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Five years of experience with biodegradable implants in paediatric surgery

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After successful animal research on minipigs and calves, it was decided in January 1988 to begin the clinical application of PLLA (poly-L-lactide) threaded plugs, nuts and woven bands made of PDS (poly-dioxanon). The implants were made of pure crystalline 1-1-PLLA with an average molecular weight between 220 000 and 500 000 I.E. Mechanical testing revealed a Young's modulus of 4000 N mm^{-2}, a fracture elongation of 2%, and strength values under tension and compression and bending of 55, 110 and 120 N mm^{-2}, respectively. The PDS bands (Ethicon Corp., type XX40) are commercially available items. Operations were carried out on 32 children, aged 11 months to 17 years, in 15 cases for craniofacial malformations, in 16 patients for neurotraumatological lesions and in 1 girl for refixation of an osteochondral flake of the patella. The follow-up time ranged from 3 months up to 5.6 years, with an average of 3 years. The stability achieved was comparable to that of metal implants. No foreign-body reaction or local infections were observed, and it did not become necessary to remove any of the resorbable implants. Furthermore, there was no interference with skull growth. In accordance with these results, PLLA implants fulfill the needs of skull surgery, and it is intended to increase the application of this type of material to orthopaedic traumatology in children.

1. Introduction

The purpose of the present paper is to show clinical results of skull reconstructions and craniofacial osteoplasties in which biodegradable fixation devices have been used. In 1987, osteoplastic reconstructions were performed in 29 Göttinger minipigs aged 6 weeks. The follow-up time was 1 week to 6 months and full stability of the skull was achieved after 4 weeks in all cases. Histological work-up showed osseous impactation of the fragmented screws and nuts, whereas the PDS bands were spread by ingrowing bony trabecula. There was no allergic or foreign-body reaction detected and at the end of the trial intracellular PDS material was observed by polarized light microscopy. Skull growth in minipigs from the sixth week to the sixth month is comparable to that in children between 3 months and 2 years. It was decided to do the first clinical trial in children at the Department of Pediatric Surgery, University Children's Hospital, Zurich. The type of PLLA material and the manufacturing process was not changed from those used in the 1987 animal research [1, 2]. The surgical procedures without and with the use of biodegradable fixation devices remained unchanged for the entire group of children in craniofacial operations and also in neurosurgery. Metal wires, screws and plates were replaced by PLLA nuts, threaded plugs and PDS bands.

2. Materials and methods

The resorbable implant material used is pure crystalline 1-1-PLLA (poly-L-lactide) in block form with an average molecular weight between 220 000 and 500 000 I.E. Mechanical testing of material samples revealed a Young's modulus of 4000 N mm^{-2}, a fracture elongation of 2%, and strength values under tension, compression and bending of 55, 110 and 120 N mm^{-2}, respectively. The implants, threaded plugs and nuts, were manufactured of moulded block material by mechanical processing. The PLLA plugs have a metric thread with an outer diameter of 2.5 mm, a length of approximately 50 mm and can be cut to the needed length. The PLLA nuts have an outer diameter of 5.0 mm and a "four-hole" driver for fixation. The nuts have a maximum thickness of 1.0 mm and are convex on one side to prevent lesions to the overlaying soft tissue. All PLLA implants underwent a normal cycle of ethylene oxide sterilization [2].

The PDS (polydioxanon) bands are produced and sold by Ethicon Corp (type XX40). The thickness is 0.25 mm, the width 10 mm and the length 100 mm. The woven band is sealed at intervals of 10 mm. Between these bars there are holes to allow the passage of threaded plugs. They are also sterilized with ethylene oxide [2] (Figs 1 and 2).

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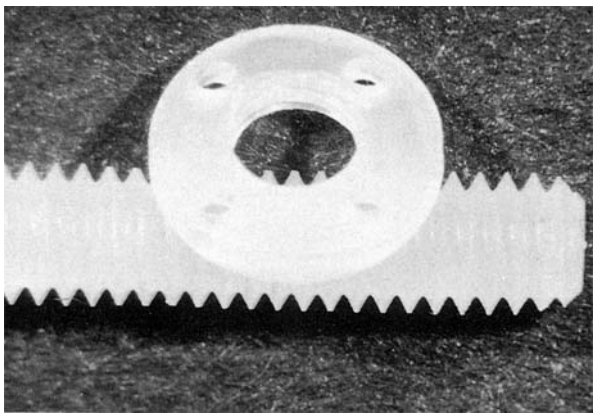


Figure 1 Threaded plugs (2.5 mm) and nuts (5.0 mm/2.5 mm) of 1-1-PLLA with a metric tread.

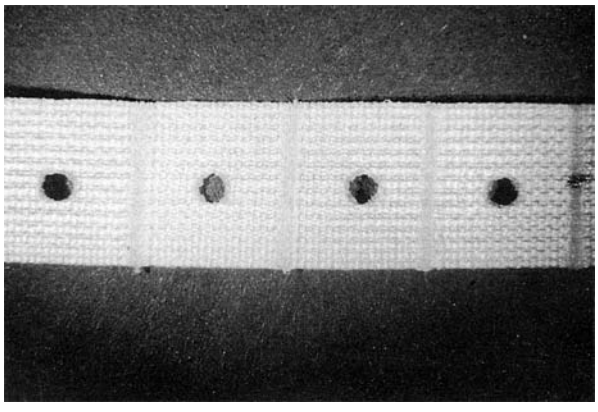


Figure 2 Woven bands of PDS, sealed and perforated at regular intervals.

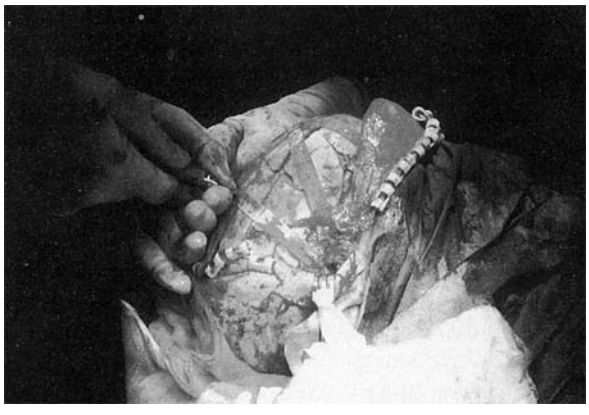


Figure 3 Open head injury of an 8-year-old boy with complete reconstruction of the frontal part of the skull.

Overall, 32 patients, aged 11 months to 17 years (average 6.5 years), have been operated on since February 1988. The follow-up time runs from 3 months up to 5.6 years with an average of 3 years.

2.1. Neurotraumatology

Sixteen patients had sustained a head injury, in six cases leading to osteoplastic trephination with evacuation of subdural and epidural hematomas as an emergency procedure (Fig. 3, Table I). In four patients, due to subdural or epidural hematoma, an osteoplastic trephination was performed several days after the accident. The remaining six children had undergone an osteoclastic trephination for open head injuries 1–4 years before. In those cases in which the skull defect remained unchanged for more than 2 years, it was

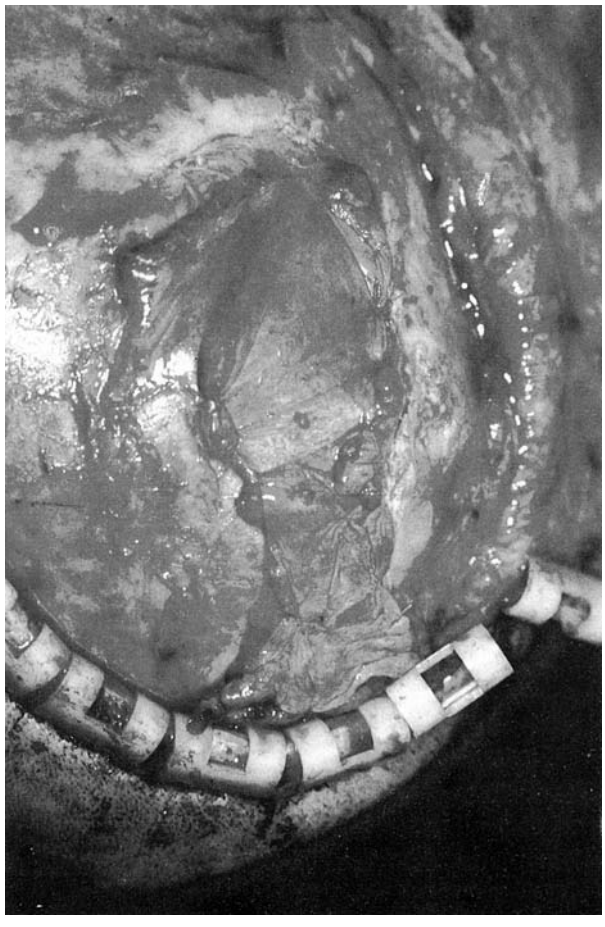


Figure 4 Skull defect of temporal region after osteoclastic trephination 5 years ago.

TABLE I Neurotraumatology ($n = 16$)

Number of patients	Type of operation	Delay since accident	Aera of defect	Outcome
6	Osteoplasty	hours	–	Perfect
4	Osteoplasty	1–10 days	–	Perfect
3	Skull splitting	1–4 years	15–50 cm^2	Perfect
3	Homologous bone substitute	1–4 years	40–78 cm^2	2 good, 1 resorption of all substitute

decided to close it in order to prevent secondary lesions. The area of the defects was 9–78 cm^2. In three cases, the skull defect was closed by skull splitting; in a further three children homologous bone substitutes [5] (Figs 4 and 5) were used.

2.2. Craniofacial surgery

The second group of 15 patients had osteoplastic trephinations and reconstructions to treat Morbus Crouzon ($n = 4$), Morbus Apert ($n = 2$), trigonocephaly ($n = 3$), plagiocephaly ($n = 5$) or occipital encephalocele ($n = 1$). Fronto-facial advancement (with Le Fort III osteotomy) was done in three, floating forehead in ten, a correction of hypothelorismus in one patient and the covering of an occipital encephalocele in one child. In this patient use was made of the same skull splitting technique as already described in the neurotraumatological group (Figs 6 and 7, Table II).

Two-thirds of all patients (neurotraumatology and craniofacial group) did not wear a helmet postoperatively and in no instance was hospital stay prolonged.

2.3. Traumatology

An 11-year-old girl showed the clinical signs of an osteochondrosis dissecans of the right proximal patella. The free body was put back in its bed and fixed with five threaded plugs (Fig. 8). She wore a cast for 6 weeks before attempting weight bearing.

Clinical controls, X-rays and CT scans were made at regular intervals in all patients up until today.

Figure 5 Same patient as Fig. 4. Coverage of defect by skull splitting.

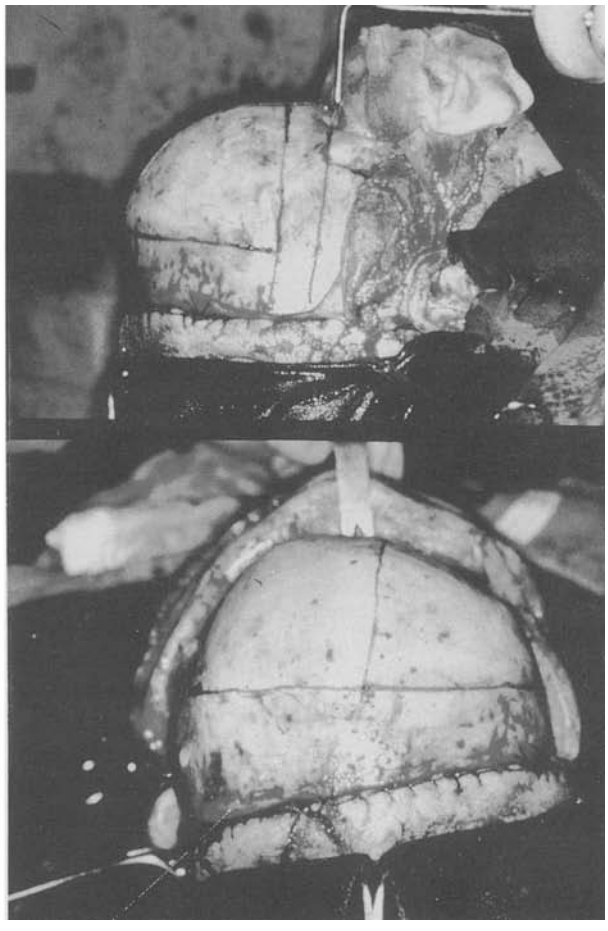


Figure 6 Planning of osteotomies in a 2-year-old boy suffering from plagiocephaly.

TABLE II Craniofacial surgery ($n = 15$)

Number of patients	Diagnosis	Type of operation	Outcome
4	M. Crouzon	Frontofacial advancement 3 with Le Fort III osteotomy	Good
		1 fronto-basal reconstruction for hypertelorism	Good
2	M. Apert	Floating forehead	Good
3	Trigonocephaly	Floating forehead	Perfect
5	Plagiocephaly	Floating forehead	Perfect
1	Encephalocele of occipital region	Skull splitting	Uneven skull at donor site

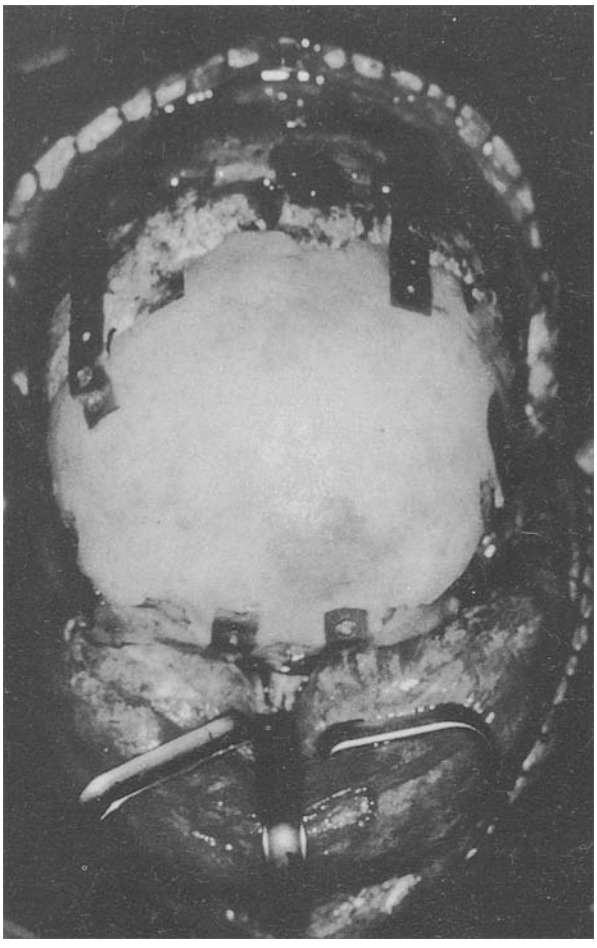


Figure 7 Same patient as Fig. 6. Result of osteoplasty fixed by threaded plugs, nuts and bands.

3. Results

The postoperative healing process was not disturbed, and in none of the patients a local infection, seroma or allergic reaction or even rejection of the implants, be found [3, 4]. On palpation, full stability was achieved and the cranial vault maintained its new shape. Hospital stay was 2–3 weeks which is no longer than with conventional implants, but the latter lead often to a second hospitalization of 1–4 days for removal of perforating wires or for cosmetical reasons when plates and screws protruded subcutaneously in the frontal area.

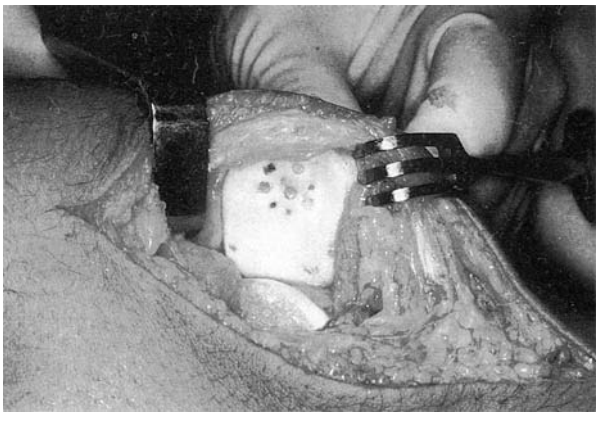
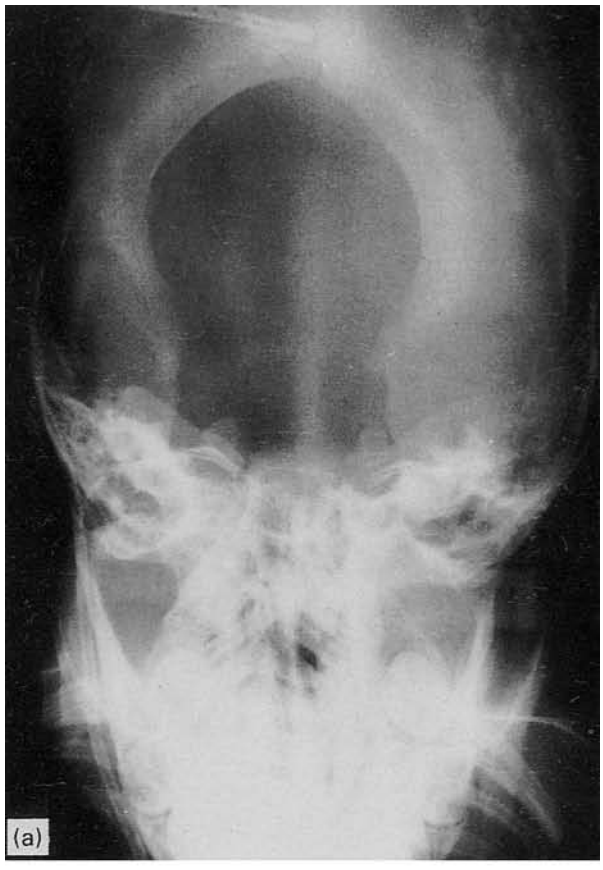


Figure 8 Intraoperative view of refixed fragment in a girl suffering from osteochondrosis dissecans of right proximal patella.



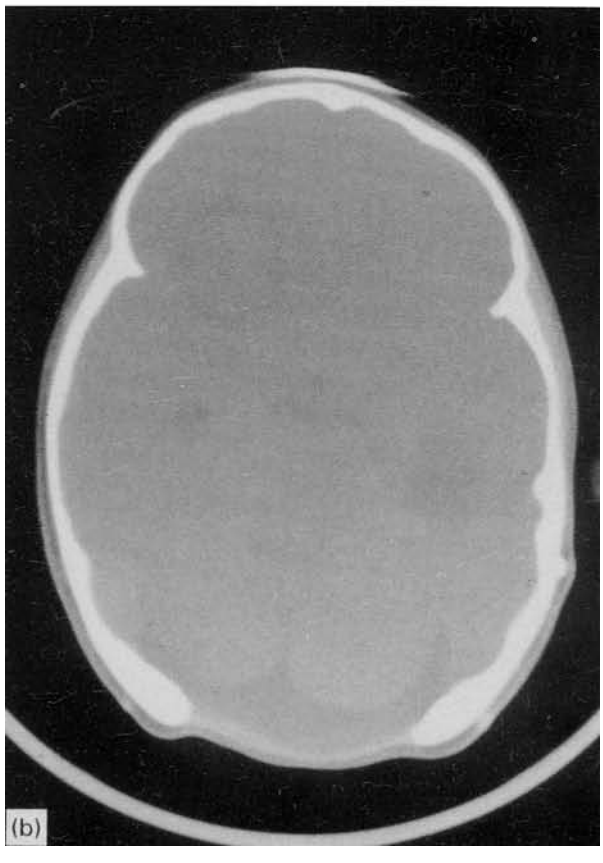


Figure 9 (a) Preoperative X-ray antero-posterior. Note: huge occipital defect (9 × 5 cm) confluent with foramen occipitale magnum in a 2-year-old girl suffering from occipital encephalocele. (b) CT-scan. Same child as Fig. 9a. Note: occipital bony defect after resection of the occipital encephalocele.

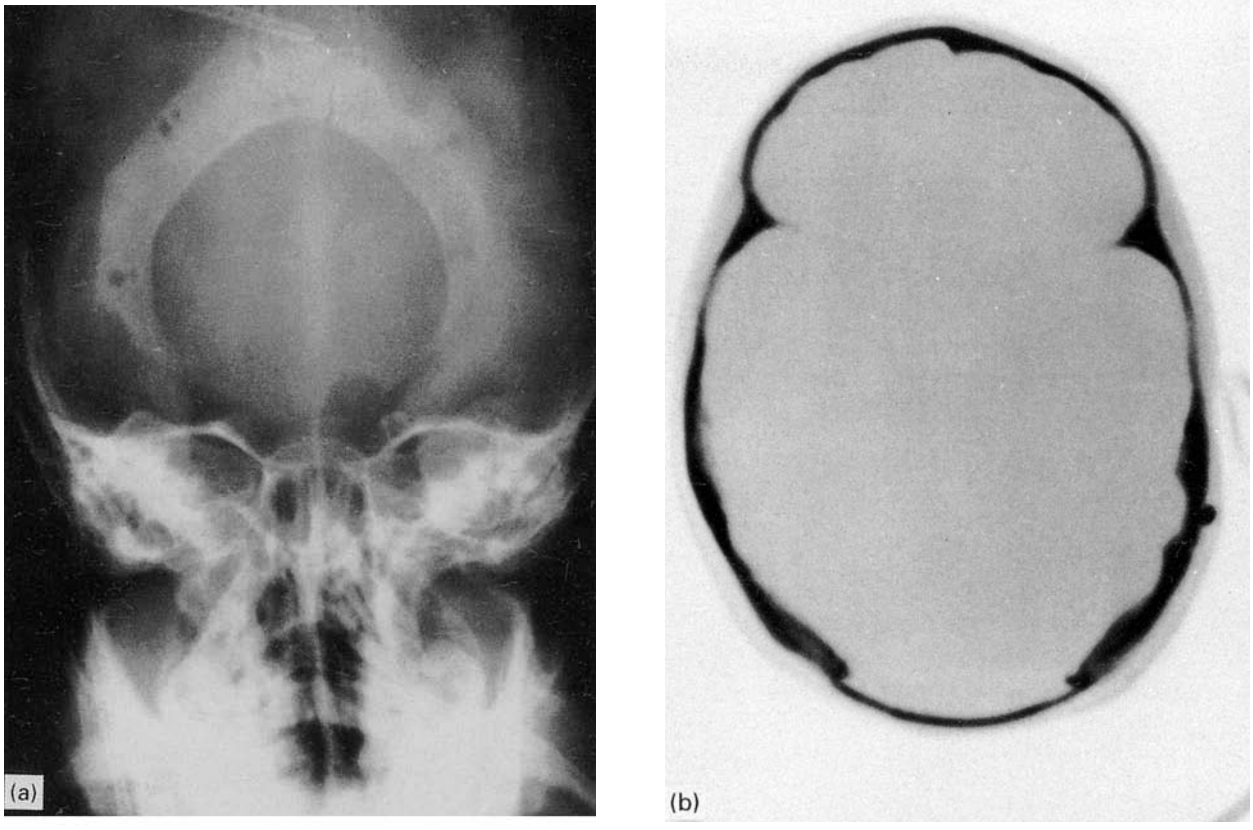


Figure 10 (a) Postoperative X-ray antero-posterior. Same patient as Fig. 9. Note: full covering of occipital defect, PLLA threaded plugs in situ. Skull splitting technique. (b) CT-scan (same patient as Fig. 9). (c) Sagital reconstruction of Fig. 10b. Note: new shape of occipital bone.

During clinical and radiological follow-up it was learned that it takes about 6 months to achieve full integrity of the cranial vault. Progressive growth of the skull with age was not disturbed (Figs 9–12)

In one child of the neurotraumatology group the skull reconstruction had to be re-done using Palacos® because a homologous bone substitute had resorbed. This was used during the primary operation for coverage of a huge triangular defect of 11×13 cm [5]. In this child, the opportunity was available to take specimens of the primary screw sites. The whole homologous bone substitute had disappeared and the borders of the skull showed only very thin apposition towards the defect. The vanishing of the plasty is thought to be due to absence of both periosteal sheets. No signs were found of overgrowth at the implantation sites. During the operation the underlying dura was removed before moulding the Palacos, but no residual implant materials were detected. The histological examination showed absence of foreign material 1 year after implantation of the PLLA threaded plugs and nuts. Foreign body reactions could not be found [4, 6].

In two children of the craniofacial group further operations were performed after 2 to 4 years to re-advance the midface in children suffering from Crouzon or Apert syndrome, with no intraoperative signs of adverse effects due to the biodegradable implants.

During follow-up until now, X-ray examinations were carried out every 3 months during the first year followed by 6 months intervals later on in all 32 patients.

In several instances a temporary radiolucency was seen around the screw sites up to 1 year. It looked like a concentric osteolysis. This phenomenon could not be found in further examinations, but it cannot be said whether the screws have been resorbed or the implants were overgrown (Figs 9–12). All reconstructions maintained the new shape, and further growth of the skull was not disturbed (Figs 9–12).

The girl with refixation of the fragment in her right patella showed an uneventful recovery and free motion of her knee during clinical follow-up [7, 8]. She does all kinds of sports 6 months after the operation. X-ray examinations proved revascularization of the fixed fragment, and 9 months after surgery the threaded plugs are no longer visible. Perhaps they would be detectable with CT-scan.

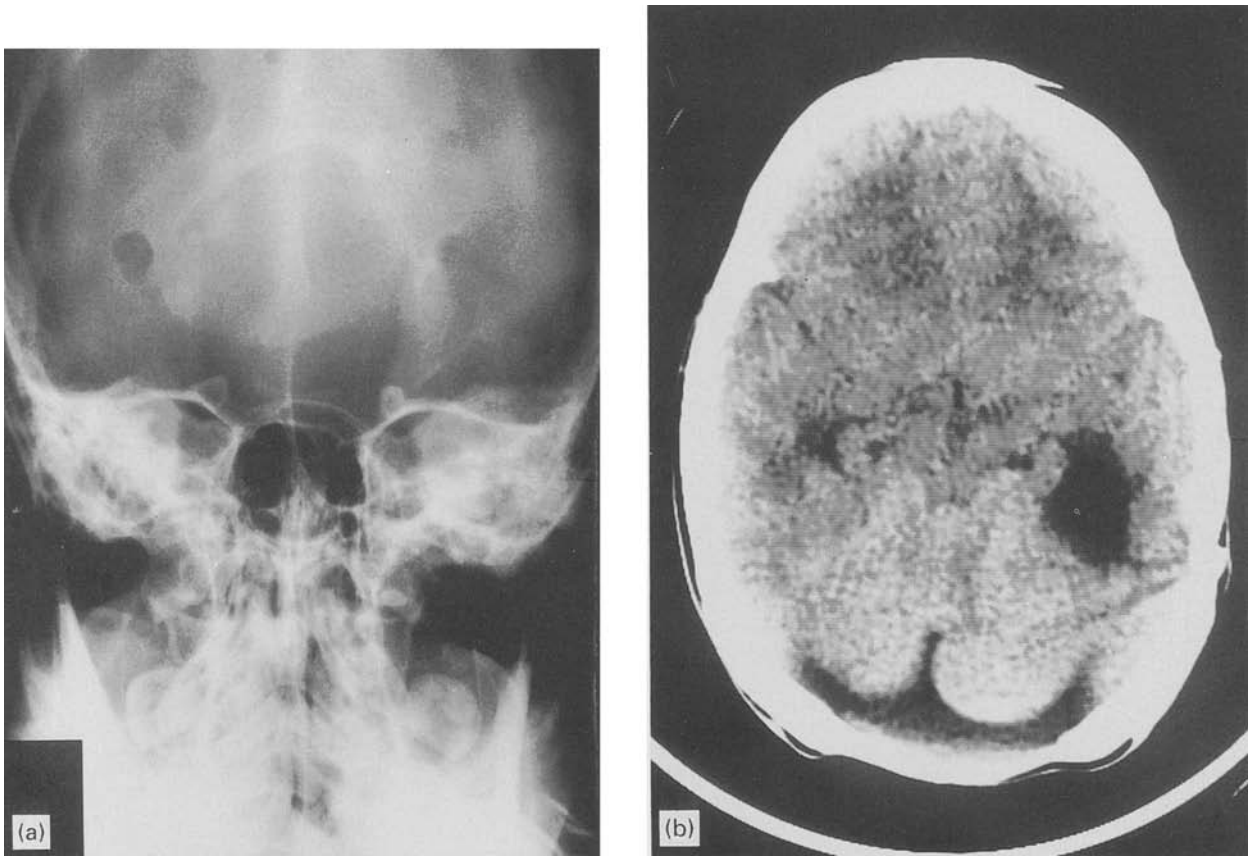


Figure 11 (a) X-ray, antero-posterior. Same patient as Fig. 9; 8 months postoperative. Note: "radiolucency" at the screw sites. Osteoplasty fully integrated, normal shape of foramen occipitale magnum. (b) CT-scan, 8 months postoperative. Same patient as Fig. 9. Note: stable consolidation of transplanted bone, undisturbed growth of the skull.

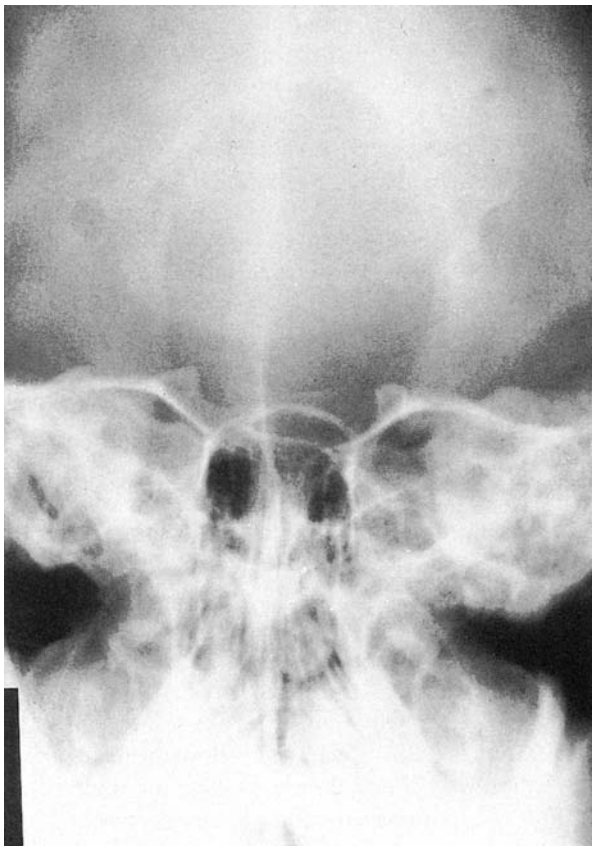


Figure 12 X-ray, 12 months postoperative. Same patient as Fig. 9. Almost complete disappearance of "radiolucencies".

4. Discussion

PLLA plugs and nuts, partially combined with PDS bands, fulfill the needs of stability in craniofacial and neurotraumatological surgery. Operation time with resorbable materials may be a little longer than with conventional techniques, however, the advantage of not having to remove part of the wires, screws and plates is nowadays a real advantage. The resorbable implants have never interfered with later operations [1, 5].

Radiological follow-up controls showed the absence of the PLLA material 12 to 18 months after surgery. It was not possible to differentiate whether the implants have been totally resorbed, or if they are only not visible due to overgrowth. However, in one child, in whom histological work-up of the resected specimen was performed during reoperation, no implanted material could be found. One reason might be the high metabolism in childhood and the additional stimulation of it during resorption of the lyophilized, homologous bone substitutes. This could lead also to quicker resorption of the implants.

In contrast with Rokkanen, Eitenmöller and others [4, 8, 11] who treated adolescents and adults, and who used different materials and manufactured the screws by injection moulding, rejections or seroma formations due to the implants were never observed in our trials. Perhaps this is because of the higher metabolism of childhood and/or the different materials and low volume of the implants. We use only pure PLLA and

our implants are machined from moulded blocks. We know also from our animal research that the machined surface of the threaded plugs and nuts shows multiple cracks of 0.02–0.1 mm depth. This not only leads to a larger overall surface but also promotes ingrowth of soft and, later on, calcified tissue. Another advantage of our implants may be the breaking into pieces after 6–8 weeks, as found in the histological work-up of the cranioplasties in the trial with juvenile minipigs [1].

The resorption time of PDS bands (Ethicon Corp.) is well known from resorption studies of suture materials, and takes about 6 months. This fact has also been confirmed by our own findings in the trial with minipigs [1].

The first application in spongeous bone of the knee has encouraged us to introduce PLLA implants partially in pediatric orthopaedic traumatology [11]. We will apply it in spongeous bone, in avulsion fractures, in refixation of the collateral bands of the knee, and handsurgery.

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