Desai, MD, James F. McKinsey, MD, Hisham S. Bassionny, MD, Daniel Katz, MD, Bruce L. Gewertz, MD, and Lewis B. Schwartz, MD, *Chicago, Ill*

*J Vasc Surg*
Open Surgery

Local Thrombolysis

Percutaneous Thrombectomy
# Open Surgery

## Surgical thrombectomy
- Residual thrombus (38-85%)
- Endothelial damage
- Patency (5y) = 19-28%

## Redo-bypass Surgery
- Very complex
- High morbidity
- Poor results in absence of autologous veins
- Patency (2y) = 32-75%

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**Long-term outcome after early infrainguinal graft failure**


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**Redo Infrainguinal Bypass: Factors Predicting Patency and Limb Salvage**

Peter J. Rosi, MD, Christopher L. Skelly, MD, Shari L. Meyerson, MD, Hisham S. Basirvoy, MD, Daniel Katz, MD, Lewis B. Schwartz, MD, James F. McKimney, MD, Bruce L. Gewertz, MD, and Tina R. Deal, MD, Chicago, Illinois.
Local Thrombolysis

**Advantages**
- ‘90s Trials Thrombolysis better than Surgery in bypass failures
- More complete thrombus removal
- No endothelial damage
- Opening of collaterals

**Disadvantages**
- Too slow in patients with acute ischemia
- Not effective in chronic occlusions
- Distal embolization
- Complications (16-41%)

**Success rate** = 69-89%

**Patency (1y)** = 32-65%

**Limb salvage (1y)** = 71-87%

(Zuckerman, Nehler, Vanheer, Lacroix, Camerota)


Ruben Vanheer, MD, Annouschka Laenen, PhD, Lawrence Bonne, MD, Sandra Cornelissen, MD, PhD, Peter Verhammer, MD, PhD, Sabrina Houthooft, MD, Inge Pourneau, MD, and Geert Maleux, MD, PhD.

Leuven and Hasselt, Belgium

**CONCLUSIONS**

...acceptable technical (83.3%) and clinical (62.6%) success

...high number of complications (36.3%)

...amputation rate remains high (18.1%, 1y)
CONCLUSION

...Ekos is very safe and effective treatment option for acute occlusion. Blood flow is restored much faster with mechanical thrombectomy.
Mechanical Atherectomy with Thrombectomy
Rotarex® S

Recanalization of Acute and Subacute Venous and Synthetic Bypass-Graft Occlusions With a Mechanical Rotational Catheter
Christian Wissgott · Peter Kamusella · Reimer Andreason
Cardiovasc Intervent Radiol 2013

Twelve months outcome after percutaneous mechanical thrombectomy for treatment of acute femoropopliteal bypass occlusion
Michael Lichtenberg · Wilhelm Stuhlhoft · Dirk Boese · Birgit Haider
Cardiovasc Interv and Ther 2013

<table>
<thead>
<tr>
<th></th>
<th>Wissgott</th>
<th>Lichtenberg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Success rate</strong></td>
<td>97.6%</td>
<td>81.8%</td>
</tr>
<tr>
<td><strong>Limb salvage (1y)</strong></td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Major complications</strong></td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Mortality</strong></td>
<td>0%</td>
<td>0%</td>
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</tbody>
</table>
Below-the-Knee

BTK “ex situ” vein

BTK Omniflow II

BTK “in situ” vein

BTK Composite
AIM of the Study

…to compare clinical outcomes and treatment costs between OS and MATH in patients with acute, sub-acute and chronic bypass failure causing CLTI in an Italian clinical setting
Clinical ENDPOINTS

- Cumulative patency at 1-year
- Limb Salvage at 1-year
- Patency duration
- Survival

Cost ENDPOINTES

- Intra-operative costs
- Post-operative costs
- Total admission costs

Cost-Effectiveness Analysis

- CEA is a form of economic analysis, where costs and health effects are estimated simultaneously against other relevant intervention
- CEA is expressed, using ICER (Incremental Cost-Effectiveness Ratio), as a ratio between the cost of health gain and the gain in health

\[
\text{ICER} = \frac{C_A - C_B}{E_A - E_B}
\]
### Demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>OS</th>
<th>MATH</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>70.6 (±6.57)</td>
<td>71.6 (±8.56)</td>
<td>0.698</td>
</tr>
<tr>
<td><strong>Male/Female</strong></td>
<td>17/0</td>
<td>24/7</td>
<td><strong>0.034</strong></td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
<td>8 (47.1%)</td>
<td>12 (38.7%)</td>
<td>0.585</td>
</tr>
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### Co-morbidities

<table>
<thead>
<tr>
<th></th>
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<th>MATH</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kidney failure</strong></td>
<td>3 (17.6%)</td>
<td>8 (25.8%)</td>
<td>0.520</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>17 (100.0%)</td>
<td>28 (90.3%)</td>
<td>0.185</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia</strong></td>
<td>15 (88.2%)</td>
<td>23 (74.2%)</td>
<td>0.252</td>
</tr>
<tr>
<td><strong>Diabetes mellitus</strong></td>
<td>7 (41.2%)</td>
<td>15 (48.4%)</td>
<td>0.632</td>
</tr>
</tbody>
</table>
Number of previous revascularizations:

- **SURGERY** = 3.0 ± 1.6
- **MATH** = 2.6 ± 1.3

\[ p = 0.366 \]
### Open surgery vs. MATH

<table>
<thead>
<tr>
<th></th>
<th>OS</th>
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<th>p-value</th>
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</thead>
<tbody>
<tr>
<td><strong>Intra-operative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success rate</td>
<td>17/17 (100%)</td>
<td>31/31 (100%)</td>
<td></td>
</tr>
<tr>
<td>Duration of operation (min)</td>
<td>223 (±81.3)</td>
<td>119 (±60.1)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Blood units transfusion</td>
<td>0.94 (±1.14)</td>
<td>0.00 (±0.00)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td><strong>Post-operative</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU (days)</td>
<td>0.35 (±0.86)</td>
<td>0.06 (±0.36)</td>
<td>0.203</td>
</tr>
<tr>
<td>Blood units transfusion</td>
<td>2.29 (±3.75)</td>
<td>0.68 (±1.54)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Length of hospitalization (days)</td>
<td>10.88 (±8.34)</td>
<td>3.87 (±2.84)</td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

- 15 Redo-bypass (88.2%)
- 2 Thrombectomy (11.8%)
- 29 Rotarex® S (93.5%)
- 2 Aspirex® S (6.5%)
Open surgery vs. MATH

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number at risk</th>
<th>OS</th>
<th>MATH</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>17</td>
<td>7/17 (41.2%)</td>
<td>15/31 (48.4%)</td>
<td>0.43</td>
</tr>
<tr>
<td>MATH</td>
<td>31</td>
<td>25/31 (80.6%)</td>
<td>15/31 (48.4%)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Primary Patency (12-months)

OS: 7/17 (41.2%)
MATH: 15/31 (48.4%)

Patency duration (days)

OS: 116.38 (±190.64)
MATH: 210.63 (±173.34)
# Limb salvage rates

<table>
<thead>
<tr>
<th>Treatment</th>
<th>OS</th>
<th>MATH</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death rates</td>
<td>6/17 (35.3%)</td>
<td>6/31 (19.3%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Limb salvage</td>
<td>15/17 (88.2%)</td>
<td>28/31 (90.3%)</td>
<td>0.83</td>
</tr>
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</table>
## COSTS

<table>
<thead>
<tr>
<th></th>
<th>OS</th>
<th>MATH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRA-OPERATIVE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O.R. minutes</td>
<td>3.345,00€</td>
<td>1.785,00€</td>
</tr>
<tr>
<td>Materials</td>
<td>2.092,00€</td>
<td>4.937,00€</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>5.437,00€</strong></td>
<td><strong>6.722,00€</strong></td>
</tr>
<tr>
<td><strong>PERI-OPERATIVE</strong></td>
<td></td>
<td></td>
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<tr>
<td>I.C.U.</td>
<td>504,00€</td>
<td>0€</td>
</tr>
<tr>
<td>Blood bags</td>
<td>405,00€</td>
<td>122,00€</td>
</tr>
<tr>
<td>Ward bed</td>
<td>3.813,00€</td>
<td>1.557,00€</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4.772,00€</strong></td>
<td><strong>1.679,00€</strong></td>
</tr>
<tr>
<td><strong>TOTAL ADMISSION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>10.159,00€</strong></td>
<td><strong>8.401,00€</strong></td>
</tr>
</tbody>
</table>
CEA (Costs Effectiveness Analysis) shows that MATH is a dominant therapy.
Take home message

- Less invasive
- Less time-consuming
- Less expensive

...producing greater health benefits
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