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Long-Term Clinical Experiences with a New Dural Substitute

Krystyna Pietrucha [a], Lech Polis [b] & Jerzy Bidziński [c]

[a] Institute of Applied Radiation Chemistry, Technical University of Łódź, Poland

[b] Department of Pediatric Neurosurgery, Polish Mother's Memorial Institute in Łódź, Poland

[c] Department of Neurosurgery AM in Warsaw, Poland

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Long-Term Clinical Experiences with a New Dural Substitute

KRYSTYNA PIETRUCHA[a], LECH POLIS[b] and JERZY BIDZIŃSKI[c]

[a]*Institute of Applied Radiation Chemistry, Technical University of Łódź, Poland,* [b]*Department of Pediatric Neurosurgery, Polish Mother's Memorial Institute in Łódź, Poland and* [c]*Department of Neurosurgery AM in Warsaw, Poland*

We have studied the application of irradiation crosslinked collagen-coated polyester mesh as a dural substitute. Earlier, the bioprostheses were characterized by in vitro measuring of physicochemical and biological properties as well as by in vivo testing on experimental animals. Further, very satisfactory effect was obtained in results on application of these bioprostheses in patients. Consequently, this work concerns mainly a delayed observation of the patients after implantation of biomaterial in repairing cerebral and spinal dura. It was found among others, that application of the bioprosthesis in the surgical treatment of dysraphic defect on central nervous system in children such as: meningocele, meningoencephalocele, meningomyelocele makes it possible to approach large hernias, disqualified for operation so far. Neither allergy nor inflammation after operation of patients with intracranial tumor in early and delayed observation was noticed. The authors suggest that the bioprosthesis could be used not only as a very satisfactory dural substitute but also as a substitute of other connective tissues.

Keywords: collagen coated polyester mesh; dural substitute; radiation crosslinking

INTRODUCTION

Injury of the dura mater may result from many causes, including craniocerebral trauma, destruction by tumor, surgical removal and various

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congenital malformation[1]. Many different artificial materials[2-4] or colagenous tissues[5-7] as well as collagen-coated vicryl mesh[8,9] have been employed for dural repair. No ideal graft material is currently available. For many neurosurgeons cadaveric human lyophilized dura mater has been popular. Recently this material has been putatively associated with transmitting Creutzfeldt – Jakob disease[10,11].

In previous studies we prepared a new collagen embedded polyester (PET) mesh as a dural substitute[12]. This material provides satisfactory biological function and compatibility when used as a substitute for dura mater in the animals[1,13]. A recent positive results on the application of this bioprosthesis in patients, suggest that it can be useful as implant in neurosurgery[14-16]. This work concerns mainly a long – term experiences with a new dural bioprosthesis in repairing dysraphic defect of the central nervous system (CNS) in children. Delayed observation of adult patients with intracranial neoplasms and with posttraumatic CSF-leakage were also performed.

EXPERIMENTAL

Materials and method

Bioprostheses of the cerebral and spinal dura were prepared as described in an our earlier report[12]. Collagen type I (Department of Transplantology, Warsaw Medical School) was derived from animals Achilles tendons. Medical-grade Dallop® mesh supplied by Tricomed, Łódź, Poland was used to reinforce the collagen hydrogels. Improved hydrophilic properties of PET were obtained by pretreating with low-temperature plasma. Cross-linking of collagen and simultaneous sterilization of final product was achieved by irradiation.

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Collagen-PET biomaterials were consequently applied as a substitute of dura mater in child neurosurgery with special regards to the treatment of dysraphic defects in the CNS or in adult patients with intracranial neoplasms. Protocol of surgical treatment with the application of collagen-coated Dallop® mesh was described elsewhere[14-16].

Clinical experiences

From January 1991 to September1998, 97 the children and 11 adult patients were operated. The age of operated children was synonymous to the operation time. In 75% of children, surgery was performed within the first hours of life. Out of the whole group of children, 60 cases were the open hernias. In 37 cases the hernia was localized in the sacro-lumbar region, being "open" in 30 cases. In 43 cases were small and 33large hernias in which the diameter of the base of the hernia sac exceeded 5 cm. Only 11 cases were meningoceles. In 8 cases parallel occurrence of lipoma was noted during operation.

The bioprostheses were also used in dural repair of 11 adult patients, 10 with intracranial neoplasms and 1 with posttraumatic CSF-leakage.

RESULTS

Collagen-coated polyester mesh was used to replace, complete or strengthen the cerebral and spinal dura in surgical treatment of children and adult patients.

Early observation

As a result of using collagen bioprostheses in 58 cases of children the wounds healed by first intention, including 5 cases of kyphosis, while only in

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27 patients the healing was completed in certain areas of the wounds by of granulation tissue growth. In 13 cases the areas in question were above the kyphosis. These results caused vertebrectomy to be performed in 3 cases of coexisting kyphosis. Healing those patients was completed by first intention. It should be noted that in children with small hernias healed the wound by first intention in 41 cases and only in 2 cases by granulation. In the cases of large hernia, till now usually disqualified for surgery, 9 of them had the wounds healed by first intention and by granulation 73%. 11 patients deceased during post-operative observation. Only in 5 cases death was caused by circulatory-respiratory insufficiency, due to general infection-possibly from hernia.

Early observation of adult patients after implantation of bioprsthesis was fully favourable.

Delayed evaluation

The 7 years follow up of those children at the Neurosurgical Out-Patient Clinic did not reveal any symptoms of anchorage nor of worse neurological condition associated with cranial hernias, that had survived, began unaided movements. Out of the children operated because of hernia of the vertebral canal (58 cases), 9 can walk with the help of another person and 5 children walk independently.

Control CT scans of the vertebral canal at the level of surgically-treated spine bifid confirmed a very good tolerance to the implanted dural substitute and, what is even more important, without any synechia. In the CT images one could see loose nervous elements in the vertebral canal and separated from the dura mater strengthened by the implanted mesh. The implant together with muscles, fascia and skin, build up a fairly strong wall, protecting the vertebral canal from the dorsal side.

Delayed observation (to 48 months) of all adult patients showed neither allergic nor inflammatory reactions. No CSF-leakage was also noticed.

CONCLUSIONS

1. In early and delayed observation neither allergy nor inflammation after operation of adult patients as well as of children were observed.
2. The application of collagen-coated polyester mesh in surgical treatment of central nervous system hernias makes it possible to approach large hernias, disqualified for operation so far.
3. The use of implant allows not only to close the hernia but protects it against possible infection and strengthen the whole structure.
4. After operation of patients with posttraumatic CSF-leakage no leakage was noticed.
5. Very good tolerance of bioprostheses by organism and their parameters such as: mechanical resistance, watertightness, flexibility and conforming to anatomical contour, easy handling, easy suturing and storing are important advantages in neurosurgical applications.
6. Radiation induced cross-linking of collagen prevents various types of contamination, e.g. by residual chemical reagents.
7. A new Polish dural substitute seems to be better than other one because of its similarity to natural dura mater and relatively low price.
8. Radiation-sterilized prostheses in contrast to other ones do not require any other treatment prior to their implantation, what is an important time-saving factor.

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9. The authors suggest that collagen-coated polyester mesh could be used not only as a very satisfactory dural substitute but also as a substitute of other connective tissues.

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