Long-term patency of vascular grafts of the RaK type with collagen – results after 10 years experience


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History

1906 – autologous vein graft (Carrel and Guthrie)
1950s – arterial homografts (Gross, Hurwith, Bill)
1966 – venous allotransplant, cryopreservation (Barner, Lavelock and Bishop)

xenogenous biological grafts

1952 – synthetic materials (Voorhees, Jaretski, Blakemore)
1955 – nylon grafts, crimping (Edvards, Tapp)
1956 – knitted seamless graft made of Orlon fibre
1960s – knitted and woven grafts made of polyester
1958 – start of manufacture of artificial vascular grafts in Czechoslovakia, 1961 first implantation of these grafts
Ra K (knitted vascular graft with collagen)

→ Ra 1v K – vascular graft, straight, crimped, with collagen
→ Ra bv K – cévní protéza bifurkační, vrapovaná s kolagenem

knitted vascular graft made of biologically inert polyester fibre and coated on the outer side with a continuous film of chemically modified bovine collagen of type I

Manufacturer: Výzkumný ústav pletařský, a.s., Brno (Metea® Division)
Study - design

- aim: to evaluate objectively the 10 years’ clinical experience with this kind of graft in the aortofemoral area (especially the long-term patency)
- prospective descriptive non-randomized study on 103 patients (operated on in the years 1992-1996) in whom an aortofemoral bypass was implanted and who met the requirements of the methodology of a clinical study according to EN 540:1993 and EN 12006-2:1998
- for each patient, a file - Clinical Research Records – was established in which all data were stored
- the set did not include patients operated on for ruptured AAA
- the 30th postoperative day – dividing line between early and late complications
- infections (both early and late) are classified according to Szilagyi
- the state of graft patency was ascertained by objective examination (palpation, Doppler pencil) at regular checkups after 1, 3, 6, 12 months after surgery and then at intervals of 6 to 12 months
Patients’ characteristics

- 5 women, 98 men
- Average age is 57.3 years (24-76)
- The largest group consists of patients from 50 to 59 years of age
- In 69% of patients (71) the main reason for operation was claudication, in 31% critical ischaemia of a limb (limbs)
Set of patients – characteristics

perioperative mortality was 3.9% (4 cases of exitus in the early postoperative period – all with more than one risk factor, ICHS, 3 x IM), altogether 27 patients died during the follow-up period (26.2%)

average time of graft patency follow-up was 62.5 months (ranging from 2 to 120 months)
Summary of diagnoses

- Leriche syndrome (51)
- Asympt. AAA (18)
- Sympt. AAA (14)
- Sten. or obl. AIC or AIE (14)
- Aneurysm AIC or AIE (6)
Risc faktors

- smoking (66)
- hypertension (54)
- obesity (24)
- COM (14)
- DM (44)
- dyslipoproteinemia (55)
- ICHS (39)

Percentages:
- 63.8%
- 42.5%
- 52.5%
- 53.8%
- 23.4%
- 38.3%
- 14.4%
# Early complication - overview

<table>
<thead>
<tr>
<th>type</th>
<th>Number of surgeries (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin infection and subcutaneous infection (Szilagyi I,II)</td>
<td>15 (14,6%)</td>
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<tr>
<td>Reoperations - other</td>
<td>13 (12,6%)</td>
</tr>
<tr>
<td>Reoperations - vascular</td>
<td>2 (1,9%)</td>
</tr>
<tr>
<td>Trombosis</td>
<td>2 (1,9%)</td>
</tr>
<tr>
<td>Embolism</td>
<td>1 (0,9%)</td>
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<tr>
<td>Bleeding</td>
<td>1 (0,9%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>2 (1,9%)</td>
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</tbody>
</table>
## Late complications - overview

<table>
<thead>
<tr>
<th>type</th>
<th>Number of surgeries (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin infection and subcutaneous infection (Szilagyi I,II)</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>Graft infection (Szilagyi III)</td>
<td>3 (2.9%)</td>
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<tr>
<td>Pseudoaneurysms</td>
<td>4 (3.9%)</td>
</tr>
<tr>
<td>Reoperations - vascular</td>
<td>18 (17.5%)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>11 (10.7%)</td>
</tr>
<tr>
<td>Embolism</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Amputation</td>
<td>5 (4.9%)</td>
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</tbody>
</table>
Long-term patency

cumulative primary and secondary patency was evaluated after 1, 3, 5 and 10 years – was evaluated using Kaplan-Meier survival analysis (life table analysis), similarly also cumulative limb-saving was evaluated

further, other factors influencing long-term patency were evaluated using univariate and multivariate analysis (infrainguinal arteries affections, stenosis or obliteration of AFP, surgery time, location of distal anastomosis)
Long-term patency

Patency curve after 1, 3, 5, and 10 years after graft implantation (life table analysis)
Long-term patency after 5 years - comparison

- Littooy F.N., 1993, USA
- Hirt S.W., 1991, Germany
- Tada Y., 1993, Japan
- van der Akken, 1994, the Netherlands
- Friedman S.G., 1995, USA
- Zannetti S., 1996, USA
- de Vries S.O., 1997, The Netherlands
- Zukauskas G., 1998, Kuwait
- Meister R.H., 1998, Germany
- Onohara T., 2000, Japan
- Mingoli A., 2001, USA
- Prager M., 2001, Austria
- Vlachovský R., 2006, Czech Republic
Long-term patency after 10 years - comparison

- Littooy F.N., 1993, USA
- Nevelsteen A., 1991, Belgium
- van der Vliet J.A., 1994, the Netherlands
- Urayama H., 1998, Japan
- de Vries S.O., 1997, the Netherlands
- Prager M.R., 2003, Austria
- Vlachovský R., 2006, Czech Republic
Conclusions

- Implantation of an aortofemoral graft is a procedure with **excellent long-term patency and limb salvage** – cumulative limb salvage is 94% (5 years) and 90% (10 years).
- **Cardiac preparation and intensive perioperative monitoring** can improve perioperative mortality.
- **Lifelong follow-up** is a condition for timely detection of possible developing complications.
- According to univariate analysis, **affection of arterial bed under ligament** („poor run-off“) is a statistically important factor influencing long-term patency.
- Our results are **comparable with those obtained at centers abroad** and currently we dispose of a high-quality and economically affordable graft made by a Czech manufacturer.
Thank you for your attention.