Acta Neurochir (Wien) (2005) 147: 973–976
DOI 10.1007/s00701-005-0581-8

*Acta Neurochirurgica*
Printed in Austria

*Technical Evaluation*

# Clinical evaluation of the polypropylene-polyester knit used as a cranioplasty material

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Received September 22, 2004; accepted June 3, 2005; published online July 20, 2005


## Summary

The paper presents clinical evaluation of the polypropylene-polyester knit used as a cranioplasty material.

*Material.* Between year 1980 and 2002 275 cranioplastic procedures using the polypropylene-polyester plates Codubix were carried out in the Department of Neurosurgery of the Medical University of Łódź. There were 146 patients who primarily sustained head injuries and 129 non-traumatic patients with craniectomies carried out for various other reasons. In the majority of cases, i.e. in 158 patients, cranioplasty was performed later than 6 months after the primary surgery. The largest implant measured 430 $cm^2$.

*Results.* Excellent and good outcome was achieved in 92% of the patients whereas the rate of local infection was 8%.

*Conclusions.* Codubix knitted polypropylene-polyester implant proved to be useful and a safe cranioplastic material.

*Keywords:* Cranioplasty; knitted polypropylene-polyester prosthesis Codubix.

## Introduction

The best material for the repair of skull defects is an autogenous bone [3, 10]. In some neurosurgical departments bone flaps removed during craniectomy are placed in the patients' abdominal walls or preserved by deep-freezing, placing them into antiseptic solutions or by irradiation [1, 3, 6, 9, 14]. However, most of them are disposed off at the time of removal. In these cases artificial cranioplastic materials are utilized. This clinical evaluation of the polypropylene-polyester knit used as a cranioplasty material is based on 275 patients operated on for cranial vault defects in the Department of Neurosurgery, Medical University of Łódź. The first implants were done in 1980, whereas the last ones at the beginning of 2002, allowing for the follow-up period of at least 6 months.

## Materials and methods

*Patients*

In the analysed group there were 193 men and 82 females. Their mean age was 40.2 (range from 12 to 83, but 68% of the patients were between 21 and 50 years old).

Depending on a factor causing the cranial defect, those patients were divided into two subgroups. Thus, there were 146 patients who primarily sustained head injuries and 129 non-traumatic patients with craniectomies carried out for various other reasons.

Amongst post-traumatic cases there were four patients with chronic subdurals operated on through enlarged burr holes. Their defects were as small as 7 $cm^2$. The other 30 patients underwent surgery for depressed skull fractures which resulted in the average defect size of 20 $cm^2$. Finally, the largest subgroup was made up of 112 cases with defects of 50 $cm^2$. Those patients sustained severe head injury complicated by cerebral oedema and raised intracranial pressure and required decompressive craniectomy.

In the subgroup without head injury craniectomy was carried out whilst surgery for a cerebral aneurysm or arterio-venous malformation in 74 patients (57%), for benign brain tumours or bone cysts in 42 (32%) and for cases of intracranial bacterial infection, namely subdural empyemas or cerebral abscesses, in 13 (11%) patients was performed. In this subgroup the size of the defects ranged from 32 up to 430 $cm^2$. The largest CODUBIX implant in this group measuring 430 $cm^2$ was used to cover a craniectomy carried out for excision of a giant convexity meningioma [8]. Causes of the skull defects in our series are summarized in Table 1.

Timing of cranioplasty differed from case to case (Table 2). In 16 patients (6%) the implant was done at the time of the original procedure, i.e. in 4 patients with chronic subdural haematomas, in 2 patients having skull tumours excised, in 4 with depressed skull fractures, in 1 with a carotico-cavernous fistula and in 5 patients with meningiomas infiltrating the bone flap.

Table 1. *Cause of skull defect*

| Traumatic – 146 | | | Non-traumatic – 129 | | |
|---|---|---|---|---|---|
| Enlarged burr holes | Depressed skull fractures | Craniectomy | Aneurysm or AVM | Brain or skull tumour | Empyema or abscess |
| 4 | 30 | 112 | 74 | 42 | 13 |

Table 2. *Timing of cranioplasty*

| | |
|---|---|
| At the time of original procedure | 16 (5.8%) |
| 3 weeks–3 months | 48 (17.45%) |
| 3–6 months | 53 (19.27%) |
| 6–12 months | 121 (44%) |
| >12 months | 37 (13.45%) |

In 48 cases (17%) the cranioplasty was done between 3 weeks and 3 months after the primary surgery. These were mostly the patients who had decompressive craniectomy due to the raised intracranial pressure following cerebrovascular disease or head injury. In these cases the implants were carried out once cerebral oedema subsided. In 53 (20%) patients the reconstruction was done from 3 to 6 months after the craniectomy. However, in the majority of cases, i.e. in 158 patients cranioplasty was performed later than 6 months after the primary surgery, including 37 patients in whom this period exceeded 1 year.

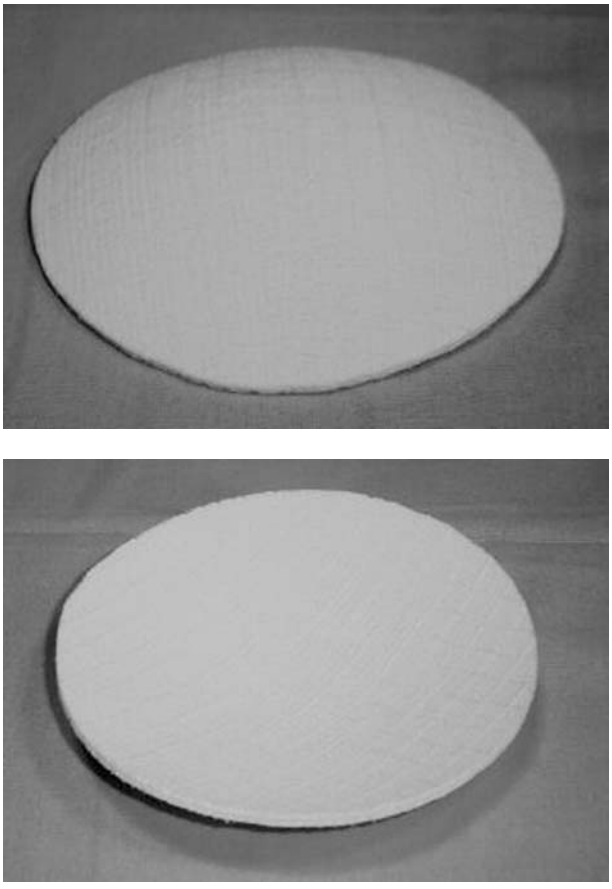


Fig. 1

*Surgical technique*

The surgical procedure was performed under general anaesthesia. The wound was reopened, the implant trimmed with scissors to the required shape, fitted in and fixed with at least three bone sutures. Then, the wound was closed in layers. In the cases operated on within the last four years, several 3 mm holes were made in the implant's centre in an attempt to allow epidural blood to drain to the subcutaneous space, thus preventing formation of an epidural haematoma. The patients were given antibiotics pre- and postoperatively, until the wound was healed and the stitches were removed.

## Results

The result of surgery was defined in a three-grade scale (Table 3). Excellent result meant that the implant healed in with no complications and its shape was adequate to that of the defect. A good result was achieved when the implant healed in without any reactions, but there was a visible asymmetry of the skull, usually due to the fact that the implant was located in the hairless region. A bad result meant that the implant had to be removed.

The outcome assessed 30 days after surgery was as follows excellent – 206, good – 64 and bad – 5 (Table 4). Thus, excellent or good results were achieved in 98% of the cases. However, those results got worse with time as late complications (occurring later than one month after the surgery) were noted in 15 patients in whom the implants eventually had to be taken out. Mean

Table 3. *Grading of the results*

| | |
|---|---|
| Excellent | no complications, perfect shape |
| Good | no complications, visible deformity of skull |
| Bad | suppuration, implant removal |

Table 4. *Outcome assessed 30 days after cranioplasty*

| | |
|---|---|
| Excellent | 206 (74.9%) |
| Good | 64 (23.3%) |
| Bad | 5 (1.8%) |

Table 5. *Overall outcome (follow-up time: 2–22 years)*

| | |
|---|---|
| Excellent | 198 (72%) |
| Good | 55 (20%) |
| Bad | 22 (8%) |

follow-up was 152 months (range 2–22 years). Finally, excellent and good outcome was achieved in 92% of the 275 patients whereas the rate of local infection was 8%, (i.e. it occurred in 22 patients) (Table 5).

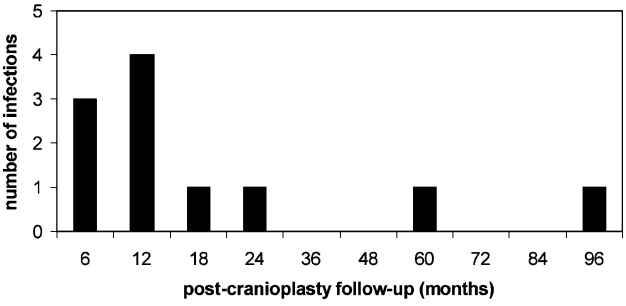
Due to significant differences in outcome, the cases operated on between 1980 and 1987 and those managed after 1987 will be looked at separately.

In the period of 1980–1987 cranioplasty was performed in 71 patients. Mean follow-up was 220 months (range 17–22 years). As many as 11 of them (15.5%) had bacterial infection at the operation site. However, those were early operations with CODUBIX material and preoperative assessment criteria had not yet been established at that time. In 5 out of 11 patients craniectomy was carried out for local osteomyelitis of the cranial vault with soft tissue infection. In those cases the time span between primary surgery and cranioplasty proved to be too short, thus not allowing appropriate healing of the wound. In other two patients the infection resulted from the fact that the cranioplasty was carried out despite intra-operative opening of frontal sinuses. Another patient had intractable epilepsy and sustained the head injury during a fit. The skin was breached over the implant and this caused local infection. Yet another patient had an implant put in despite having post-DXT radionecrosis of the soft tissues in the region of surgery. We have been unable to establish a cause of infection in two patients from that period, the more so because those occurred 5 and 14 months after the surgery.

In 1987 the treatment results with Codubix material were analysed and this allowed us to reach certain conclusions concerning preoperative assessment of the patients. Then we established that cranioplasty with Codubix plates gave the best results when performed at least six months after craniectomy. From that moment on the procedure was carried out only once the site of the craniectomy had completely healed.

Between year 1988 and 2002, 204 cranioplasty procedures were performed. Mean follow-up was 93.6 months (range 2–16 years). Excellent and good results were achieved in 194 cases, i.e. in 95% of the patients. Infection rate was 5.4% (11 patients). Since all of those occurred later than 3 months after the surgery, they are not considered as instances of intra-operative infection. Five of those patients sustained soft tissue injury with skin breach over the implant which then started off the infection. Another patient developed a CSF fistula through the frontal sinus approximately 2 weeks prior to development of infection at the site of the operation.

Table 6. *Occurrence of the infections (1988–2002)*




A cause of infection was not found in 5 patients. Occurrence of the infections is presented in the Table 6.

## Discussion

From the biological point of view the best cranioplasty material is autogenous bone [3, 10] taken e.g. from patients ribs or iliac crest or most notably in a form of the patient's own bone flap obtained during craniectomy. Until cranioplasty procedure, such bone flaps may be stored in the patient's abdominal wall or preserved by deep-freezing, by placing into antiseptic solutions or by irradiation [1, 3, 6, 9, 14]. However, in most circumstances, the availability of this ideal cranioplasty material is very limited. That is why synthetic implants play an important role in repairing skull defects.

The most widely utilized alloplastic cranioplasty material is methylmethacrylate.

However, using it comes with a high risk of infection, estimated in older series at the level of 14 per cent [2, 7]. What is more, fatal systemic allergic reactions to acrylate have been reported [12]. Recently, new safer materials for the repair of skull defects have been introduced: carbon fiber reinforced polymer (CFRP) [15, 16], quick-setting hydroxy-apatite [4, 5, 13] and polyethylene [11].

Codubix cranial bone prosthesis is made of isotactic polypropylene and polyester yarns. Codubix characteristics are as follows: the prosthesis indicates the average pore size of 250 μm, non-hydrophilic fluids absorption determined by water retention value (WRV), density of $0.92\,g/cm^3$; surface weight of $1.9\,kg/m^2$ as well as minimal bending strength of 60 N. The measured Elastic Modulus during compression is 2600 MPa. The crystallinity index of Codubix grafts shows the high value of 0.53 responsible for increase in the resistance against biodegradation.

The prosthesis can be promptly and easily contoured to the required shape during the surgical procedure. Due

Table 7. *Comparison of cranioplasty materials*

| Material | Rate of infections |
|---|---|
| Knitted polypropylene-polyester implant (Codubix 1981–1987) | 15.5% (11/71) |
| Knitted polypropylene-polyester implant (Codubix 1988–2002) | 5.4% (11/204) |
| Carbon fiber reinforced polymer (CFRP) | 4.9% (2/41) |
| CFRP | 0 (0/29) |
| Hydroxyapatite cement (HAC) | 2.6% (2/76) |
| HAC reinforced with tantalum mesh and titanium miniplates | 22.2% (2/9) |
| Quick-setting HAC | 4.8% (3/62) |
| Porous polyethylene implant (Medpor) | 0 (0/611) |

to its disc-like shape it excellently fits into cranial defects. It other advantage is radiolucency and compatibility with magnetic resonance imaging. It is also important that Codubix plates are available in various sizes.

In our series there were mainly fronto-temporal defects following craniectomies for trauma and aneurysm clipping. Most of them were not adjacent to opened paranasal sinuses. Excellent and good cosmetic results were achieved in the great majority of patients.

The infection rate of 5.4% in our newer series makes Codubix a safe cranioplasty material carrying moderate risk of complications when compared with recently published results for other implants [4, 5, 11, 13, 15, 16] (Table 7). The main disadvantage of these prostheses is the fact that it is difficult to achieve excellent cosmetic result in fronto-orbital defects.

## Conclusion

Codubix knitted polypropylene-polyester implant has good capacity of assimilation as a cranioplasty material.

Its obvious advantage is that it can easily be trimmed to the required size during the operation. The other advantages include high strength, low specific weight and lack of water absorption. With strict preoperative assessment of the patients, the postoperative infection rate can be brought down to 5%, which makes CODUBIX one of the safest cranioplasty materials available.

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## Comment

This paper is a description of the results of cranioplasty in one single neurosurgical department using one single method. 275 cranioplasties were carried out during the years between 1980 and 2002 using polypropylene-polyester plates (trade mark Codubix). 8% of flaps had to be removed because of infection, and there was a learning curve, results improved during the study.

This is a presentation of one cranioplasty material, it really is just one among many others. The merit of this paper is that it is a rather large series from one single unit. There is nothing spectacular or unusual in the results, but they give a good base for comparison.

The comparison is important as completely new cranioplasty methods are marketed at the moment; individually designed cranioplasties made with computer aid. They are very expensive and it remains to be seen how much better than the traditional ones they will be.

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