Late favorable results of duroplasty with biocellulose: clinical retrospective study of 20 cases

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ABSTRACT

Objective: *Considering the importance of dural replacement in neurosurgery, mainly in times of advanced endoscopic skull base approaches, the authors report the late results after implanting of pure biocellulose membrane in 20 patients harboring different types of lesion, from 1996 to 1999, with objective of demonstrate its use in neurosurgery.* ***Method:*** *The casuistic was followed clinically and image studies were indicated when necessary. Dural substitution was achieved by continuous 4:0 prolene suture without additional glue.* ***Results:*** *The casuistic is constituted by four convexity or parasagittal meningiomas, three single cortical metastasis (melanoma, lung and renal carcinomas), two cerebellar gliomas (one multicentric GBM, one pilocytic cerebellar astrocytoma), one decompressive craniectomy for brain edema due to vasosespasm after aneurysm clipping one decompressive craniotomy for cerebral edema after hemorrhage of a giant fronto-parietal AVM, two mirror MCA aneurysms, one pineal and mesencephalic astrocitoma, one quadrigeminal cistern cyst, one accoustic schwanoma, one spontaneous cerebellar hematoma, one decompressive neurovascular operation for trigeminal neuralgia; 1 cauda equina ependimoma, one lombar myelomeningocele. Currently nine patients are alive, none had direct complication of implant. Recent NMR images of survivors do not show the membrane. Three wound infections could not be definitively attributed to patch.* ***Conclusion:*** *The material was considered safe for dural replacement. Due to inadequate elasticity of pure cellulose, the research was interrupted, waiting for a better product, which is currently being tested.*

KEYWORDS

Dura mater/transplantation, brain injuries, neoplasms, prostheses and implants, biocellulose/adverse effects.

RESUMO

Resultados tardios favoráveis de duraplastia com biocelulose: estudo clínico retrospectivo de 20 casos

Objetivo: *Tendo em vista a importância da substituição da dura-máter em tempos atuais, em que a cirurgia de base de crânio apresenta grande demanda, os autores reportam os resultados tardios após implante da membrana de biocelulose pura em 20 pacientes portadores de diversos tipos de lesões neurológicas, entre os anos 1996 e 1999, com a finalidade de demonstrar a viabilidade de seu uso em neurocirurgia.* ***Método:*** *A casuística foi acompanhada com avaliações clínicas periódicas, aleatoriamente realizadas, além de estudos de imagem, indicados quando necessários. A substituição dural foi realizada por sutura contínua de fio prolene 4:0, sem cola de fibrina adicional.* ***Resultados:*** *Foram operados quatro meningiomas parassagitais, três metástases corticais únicas (melanoma, pulmão e carcinoma renal), dois gliomas cerebelares (um GBM multicêntrico e um astrocitoma pilocítico), uma craniectomia descompressiva por edema cerebral hemisférico devido a vasoespasmo após clipagem de aneurisma, uma craniectomia descompressiva por edema após cirurgia de MAV frontoparietal, dois aneurismas de ACM em espelho, um astrocitoma de mesencéfalo e pineal, um cisto aracnóideo de cisterna quadrigeminal, um schwanoma de vestibulococlear, um hematoma cerebelar espontâneo, uma descompressiva neurovascular de trigêmeo, um ependimoma de cauda equina e um mielomeningocele lombar. Atualmente nove pacientes estão vivos e nenhum apresentou complicação relativa ao implante. Exames de RNM recentes dos sobreviventes não mostrou alteração especial no local do implante, não sendo possível reconhecer a membrana. Três infecções de ferida não foram definitivamente relacionadas ao implante.* ***Conclusão:*** *O material foi considerado seguro para substituir a dura-máter. Por causa da inadequada elasticidade e tendência a rasgar da celulose pura, a pesquisa foi interrompida, aguardando material mais adequado, que está atualmente sendo testado.*

PALAVRAS-CHAVE

Dura-máter/transplante, traumatismos encefálicos, neoplasias, próteses e implantes, celulose/efeitos adversos.

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Introduction

In an era of advanced skull base technics, where the efficacy correlated to cost of dural substitutes is questioned, the use of a new substance is justified. Searching for an efficient, safe and cheap material for duroplasty, we report the retrospective late results of twenty patients where a membrane of biocellulose was implanted as dural substitute in different neurosurgical lesions. The objective of this report is to demonstrate the safety and effectiveness in long term observation of a new material, used in humans after preclinical animal studies, in a research carried on at a same institution.[1-3]

Casuistics and methods

During the period from 1996 to 1999 a membrane constituted of pure cellulose, produced by *Acetobacter xilinium* bacteria, submitted to purification and dessecation, was implanted during surgery in different neurosurgical lesions, utilizing a 4:0 prolene continuous suture. The patients were followed postoperatively by clinical observation and image control using CT or NMR. This project was authorized by the Ethics Research Committee of the Federal University of São Paulo (Unifesp).

Results

The casuistic is constituted by four convexity or parasagittal meningiomas, three single cortical metastasis (melanoma, lung and renal carcinomas), two cerebellar gliomas (one multicentric GBM, one pilocytic cerebellar astrocytoma), one decompressive craniectomy for brain edema due to vasosespasm after aneurysm clipping, one decompressive craniotomy for cerebral edema after hemorrhage of a giant fronto-parietal AVM, two mirror MCA aneurysms, one pineal and mesencephalic astrocitoma, one quadrigeminal cistern cyst, one accoustic schwanoma, one spontaneous cerebellar hematoma, one decompressive neurovascular operation for trigeminal neuralgia, one cauda equina ependimoma, one lombar myelomeningocele. Patients were operated on at the Neurosurgical Section of Hospital Santa Isabel, Blumenau, by the same surgeon (LRM), who followed clinically all the subjects, performing neurological assessment and imaging (CT of NMR) control examination without a pre-determined schedule. Image was ordered when clinically necessary.

From the whole casuistic, nine are alive with asymptomatic implant. Five died from basic disease, three brain metastasis and two glioblastomas. Three died of extra neurological septic complications. Two of them had also wound infection: a decompressive craniotomy for rupture of giant fronto-parietal AVM with edema, followed by bronchopneumonia, wound dehiscence, infection and sepsis; a myelomeningocele and hydrocephalus in a newborn, wrongly selected for duroplasty, complicated by wound infection, renal insufficiency and sepsis. The third death was a cerebellar spontaneous hematoma that died with bronchopneumonia. There was a wound dehiscence after a neurovascular decompression causing CSF fistula followed by meningitis. Treated with antibiotics, the fistula closed and the wound healed with graft in place. Currently the patient is cured of his neuralgia and no late symptoms related to patch.

One patient harbouring bilateral middle cerebral artery aneurysms successfully operated at the bleeding site, died two months later due to bleeding of the opposite side aneurysm, while waiting for a second surgery. A parasagittal meningioma totally resected, with an uneventful post-operative period, died ten years after surgery, by hanging at a door latch during a convulsive attack (Table 1).

One melanoma was reoperated for reccurrency. At the reoperation, it was observed by reopening of duramater, no cortical adhesions whatsoever. By another reoperated case with multicentric GBM of the posterior fossa, a thick occipital epidural membrane was detected at the site of the previous implant. The thickening was at the external side, in contact with nuchal muscles, turning difficult the dissection of the dura. When the thickened dura was opened, on the contrary, no adhesion was encountered. At the site were cellulose was implanted, a thin neo pial structure protected the cerebellar surface.

NMR images control studies, done 12 to 14 years after operation showed integration of membrane with no special clue for the site of implant, suggesting late absorption of the material (Table 2).

Discussion

Historical data

Since the report of the first duroplasty performed in 1890, different substances were used for this purpose, which can be divided into five groups for better understanding: metal sheets: gold, silver, platinum, nickel, aluminium, stainless steel and tantalum. Elaborated animal membranes: primary egg membrane, cargill, allantoic,

amniotic, catgut, sheep peritoneum, bovine pericardium[4,5] porcine dermis, meninges and peritoneum,[6,7] bovine and equine collagen.[7-14] Elaborated autologous membranes: fascia lata, fascia temporalis, pericranium, fat, elaborated cadaveric dura mater, industrialized or lyophilized dura mater. Natural or semi-synthetic substances: rubber, collagen, fibrin, gelatine, olive oil and oxidized cellulose. Synthetic substances: celluloid, cellophane, polyvinyl alcohol, polyvinyl sponge, polyethylene, "Orlon", "Vynion N", politetrafluoretilene derivates as PTFE, silicone, mersilene, polygalactine, polyurethane derivates, among others.[15-21]

The majority of those implants was abandoned because of adverse effects as neural tissue adherence, citotoxicity, inadequate mechanic and physical properties. The search for an implant to repair dura mater will go further until the ideal substance be reached, that must be inert, watertight, slowly reabsorbed, without meningocortical adhesions, not capable to tear by suturing, non-toxic, non-carcinogenic, less expensive, easy to obtain and easy to handle by sterilization.[3,22,23]

Pericranial and temporal fascia remains the most used grafts despite the necessity of additional surgical procedure.[24] Recent study attributes the best result in posterior fossa closure when using autologous fascia.[5,15,25] Reinforced fascia lata membrane with pediculated muscular flap is also efficient in treatment of CSF fistulas.[24]

Modern implants

Reviewing the currently most used grafts, we may notice some preferences depending the type of surgery. Various presentations of collagen membrane are currently used in many countries, since the introduction in 1995 by Narotam *et al.*[26] collagen derived membrane either from bovine or equine are abundantly used in USA and Europe, alone or associated with different types of fibrin glues.[7-13,26-29] Extended endoscopic trans nasal. Approaches for skull base report good results with equine collagen, due to its tensor resistance and efficiency in closing midline skull base defects avoiding CSF fistulae, when fibrin glue and nasal mucosa patch is associated.[8-10,12-14,29]

For convexity craniotomies and decompressive craniectomies, besides collagen derivates, porcine small intestinal submucosa, artificial resorbable polyurethane, PTFE (politetrafluoretilene) and propylene glycol membranes are considered safe, with acceptable morbidity.[4,6,16,18,19,21,30-35] At the other side, for closure of posterior fossa and Chiari malformation, comparative studies with fascia and heterologous implants, demonstrated less complications as fluid collection and late healing of wound, when fascia was inserted.[5,15,25]

Biocellulose

The cellulose from vegetal origin can be obtained by industrial synthesis but its use as an intern implant in humans is not recommended because it contains biopolymers, mainly hemicellulose and lignine, which compounds 25% to 50% of the dry plant weight. Besides this, it is known that the mammalian organism does not possess cellulase, enzyme that promotes the cellulose hydrolysis.[36]

Cellulose is also produced by some aerobic bacteria of the order Aetinobacterias, and anaerobic bacterias of the order Clostridium, in smaller amounts. The termites and lobsters produces cellulose in a very small amount, not enough for industrial use. The type *Acetobacter xilinium*, synthetizes cellulose in larger quantities.[36] The bacterial cellulose has a characteristic fibrillar nanostructure, which allows the ability to interact at the induction of tissue regeneration in several mammalian.[37,38] In 1990, Fontana *et al.*[39] reported the possibility of Acetobacter bacteria to produce pure cellulose, in large quantity, if certain type of nutrition is used, such as specific algae. Other Brazilian authors described the use of the membrane for burn lesions, as infection protector and skin regeneration inductor, indicated specially in pediatrics, with expressive reduction of the mortality on this age group.[40-43]

In odontology, it was verified utility of biocellulose in dental furca lesions, for protecting the teeth base after the lesion removal, inducting the healing on the implants bottom area.[44] Its use was also tested in varicose ulcer at the lower limb with success.[45,46] As well as for inducing the formation of a neoduramater following prenatal correction of meningomyelocele in fetal sheep.[47]

Motivated by the similarities between cellulose membrane and some materials used as dura mater substitute in humans, animal trial with biocellulose in dogs detected low fibrotic reaction and enveloping of the implant by a thin internal and a thick external connective membrane, formed by layers of fibroblasts. No cortical adherence and reduction of cellulose thickness with time was observed, suggesting active long-term absoption.[2,3]

Eventual haemostatic effect was not adequately demonstrated but active reabsorption of the material was observed after implanting it inside liver tissue. Strong foreign body reaction and the presence of cellulose granules inside the cytoplasm of liver giant cells were detected by polarized light, after 90 days of implant.[2] Animal studies gathered the idea that cellulose could be used as implants in humans, mainly for dural reconstruction.

The above mentioned experiments allowed the Ethics Committee of Federal University of São Paulo in the year 1995 to authorize the use of the membrane in a small number of patients. The trial should be directed

mainly to severely ill patients, as at that time, there was a general fear of major adverse effects.

After no complications of the first four cases, we gained confidence to use the membrane in benign lesions, starting with a small piece of the material in a cortical and basal multiple meningioma (Figure 1 A-D – Case 5). Two other meningioma cases also received the implant with no adverse effects (Figure 2 A-D – Case 9).

Of the 20 implanted patients, nine are alive with no problem related to implant. Basic illness caused death in nine patients, Case 13 (Table 1) deserves special report as it was an extensive ruptured fronto-parietal AVM which caused an intracerebral hematoma. The first operation was removal of hematoma and partial resection of AVM. After five days he was shunted for hydrocephalus. After seven days the entire malformation was removed and a biocellulose membrane was implanted. Suture line suffered dehiscence with exteriorization of cellulose membrane and infection. Despite external infection, duramater suture line remained closed, avoiding external contact of brain. Careful daily care maintained wound secondary healing despite extradural infection. Lung infection and sepsis, associated with wound problems caused death 90 days after the operation.

Dural patches should not induce infection, despite reports of this complication in presence of some materials without increasing infective power.[17,48]

Case 10 (Table 1) was a mistaken indication of duroplasty in a dorso lumbar myelomeningocele, with secondary infection of the malformations site, a clear misindication for dural replacement. Some pediatric neurosurgeons recommend use of patches, but the preference is always for fascia implant.[5,48,49]

All implanting procedures were relatively easy to perform but elasticity of the membrane was not quite adequate because in some cases it teared during suturing. As tearing tendency is a bias for any dural substitute, we stopped the trial, waiting for modification of the product. In a recent multicentric clinical study, based on our pre-clinical studies, biocellulose was compared favourably with some currently employed dura substitutes.[50]

Recently, the membrane was modified by liophylization, turning it more elastic. A human trial was authorized by National Agency of Health Surveillance (Anvisa) for year 2011 with the new material. The preliminary results of the first ten cases demonstrate also good results and will be published soon.

Table 1 – Summary of the casuistic emphasizing age, type of lesions, method of follow the behavior of the membrane and the outcome until 2009

NR	Age/Gender	Lesion	Methodology of control	Complications/dead - 2009
1	71/F	Right middler cerebral artery aneurysm	CT	Death vasospasmo – no local cheanges
2	65/F	Descompensated hydrocephalus and cerebellar hematoma	Necropsy	Early lung infection – death
3	59/M	Metastasis of right frontal-parietal melanoma	Reop. Recurrency – MRI	None – death primary cancer
4	52/M	Cerebellar vermis tumor	Reop. Recurrency	Death – multicentric GBM
5	45/F	Multiple meningiomas – small convexity meninigioma	MRI	None – alive asymptomatic
6	41/F	Right cerebellar GBM	Reop. Recurrency – CT	Death due to tumor
7	68/M	Metastasis of right cerebellum	MRI	Death due to primary cancer
8	23/M	Parassagital parietal bilateral meningioma	MRI	Death 2006 – accidental hanging
9	53/F	Parassagital parietal frontal right meningioma	Reop. Recurrency – MRI	None – alive asymptomatic
10	2 days/F	Dorso lumbar myelomeningocele	Shunt reop. Inf. – CT	Wound infection and sepsis – death
11	62/M	Left trigeminal neuralgia	MRI	CSF fistula – late wound closure – alive
12	40/F	Right fronto-temporal meningioma	MRI	None – alive asymptomatic
13	33/M	Hematoma intracerebral and AVM	Reop. for infection – CT	Wound infection and sepsis – death
14	22/F	Pineal region tumor	Reop. recurrency – MRI	None – alive with epilepsy
15	62/F	Ependimoma cauda equina	Reop. recurrency – MRI	None – alive with feet pain
16	45/F	Left middle cerebral artery aneurysm	Reop. – CT	None – death contralateral SAH
17	15/M	Cystic astrocitoma	Reop. Occip. Extrad. Hematoma – MRI	None – alive asymptomatic
18	73/M	Left occipital metastasis	MRI	None – death primary cancer
19	62/F	Arachnoidcyst of quadrigeminal cistern	Shunt – MRI	None – alive asymptomatic
20	39/M	Acoustic neuroma	MRI	Right side deafness – alive

Table 2 – Casuistic with outcome according to type of lesion

Type of lesion	Amount of pts	Outcome
Meningiomas	R$ 4	3 alive – 1 late wound healing
		1 late death by hanging
Brain metastatasis	3	3 deaths not related
Glioblastomas	2	2 deaths not related
Aneurysm	R$ 2	1 alive – no complications
		1 died – bleeding opp. Side.
Post. fossa astrocitoma	1	Alive – reop. once
Trigeminal neuralgia	1	Alive – CSF fistula, miningitis, graft left in place, late wound closure
Vestibular schwanoma	1	Alive – no complications
Cerebellar hematoma	1	Death – sepsis, bpn, not related to graft
Parietal AVM – Dec. craniectomy	1	Death – bpn, wund infection, sepsis
Dorsolumbar myelomeningocele	1	Death – wound infection, sepsis
Lumbar ependimoma	1	Alive – no complications
Post. fossa arachnoid cyst	1	Alive – late wound healing
Pineal astrocitoma	1	Alive – good healing

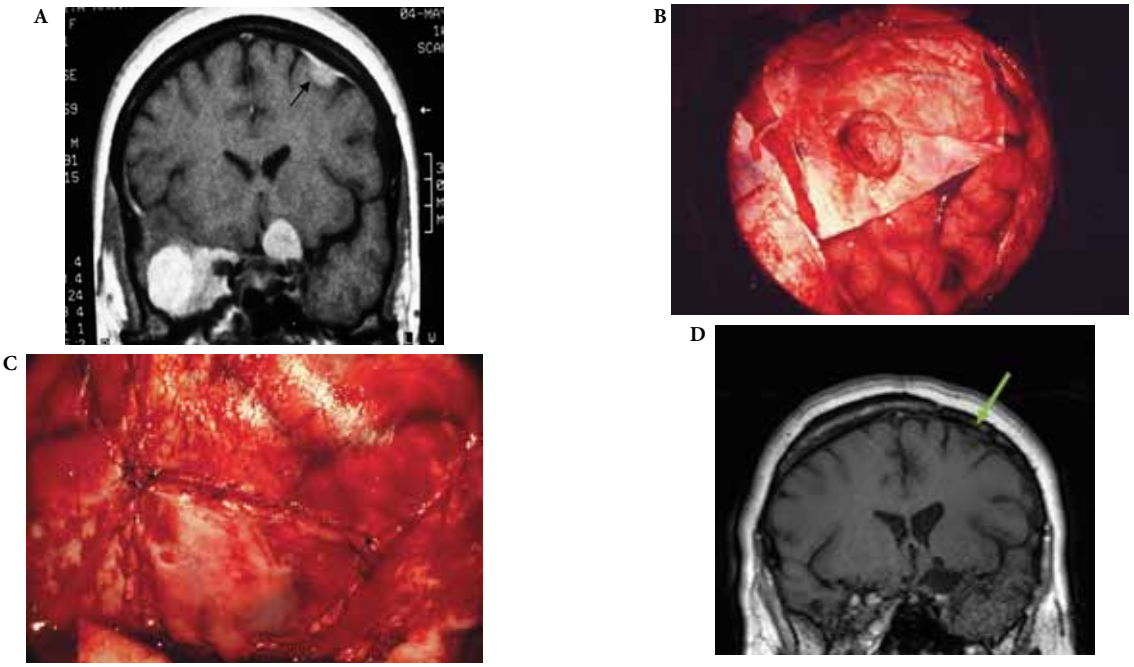

Figure 1 – Case 5 – A. NMR showing multiple meningiomas. B. Ressection of the small left frontal convexity meningioma, substituting with pure biocellulose membrane. C. Aspect of the suture. D. Control NMR from 2009 demonstrating no clue of tumor and absorption of material (note arrows).

Conclusion

In a heterogeneous group of patients, pure biocellulose membrane was implanted as dural substitute with no clinical signs of adverse effects, no increase of CSF fistulas and no special enhancing of the material on control NMR, suggesting late absorption, Two wound infection were by very ill patients. In a patient with post-operative meningitis, the patch remained unaffected.

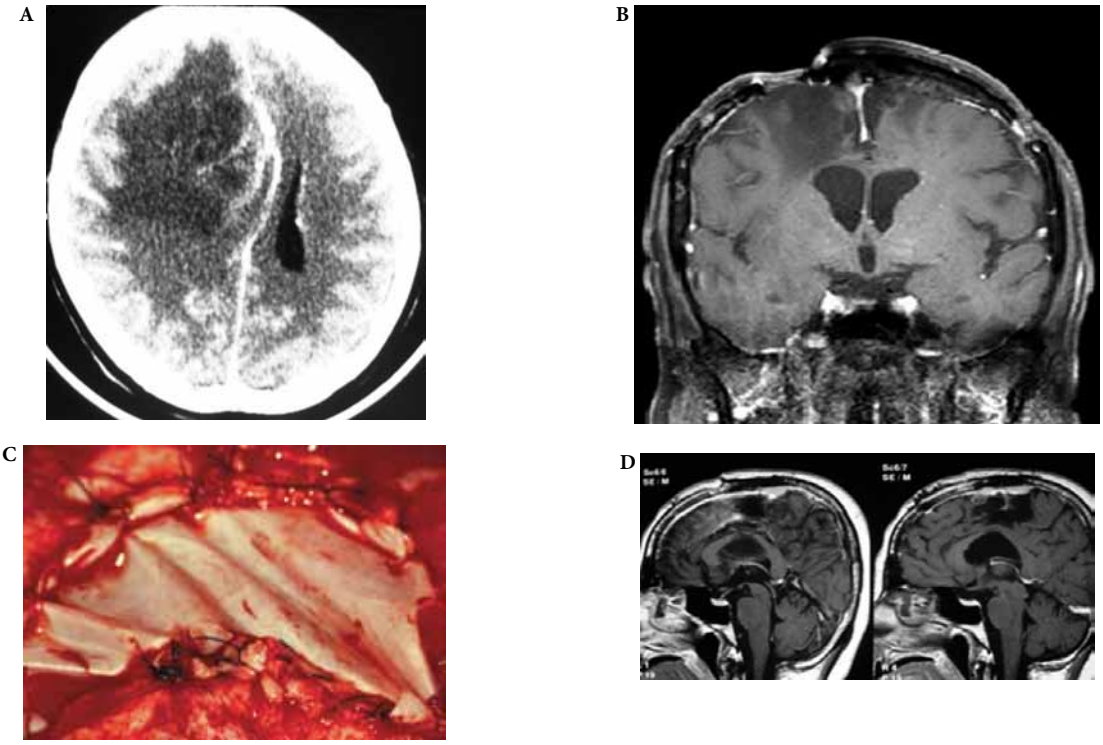

Figure 2 – Case 9 – A. Tomographic aspect of a right frontal meningioma, operated in 1996. B. Picture of dural substitution with biocellulose – Biofill®. C. Control AP and saggital. D. NMR at year 2008, showing total disappearance of the membrane and small tumor remnant at the midline (50 mm).

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