CLINICAL STUDY

Vascular collagen prosthesis of RaK type — long-term patency

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Abstract

In 1990, the vascular prosthesis of RaK type (collagen-impregnated knitted prosthesis), produced by the Research Institute of Hosiery in Brno, was introduced into clinical practice. In 1998, we published our experience with this type of prosthesis in form of a clinical evaluating study performed according to the methods of the EN 540 European Norm.
Now we inform about the results of the studed group followed during 3 years. The long-term patency of the prosthesis in the aortic-phemoral part is 88.8 %; the incidence of infection of the vascular prosthesis in our group studed in the 3-year period is 2.5 %.
Thus we can say that even long-term results confirm our previous good experience with this vascular prosthesis produced in Brno. ***(Tab. 8, Fig. 1, Ref. 11.)***
Key words: collagen impregnated vascular prosthesis, clinical study, long-term patency.

The Second Departement of Surgery of Faculty of Medicine in Brno has a long vascular surgery tradition. In co-operation with the Research Institute of Hosiery in Brno, the departement participates in the research and development of artificial vascular prostheses.

At present, in most cases of vascular reconstructions, the collagen-impregnated knitted prosthesis of RaK type is preferred. It is used in the whole area of the abdominal aorta and iliac arteries as far as the inguinal ligament. When the flow is sufficient and when it is impossible to gain an autologous venous graft, it is used also in the femoropopliteal area above the knee joint.

The aim of the retrospective study is the evaluation of clinical experience with this type of vascular prosthesis and a comparison of some parameters (especially long-term patency) with the results gained in other workplaces. This study is a free follow-up of the Clinical evaluating study, the conlusions of which were published in 1998 (Staffa et al., 1998). Now we report the results of the followed study group after 3 years.

The methods of the clinical study are based on the requirements of the EN 540 European norm that was elaborated and approved by CEN — Commission for European Normalisation. The clinical research protocol was elaborated in accordance with the requirements of the EN 12006-2 European norm, which specifies the previous norm in the problems of vascular surgical implants.

Methods

For an objective evaluation of the long-term patency of the collagen vascular prosthesis, a study group consisting of 80 patients was set up. The patients met the requirements of a retrospective study, that means it was possible to find out the required anamnestic data from the documentation or from an interview, and it was possible to follow them for at the least 36 months. In all patients of this group, a biffurcation aortobifemoral prosthesis was implanted.

Patients with ruptured abdominal aortic aneurysms admitted to the hospital and operated on in an overall severe condition (haemorrhagic shock), who died in an early postoperative period, were not included into the study group. Higher postoperative mortality of these patients does not allow a long-term monitoring of the prosthesis patency; the death of these patients is not related to the implantation of the prosthesis but results from the overall severe condition. On the other hand, all the patients in risk whose death was a result of occlusion or some other complication related to the implantation of the arteficial vascular prosthesis were incorporated into the study group.

That is why our study group consists of patients in whom the prosthesis patency was checked up by an objective examination (pulse palpation, ultrasound probe). The check-ups were regular — after 1, 3, 6 and 12 months and then in biannual intervals, with a minimum follow-up period of 36 months and this condition was recorded in the outpatient documentation. Complications were divided into early and late, the dividing point being the thirtieth postoperative day.

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Tab. 1. Number of patients included in the study group in 1992—1996.

Year	Total number	Number of males	Males %	Number of females	Females %
1992	8	8	100	0	0
1993	18	18	100	0	0
1994	17	16	94.1	1	5.9
1995	25	22	88.0	3	12.0
1996	12	11	91.7	1	8.3
Total	80	75	93.7	5	6.3

Tab. 2. The average age of patients.

Year	Total number	Total average age	Number of males	Male average age	Number of females	Females average age
1992	8	53.1	8	53.1	0	0.0
1993	18	57.4	18	57.4	0	0.0
1994	17	56.5	16	56.4	1	58.5
1995	25	55.0	22	55.8	3	49.3
1996	12	62.9	11	61.7	1	76.3
Total	80	57.0	75	56.9	5	61.4

Tab. 3. Patients' age structure.

Age	Total number	Total %
20-29	1	1.2
30-39	0	0.0
40-49	21	26.2
50-59	24	30.0
60-69	27	33.8
70-79	7	8.8
Total	80	100

Tab. 4. The summary of diagnoses.

Diagnosis	Leriche sy	aAAA	sAAA	rAAA	other aneur.	sten. AIC
number	46	11	9	2	3	9
%	57.5	13.6	11.3	2.5	3.8	11.3

AAA — abdominal aortic aneurysm, a — asymptomatic, s — symptomatic, r — ruptured, sten. AIC — stenosis or obliteration of iliac bed.

Tab. 5. Risk factors.

Risk factor	Number	%
smoking	51	63.8
DM	34	42.5
hypertension	42	52.5
disorder of lipids	43	53.8
excess weight	19	23.4

Data collection was implemented by means of gradual completion of required information on individual patients into the clinical research protocol. Each patient had his or her own protocol.

Study group charakterization

Our study group consists of 80 patients in whom the biffurcation aorto-bifemoral RaK prosthesis was implanted between 1992 and 1996. Table 1 shows the percentage of male and female patients and the number of operations in the study group in the years 1992—1996 (Tab. 1).

Patients' average age is 57 years. Table 2 illustrates age difference between the group of males and females.

The age group between 60—69 years represents more than one third of the study group (33.8 %) (Tab. 3).

Leriche syndrome was the most frequent diagnosis in the study group (46 patients, i.e. 57.5 %) and abdominal aortic aneurysm was the second most frequent one (22 patients, i.e. 27.5 %) (Tab. 4).

According to the classification of lower limb ischemia by Fontain, most patients are in preoperative stage IIB — they complain of claudication after 200 metres and less: 47 patients (58.8 %). 14 patients (17.2 %) complain of claudication after more than 200 m — stage IIA. 5 patients (6.3 %) suffer from resting pains — stage III.

Table 5 demonstrates risk factors of patients in the followed study group.

The most frequent risk factors in the study group were smoking (63.8 %), disorder of lipid metabolism (53.8 %), and hypertension (52.5 %).

Results

All the patients had been examined before an operation and prepared by an internist, and before the implantation of a vascular prosthesis all of them were prophylactically i.v. applied antibiotics (most often Zinacef for 2—3 days). Reconstruction operations were carried out under epidural, general, or balanced anaesthesia (Petrašovič et al., 1996) and under systemic heparinization.

25 patients (31.2 %) had already undergone a vascular operation before. For 55 patients (68.8 %) this was the first arterial reconstruction.

33 patients (41.3 %) were given supporting medicaments, from which anti-aggregants (Anopyrin, Curantyl) were given to 23 patients (28.8 %), Pelentan and Warfarin to 7 patients (8.8 %), and other supporting substances were used for 3 patients (3.8 %).

Postoperative complications have been divided into early (within 30 days after operation) and late, which appeared after the thirtieth day after operation.

Among the most frequent complications (Tab. 6) are infections of skin and subcutis (stage I according to Szilagyi). 15 patients (18.8 %) suffered from it and this is also connected with the number of reoperations other than vascular ones (necrectomy of wounds healing per secundam, resutures). One of the patients had to undergo a vascular reoperation, five patients died in an early postoperative period (2, 12, 16, 21, and 27 days after operation). All of the patients who died belonged to patients with cumulation of risk factors, all of them had suffered from ischemic heart disease before the operation. Only in one case death was directly rela-

ted to an implanted prosthesis as a result of infection of vascular prosthesis (stage III according to Szilagyi).

There are much fewer later complications (Tab. 7) and the most frequent is thrombosis (6 patients; 7.5 %) with a subsequent vascular reoperation in 4 patients. Infection of skin and subcutis (Szilagyi I) was most often cured in our out-patient department (2 patients). A patient operated on for Leriche syndrome died on the 38th postoperative day from peritonitis after repeated revisions of the abdominal cavity because of a pancreatic fistula. We have not encountered late infection of a vascular prosthesis (Szilagyi III) in our study group.

Long-term patency of a vascular reconstruction

From the total number of 80 vascular operations in aortofemoral area, 9 occlusions have been registered (11.2 % of patients) within three years after the operation — 352 days after operation on average. The patency of collagen prosthesis RaK after a year was 92.5%, after two years 90 % and 88.8 % after three years (Fig. 1). One case of death has been included among occlusions (the death was directly related to the infection of the vascular prosthesis). Successful thrombectomy was carried out in 5 cases of occlusion, mid-thigh amputation was implemented in 3 cases. In the followed study group, 6 patients died at the average age of 69 years (the 19th postoperative day on average). Mortality in the monitored study group was 7.5 %.

We have attempted to evaluate statistically whether there is a difference in the incidence of risk factors between the groups of patients with and without occlusion of the vascular prosthesis. Fischer's exact test did not prove any significant difference in the incidence of risk factors in the two groups of patients. A possible explanation can be that there is a small number of patients in the group with occlusion (only 9) or the assumption that the main limiting factor for the function of a vascular prosthesis is the state of the vascular flow tract.

A life-table analysis of the 80 patients has been worked out (Tab. 8).

Conclusion

Our study group includes 80 patients who had the collagen vascular prosthesis of RaK type implanted in aortofemoral area. All of the patients meet the requirements of a retrospective study. After 12 months, the prosthesis is patent in 92.5% of patients, after 24 months it is patent in 90 %, and after 36 months in 88.8 % of patients.

Tab. 6. Early complications.

Type of complication	Number of operations	% of operations
embolism	1	1.3
bleeding	2	2.5
skin and subcutis infection	15	18.8
prosthesis infection	2	2.5
vascular reoperation	1	1.3
compartment syndrome	3	3.8
other reoperation	12	15.0
death	5	6.3

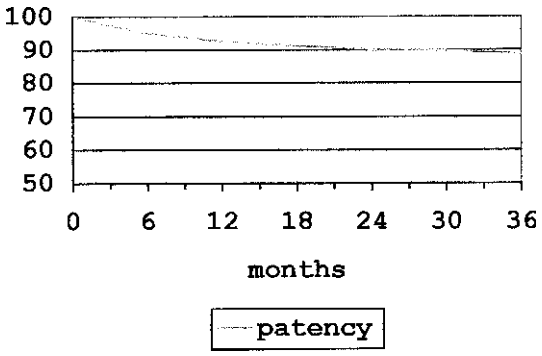

Fig. 1. Long-term patency of the collagen vascular prosthesis RaK.

In the past 10 years, many papers dealing with long-term patency of the vascular prostheses in aortofemoral region have been published. The results, depending on the length of the follow-up period, range from 86—92 %: (de Vries and Hunink, 1997) — 89 %, (Littoy et al., 1993) — 91 %, (Mazuch et al., 1993) — 90 %, (Nevelsteen and Suy, 1991) — 92 %, (Samson et al., 1999) — 86 %, (Staffa et al., 1998) — 90,7 %. Our results are comparable to the conclusions published in foreign literature, that is why we can claim that collagen prosthesis RaK developed and manufactured in Brno is a quality prosthesis and that it fully meets the requirements of the long-term patency (Staffa et al., 1998).

Infection of skin and subcutis (Szilagyi I), which is clinically manifested as impaired healing of operation wounds, was recorded as an early complication in 15 patients (18.8 %). The relative higher frequency of this complication can be explained by the fact

Tab. 7. Late complications.

Type of complications	Number of operations	% of operations
thrombosis	6	7.5
atherosclerosis	2	2.5
skin and subcutis infection	2	2.5
other reoperations	1	1.3
vascular reoperations	4	5.0
death	1	1.3

Tab. 8. Life-table analysis.

Interval months	Obliteration	Losses	Continue	Non-obliterated (%)
0-6	3	6	80	96.3
7-12	2	0	71	93.0
13-18	1	0	69	91.3
19-24	1	0	68	89.7
25-30	0	0	68	89.7
31-36	1	0	68	88.2

that more than 40 % of patients in our study group suffered from diabetes.

Collagen impregnated prostheses heal well in general and therefore they are relatively resistant to infection (Becquemin et al., 1996).

Two patients (2.5 %) of our study group suffered from infection of the vascular prosthesis (Szilagyi III); this number is lying in the bottom third of the interval presented in foreign literature: 0.7—6 % (Franke and Voit, 1996; Hennes et al., 1996).

An important advantage of the RaK prosthesis are lower economic costs.

So we can conclude that even long-term results confirm our previous good experience with this vascular prosthesis produced in Brno.

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