WILL THE CZECH COLLAGEN PROSTHESIS STAND FOREIGN COMPETITION?

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Abstract

The Czech collagen prosthesis - the so-called RaK Prosthesis made by Výzkumný ústav pletašský Brno, was introduced into clinical practice in 1990.

It is a knitted prosthesis finished on its external side by a continuous film of a chemically modified bovine collagen. That secures its nearly zero permeability and thus even extensive vascular reconstructions can be performed without a more significant blood loss. However, some rules must be kept, particularly moisturing the prosthesis in saline solution immediately before its implantation.

The collagen layer is gradually degraded by enzymes. That enables a good healing-in of the vascular prosthesis and secures its resistance against infection as well.

Due to these properties, collagen prosthesis has attracted the interest of vascular surgeons.

The demands laid on an artificial vascular prosthesis are met by that of RaK type as shown by the results of the study carried out, according to the methodology of EN 540 European Norm Proposal, at the IInd Clinic of Surgery in Brno.

Besides others, 90,7 % long-lasting patieny, 0,9 % infection incidence of Szilagyi III type, and last but not least, even economical availability made us to state that RaK Prosthesis can stand well even in the competition with foreign collagen vascular prostheses.

Key words:
collagen-impregnated vaskular prosthesis - clinical study.

INTRODUCTION

One of the basic types of artificial vascular prostheses is represented by a knitted prosthesis (Firt et al., 1991). It has passed through the development from porous prosthesis with the necessity of pre-shrinking, through the so-called DKB prosthesis impregnated by a fibrine glue before implantation up to knitted vascular prosthesis impregnated with collagen during its production. Thus, the impermeability of the prosthesis is secured and blood loss during implantation minimalized (Barral et al., 1995). Then gradual absorption of this artificially placed collagen layer enables a good healing-in of the prosthesis as the principal precondition for the vascular prosthesis resistance to infection. This complies with the demands of vascular surgeons on low porosity with simultaneous ability of good healing-in.

The latter also involve collagen vascular prostheses developed in the Výzkumný ústav pletašský (Research Institute of Hosiery) in Brno (Fig. 1). They
are referred to as RaK Prostheses and have been implanted at our clinic since 1990 (Roubal, 1991).

METHODS

Clinical evaluating trial aimed at objective evaluation of the results achieved by RaK Prosthesis implantation and comparison of those results with the data published in foreign literature was completed at the 1nd Clinic of Surgery in Brno in 1997. For the sake of valid comparison, the trial was drawn according to European Norm EN 540 for clinical trials, and a set of 107 patients corresponding with the demands of a retrospective study was created. Totally 108 collagen vascular prostheses have been implanted in that set.

"Protocol of Clinical Investigation" was built up according to the principles of European Norm EN 12006-2 that gives the concrete expression to the previous norm as regards vascular surgical implants. Besides others, it requires the studied group to have at least 75 patients and 12-months' period of clinical investigations after implanting the last prosthesis in the given set.

The data were collected by means of supplementing necessary information from each patient into the protocol of clinical investigation so that each patient was given one protocol. Then the data were processed and evaluated by computer.

SET CHARACTERISTICS

Leriche syndrome and the abdominal aorta aneurysm were the most frequent diagnoses in the set - which even corresponds with the most often implanted type of prosthesis - bifurcation one (totally in 66 patients) - Fig. 2.

The average age of patients was 57.3 years, men and women formed 96.3% and 3.7%, respectively.

The most frequent risk factor in the set was smoking (68.2% patients), and disturbed lipid metabolism (55.1% patients). Diabetes mellitus was present in 41% patients of the set. More than one-fifth of patients had at least 4 risk factors, only one patient was without the risks mentioned. Table 1.

All the patients were given a prophylactic dosis of antibiotics. The operation was carried out in epidural, or in combination with general anaesthesia (Petrášovíč et al., 1996).

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>73</td>
<td>68.2</td>
</tr>
<tr>
<td>Disturbed lipid metabolism</td>
<td>59</td>
<td>55.1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>50</td>
<td>46.7</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>44</td>
<td>41.1</td>
</tr>
<tr>
<td>IHD</td>
<td>41</td>
<td>38.3</td>
</tr>
<tr>
<td>Positive family anamnesis</td>
<td>33</td>
<td>30.8</td>
</tr>
<tr>
<td>Overweight</td>
<td>22</td>
<td>20.6</td>
</tr>
<tr>
<td>Vascular-cerebral emergency</td>
<td>15</td>
<td>14.0</td>
</tr>
<tr>
<td>Others</td>
<td>8</td>
<td>7.5</td>
</tr>
</tbody>
</table>

RESULTS

Out of the total number of 108 surgeries, 92 interventions (i.e. 84.4%) were completely without early or late complications. The occlusion of vascular
reconstruction occurred in 10 patients (9.3%), namely on the average of 117 days after surgery.

Successful thrombectomy was carried out in 5 of them, i.e. total long-term patency of vascular reconstruction forms 90.7%. The others underwent the amputation of the affected extremity, two patients in early and three patients in late post-operative period. Infection of vascular prosthesis Szilagyi III was recorded in one patient (0.9%). 6 exits in the set gives 5.6% mortality rate, the average age of the died was 67 years, all of them belonged to a group of patients with more risk factors.

DISCUSSION

Výzkumný ústav pleťový (Research Institute of Hosiery) in Brno introduced vascular prostheses of RaK type (knitted collagen-impregnated prostheses) to market in 1990. They started to be used at our clinic in the same year. Due to their properties they have been getting into limelight of vascular surgeons, so that nowadays they have been applied in most vascular-reconstructive interventions. Similarly, the data published in foreign literature have shown the increasing popularity of collagen-impregnated prostheses (Barral et al., 1995; Firt et al., 1991).

This trial aimed at objective evaluation of our clinical experience with the Czech type of collagen prosthesis. The results have shown the increasing and justified popularity of this type of vascular prosthesis.

The essential demands made on a vascular arterial prosthesis involve:
1) long-term patency
2) resistance to infection
3) economical availability

ad 1) Long-term patency of artificial vascular prostheses usually ranges around 90% (Wilson et al., 1987; Barral et al., 1995). Our set involved 90.7% vascular reconstructions with long-term patency, which makes us to state that this aspect is complied with by Czech collagen prosthesis.

ad 2) Infection of vascular prosthesis (Szilagyi III type) occurred in 1 patient (0.9%) in our set. The data published in foreign literature have reported on 0.7 - 6.0% incidence of this complication (Franke et al., 1996), in one of their recent extensive trials, the authors from vascular clinic in Düsseldorf have recorded infection of vascular prosthesis in 1.2% patients (Hennes et al., 1996). Even in this respect, Czech collagen prosthesis can acquit well.

ad 3) If comparing economical costs, the implantation of Czech collagen prosthesis has been shown to be now 3-4x cheaper than the implantation of collagen prosthesis of comparable parameters made by Braun and Vascutek.
CONCLUSION
The results of clinical evaluating trial have confirmed our good experience with Czech collagen prosthesis. It is possible to state that, at present, we have at disposal a very good, reliable and economically acceptable vascular prosthesis of Czech provenience.

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OBSTOJI ČESKÁ KOLAGENOVÁ PROTEŽA V ZAHRANIČNÍ KONKURENCI?

Souborn
Česká kolagenová proteža - tzv. RaK proteža, jejímž výrobcem je Výzkumný ústav pletašský v Brně, byla do klinické praxe zavedena v roce 1990.

Jedná se o protežu pletenou, jež je z vnější strany upravena souvislým filmem chemicky modifikovaného boviního kolagenu. Tim je zajištěna její téměř nulová propustnost, a tak i rozštěpení cévní rekonstrukce lze provést bez významnější krevní ztráty. Je nutno však dodržet některá ustanovení, zejména pak smocení protežy ve fyziologickém roztoku, řízeně před její implantací.

Kolagenové vratva se postupně enzymaticky odbourává. To umožňuje dobré vhojování cévní protežy a zajišťuje zároveň odolnost proti infekci. Pro tyto vlastnosti se kolagenové protežy dostávají do popředí zájmu cévních chirurgů.

Požadavkům kladeným na umělou cévní náhradu odpovídá i proteža typu RaK, jak vyplyvá z výsledků studie provedené podle metodiky návrhu evropské normy EN 540 na II. chirurgické klinice v Brně.

Mimo jiné dlouhodobá průchodu 90,7 %, incidence infekce protežy typu Szilagyi III 0,9 % a v neposlední řadě i ekonomická dostupnost nás opravdu konstatovat, že RaK proteža obostojí v konkurenci zahraničních kolagenových cévních náhrad.

REFERENCES