Scientific Foundations

Biodegradation of Inion Fast-Absorbing Biodegradable Plates and Screws

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Biodegradable plates and screws are recommended for use in surgery of the craniofacial skeleton of children. To be effective and not interfere with growth of the child's skull, the plates must biodegrade sufficiently to release the holding power of the plate and screw within 1 year. It is also essential that excessive foreign body reaction and cyst formation does not occur when the plates and screws biodegrade. The purpose of this experimental study was to evaluate the rate of biodegradation of Inion CPS Baby biodegradable plates and screws under different clinical circumstances in the rabbit craniofacial skeleton and evaluate their efficacy for use in pediatric craniofacial surgery. Foreign body reaction would be evaluated. Inion baby plates and screws were tested in a rabbit model. Plates were applied to the frontal bone, over a bony defect of the parietal bone, to a nasal bone fracture, and inserted in the subcutaneous space over the occipital bone in thirty 6-week-old rabbits. Six rabbits were euthanized at 9, 12, 15, and 18 months' postoperative time point and examined for residual plates and screws. Bone from each surgical site was excised, fixed by immersion in 10% neutral-buffered formalin, decalcified in Immunocal solution, and examined by 7-μm paraffin sections stained with hematoxylin and eosin. At 9 months, the plates and screws had effectively biodegraded and no longer had holding power on the bones. Fragmentation of the implant material was noted. Residual implant material was still present on gross and histologic examination in rabbits at 9, 12, 15, and 18 months. Residue of a screw was still palpable in 1 rabbit at 18 months. There was no evidence of cyst formation in any of the examined specimens. Macrophages and giant cells were present in most of the specimens at 9, 12, 15, and 18 months. Findings from the current study revealed a relative short resorption time (9 mo) and normal inflammatory sequelae in an adult rabbit model. These findings suggest that these plates may be used safely in fixing the pediatric craniofacial skeleton.

Key Words: Biodegradable plates and screws, poly L-lactic acid, polyglycolic acid

Biodegradable plates and screws have many advantages over metal plates and screws and have specific indications for their use. The most significant indication for the use of biodegradable plates and screws is in surgery on pediatric craniofacial bones. Because these materials biodegrade, they eliminate interference with normal growth and do not require removal, as is the case with metal fixation devices. Major concerns about biodegradable plates and screws include the inability to biodegrade rapidly enough and the potential for foreign body reaction and residual cyst formation. To be effective and safe in children, the plates and screws must biodegrade in less than 1 year.[1,2] If biodegradation takes significantly longer than a year, the implants may interfere with normal growth. This is particularly significant if they are used in relationship to craniofacial sutures or areas of bone growth.

A variety of biodegradable plates and screws are currently available (Table 1). Based on a review of the literature, these products can be subdivided into those

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Table 1. Composition of Biodegradable Plates and Screws

Manufacturer	*Chemical Composition*
Lorenz	82% l-PLA, 18% PGA
Inion 1.5-mm baby plates	82% l-PLA, 12% PGA, 6% TMC
Stryker Leibinger Delta System	85% l-PLA, 10% PGA with 5% DL-PLA
KLS Martin DL-PLA	DL-PLA
Inion CPS 1.5 to 2.8 mm	L-PLA, dl-PLA, TMC—percentages vary according to plate application
Macropore 70% l-PLA 30% DL-PLA	70% L-PLA 30% DL-PLA
Macropore fast-absorbing plates and screws	
Synthes	70% l-PLA 30% DLL-PLA
Bionx	70% l-PLA, 30% DL-PLA

that will biodegrade in less than 1 year and those that will take longer than a year. The product that has been most extensively investigated is Lactosorb, which biodegrades in less than 1 year.[1–3] The Lactosorb, Inion CPS baby plates, Stryker Leibinger, Macropore fast-absorbing plates have a similar chemical composition and have similar biologic properties in vivo. It is difficult to evaluate the biodegradation of 70/30 (70% poly-L-lactide [L-PLA], 30% poly-D,L-lactide [DL-PLA]) in children because tissue cannot be sampled during the degradation process. Previously, we have performed experiments on 70/30 plates and screws in a fractured nose rabbit model and found that the plates were not completely biodegraded at 2.5 years.[4–9] For this reason, we discontinued our research on this material. Each of the manufacturers of plates of 70/30 state that they biodegrade in 2.5 years. Because of this slow biodegradation, plates made of 70/30 are not advised for use in the growing craniofacial skeleton of children. A plate or screw being visible at 2 years is unacceptable. One of the additional concerns with biodegradable plates is the development of gross foreign body reactions to the chemical ingredients. Fortunately, the foreign body reaction to these products is extremely rare. The first biodegradable plates that were introduced took a long time to biodegrade. Foreign body reaction developed, and cyst formation was reported in patients.[10,11] It was generally thought that the foreign body reaction to the early biodegradable plates was caused by impurities in the plates.[10] Another theory was that the reaction was caused by encapsulation of plates that took too long to biodegrade.[12]

Adverse tissue responses to fixation implants made of polyglycolide have been reported in more than 15 clinical studies. The incidence has varied from 2.0% to 46.7%. In studies concerned with slow-degrading polylactide implants, the adverse tissue reaction rate has usually been lower than with fast-degrading polyglycolide. A recently published study examined 2528 surgical patients with implanted bioabsorbable pins, rods, bolts, and screws made of polyglycolic acid and/or polylactic acid.[13] Polyglycolic acid devices were used in 2037 patients (exclusively in 1660 patients and simultaneously with at least 1 polylactic acid implant in 377 patients), and polylactic acid implants were used exclusively in 491 patients. The incidence of inflammatory response was 5.3% (107/2037) with polyglycolic acid and 0.2% (1/491) with polylactic acid. Another clinical study of polylactide implants reports fluid accumulation in 3 patients of 1043 operated (0.3%). The timing of these adverse tissue reactions has been up to 2 years after surgery. The highest tissue reaction rates have been observed in bone sections with a recognizably poor vascularity.[13,14] Although there is a significant body of literature on adverse tissue reactions to biodegradable polymer implants, a meaningful comparison of the complication rate between implants made of the same polymers but different manufacturers is made difficult because raw materials from different sources may have different characteristics. This, in turn, may affect the biocompatibility of the implants.[13] Unfortunately, many of the biodegradable plates and screws available for clinical use have never been evaluated for reaction to biodegradation in animals. The purpose of the current study was to evaluate the long-term (18 mo) biodegradation rate of Inion CPS Baby biodegradable plates and screws used under different clinical circumstances (i.e., soft tissue pockets, normal bone onlays, and biomechanically loaded and unloaded bony wound fixation) in the rabbit craniofacial skeleton.

Materials and Methods

Thirty 6-week-old rabbits were used in the study. Twenty-four rabbits were to be used for the study, with 6 spare rabbits in the eventuality that any rabbits died before the completion of the study. The rabbits were both male and female and had ad lib access to food and water and were housed under the same conditions. This protocol was reviewed and approved by the Institutional Animal Care and Use Committee at the University of North Carolina.

Surgical Procedure

All rabbits were anesthetized, and the scalps were shaved and prepared with Betadine. General anesthesia was induced with ketamine (30 mg/kg), medetomidine

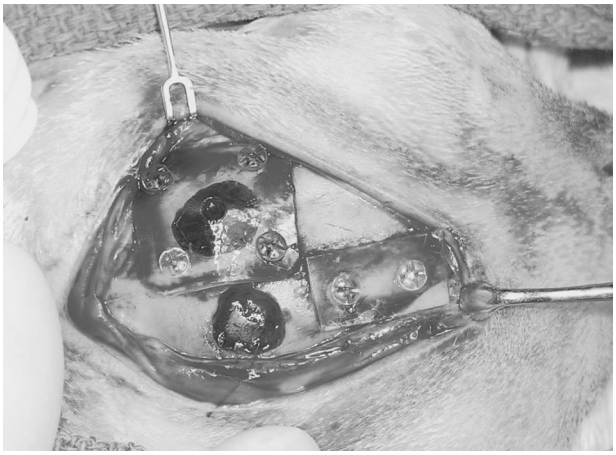

Fig 1 A 2-hole Inion mesh plate and 2 screws on the right frontal bone and bilateral 8-mm bony defects of the parietal bone. Left side covered with a mesh plate with 4 screws in a rabbit.

hydrochloride (0.5 mg/kg; Domitor; Pfizer, New York, NY) and acepromazine (0.1 mg/kg). The rabbits were intubated, and anesthesia was maintained on isoflurane 0.5% to 2%. The rabbits received 1 mg/kg atipamezole hydrochloride (Antisedan; Pfizer) for reversal of anesthesia. All rabbits received all 4 of the following surgical procedures.

After anesthesia, a midline incision was made in the scalp and snout of each rabbit. To study condition 1 (degradation in normal bone fixation), the right side of the frontal bones was exposed, pilot holes were drilled, and a 2-hole, 0.5-mm-thick rapidly absorbing biodegradable Inion plate was fixed with two 4-mm Inion biodegradable screws (Fig 1). The Inion baby plates were made of 82% L-PLA, 12% polyglycolic acid (PGA), and 6% trimethylene carbonate copolymers (TMC).

To study condition 2 (degradation in biomechanically unloaded, wounded bone), bilateral 8 × 8-mm bony defects were made in the right and left parietal bones of each rabbit with a round burr, and a 0.5-mm-thick biodegradable mesh was fixed to the bones covering the defect on the left side. The mesh was fixed with a single screw into each of the 4 sides of the mesh. The right side was left open as a control defect.

To study condition 3 (biomechanically loaded from masticatory forces and wounded bone), an incision was made over the nasal bone; the left nasal bone was fractured in the center. The fracture site was fixed with a 3-hole plate of 0.5-mm thickness and two 4-mm biodegradable screws (Fig 2).

To study condition 4 (degradation in soft tissue), the skin over the occipital and nuchal areas was undermined, and a 0.5-mm-thick 2-hole plate was placed between the periosteum and the skin on the right side. No plate was placed on the left side. This evaluated the biodegradation of the Inion plate in subcutaneous tissue. After all 4 procedures, the incisions over the scalp and the nose were closed with a 5-0 Vicryl subcuticular suture (Ethicon, Somerville, NJ).

Tissue Harvesting

At 9, 12, 15, and 18 months postoperatively, 6 rabbits were randomly chosen and euthanized with an intravenous injection of pentobarbital (300 mg/kg).

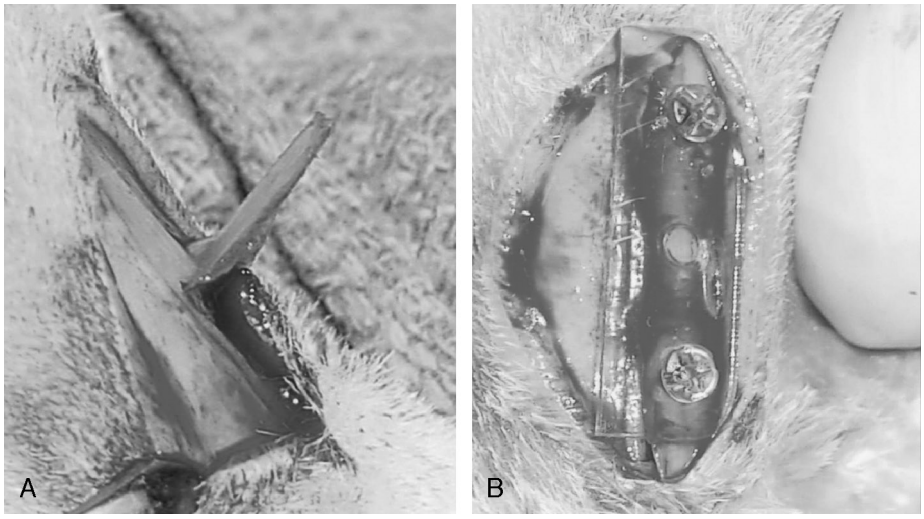

Fig 2 Greenstick fracture of the left nasal bone (A). Nasal bone fracture fixed with 3-hole plate and 2 screws (B).

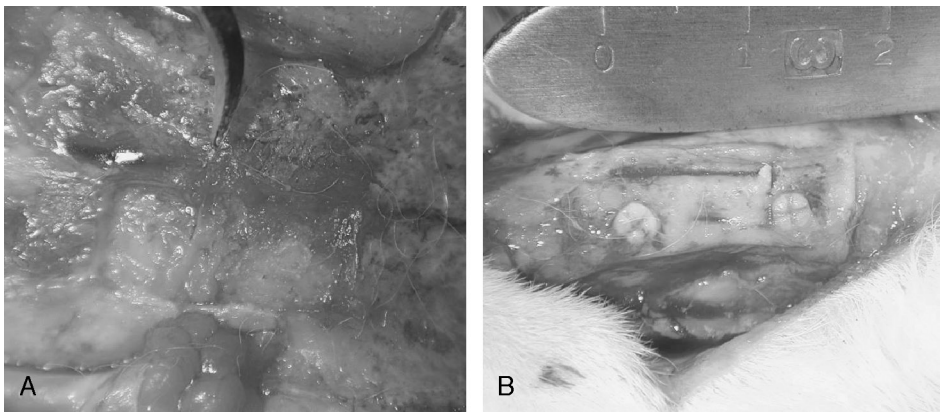

Fig 3 Frontal bone at 9 months with the plate and screws completely biodegraded in 3 of 6 rabbits, leaving an indentation in the bone (A). At 9 months, the plate and screws were still present in 2 rabbits (B). The plate was soft to palpation.

The heads and cervical regions were harvested, grossly examined, and put in 10% buffered formalin. After fixation, the 4 surgical sites were identified, examined for residual plates and screws, and the individual sites were harvested en bloc for histologic processing. Histologic blocks were created by decalcification in Immunocal (Decal Chemical Corp., Tallman, NY)., routine processing, and paraffin embedding. The specimens were then sectioned at a thickness of 5 to 7 μm and stained with hematoxylin and eosin for gross light microscopic analysis. Specimens were examined using a Nikon Eclipse E800 microscope, and the qualitative assessment of degradation timing of the resorbable plates, mesh, and screws, and the extent of inflammatory sequelae, foreign body reaction, and cyst formation by surgical condition at the different postoperative times were performed.

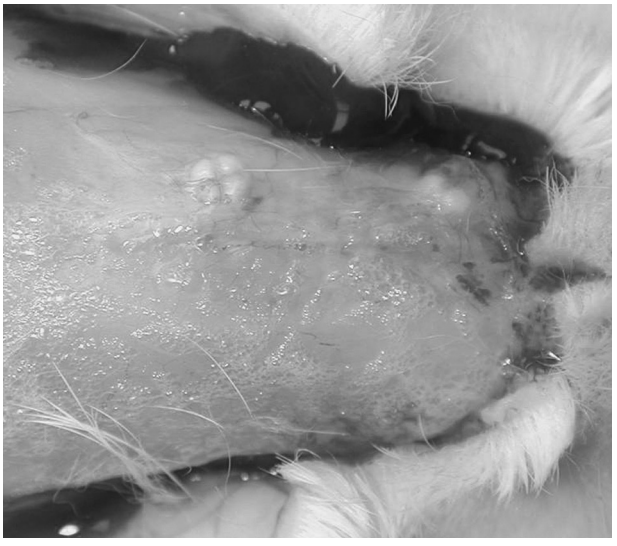

Fig 4 At 9 months, the plate and screws were still present in 2 of 6 animals. No evidence of inflammatory reaction in soft tissue around plates and screws.

RESULTS

Findings at 9 Months

Gross Observation

In the frontal bone, the plates and screws had completely disappeared in 3 of 6 animals. Indentation was present in the bones where these plates had biodegraded (Fig 3A). Remnants of biodegradable plates were present in 3 of 6 rabbits. The 10 × 2- and 7 × 2-mm plates were present in 2 animals, and remnants of screws were still present in 4 of 6 rabbits. The plates had converted to a whitish yellow paste (Fig 4B). In the left parietal bone, where an 8 × 8-mm bone defect was covered with mesh plate and screws, there was an almost complete degradation of plate to a paste in 2 of the 6 rabbits killed at 9 months. A 2 × 2-mm plate was noted in 4 rabbits. Hypervascularity of the left parietal bone compared with the right side control was noted in 2 of 6 animals.

In the nasal bone fracture model, a small remnant of paste was present in 1 animal. The plate was completely biodegraded, and only screws were present in 2 animals. Plate and screws were still present, with a capsule around the plate in another 2 (Fig 4). A 5 × 2-mm plate was still present in 1 rabbit with a soft remnant plate. In the occipital subcutaneous tissue, no evidence of plate material was identified in any of the animals at 9, 12, 15, or 18 months. There was no evidence of any inflammatory reaction.

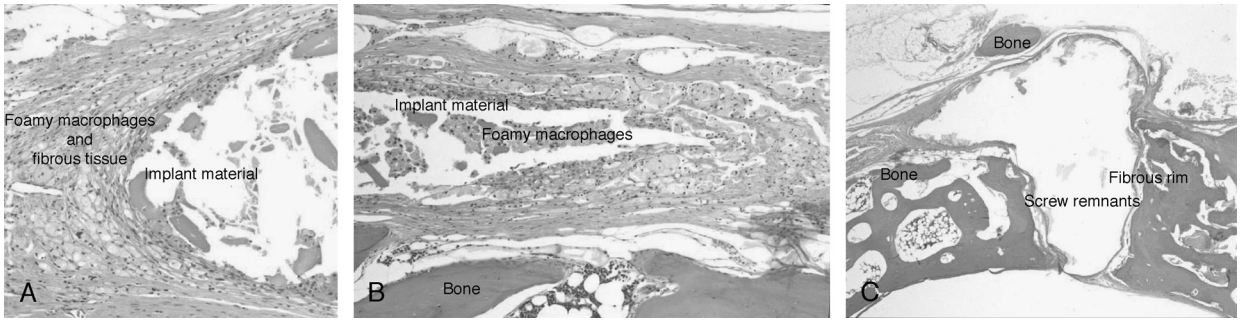

Fig 5 A, Histology of parietal bone at 9 months with implant material and large foamy macrophages surrounded by fibrous tissue. B, Histology of parietal bone at 9 months with implant material invaded and surrounded by large foamy macrophages. C, Histology of parietal bone screw hole at 9 months with implant material and large foamy macrophages. There is a focus of mature bone on top of the screw.

Histologic Observations

In the frontal bone at 9 months, microscopic shards of implant material were present surrounded by macrophages. Within this pocket, there were shards of pink fibrillar implant material mixed with large foamy macrophages and surrounding fibrous tissue (Fig 5A). Foamy macrophages were found in the implant material and around it (Fig 5B). There was a focus of mature bone in the fibrous rim of the hole and some bone over the top of the screw (Fig 5C). This bone was mature compact bone and was interpreted as extension of adjacent bone, not regrowth of bone at the surgical site. The cortical bone beneath the plates and screw heads showed normal remodeling associated with compressive forces, and the plate remnants seemed to have been encapsulated by fibrous connective tissue. In all of the specimens, there were macrophages and multinucleated giant cells associated with microscopic remnants of the implant materials. In 1 section from a single animal, there was a focus of lymphocytes in the fibrous rim around the implant materials. There was no evidence of neutrophils in any specimen.

In the nasal bone, a large hole contained implant material and foamy macrophages along a fibrous rim. The screw holes were well defined, and the thread marks were visible in the diploe. There was no bone resorption along the margins, no inflammation in the adjacent soft tissue, and the screws seem to be well integrated into the surrounding bone. In 1 specimen, it was noted that 1 of the larger trabeculae of new bone contained cartilage at the center.

Findings at 12 Months

Gross Observations

In the frontal bone, there was no evidence of plate or screw in any of the 6 rabbits (Fig 6). Additionally, there was no evidence of residual indentation in bone in any of the rabbits. In the left parietal bone, there was no evidence of residual plates or screws in 5 rabbits. A 1 × 1-mm plate fragment was still visible in 1 rabbit. Good bone formation was noted under the plate in the bone defect in all animals. Periosteal thickening was present in 1 rabbit. There was good bone formation in response to the right parietal bone defect where no plate had been applied. In the nasal bone fracture model, a 3 × 1-mm area of residual paste-like material was present in 5 rabbits (Fig 7), and a small plate remnant was visible in 1 rabbit. Thickened periosteum was noted over the residual pasty material from the plate.

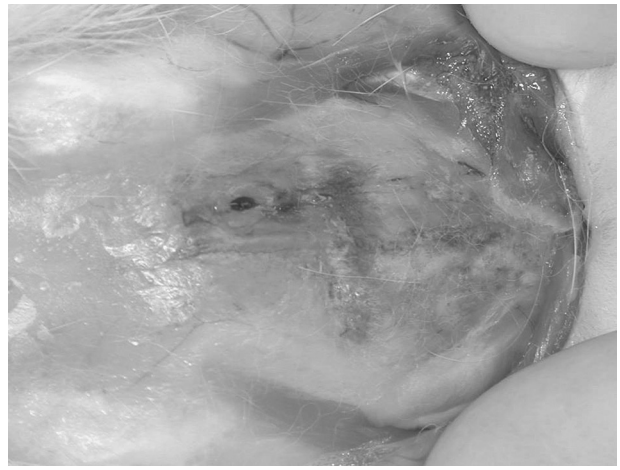

Fig 6 At 12 months, right frontal bone was well healed, with no evidence of plate and screws and no bony depression in all 6 animals. Left parietal bone shows no evidence of plate or screws, and bone healed well in 5 of 6 animals.

Histologic Observations

Histology of the frontal bone plates in 12-month postoperative rabbits revealed shards of implant material and associated macrophages within a fibrous rim. In the screw holes, there were fibrous rims and multinucleated giant cells. In the nasal bone, amorphous implant material was present with foci of macrophages. Multinucleated giant cells were noted, and rare neutrophils were present in a single section of a screw hole. Thickened cortical bone was present beneath the plate remnants.

Findings at 15 Months

Gross Observations

In the frontal bone, there was complete biodegradation of plates and screws in 5 of 7 rabbits. There was still indentation into bone in 1 rabbit. One screw and a small segment of plate were present in 1 rabbit. In the parietal bone defect, covered with a plate, there was no evidence of residual plates or screws in 5 rabbits. There was good bone formation in the defect in all 5 of these rabbits. In the right parietal bone where no plate was used, a depression remained at the site of the bone defect. In the left nasal bone fracture model, there was no evidence of plates or screws in 4 rabbits. A small fragment of plate and 1 screw were still visible in 1 rabbit. The left nasal bone was noted to be shorter than the right nasal bone.

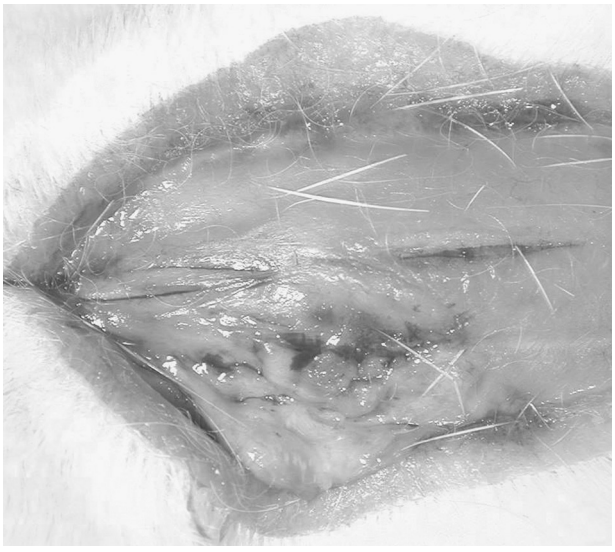

Fig 7 Left nasal bone at 12 months, with only a small amount of granular material left in 5 of 6 rabbits.

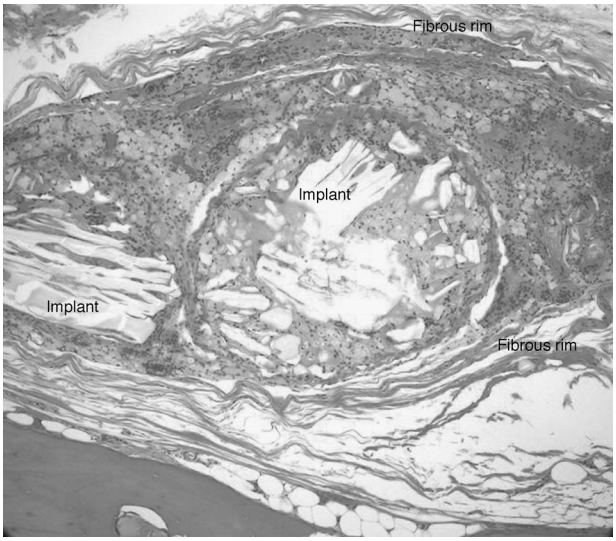

Fig 8 Focally extensive macrophages and giant cells around residual implant material with a fibrous tissue border at 15 months.

Histologic Observations

Sections from the 15-month rabbits showed no evidence of implant materials in the frontal bones. Remnants of amorphous material associated with macrophages and a fibrous rim were present in the parietal bone in 2 of 7 rabbits. Shards of implant material were noted in the nasal bone in 6 of 7 rabbits. Periosteal fibrous thickening with macrophages was present around the residual implant material (Fig 8). This reaction constituted a focal granuloma on the nose of 1 rabbit.

Findings at 18 Months

Gross Observations

At 18 months, normal bone and periosteum were present in 3 of 6 rabbits in the frontal bone. Screw holes were still present in the frontal bone in 2 rabbits. Bone seemed irregular in 1 rabbit. In the parietal bone sections, normal periosteum was present in all 6 rabbits. Bone was normal to palpation in 5 of 6 rabbits and irregular in 1 rabbit. In the nasal bone, there was complete biodegradation of all plates and screws in 5 of 6 rabbits. One screw was palpable in 1 rabbit (Fig 9A). Periosteum was thickened in 2 rabbits, 1 of them being the rabbit with the residual screw present.

Histologic Observations

In the frontal bone of 18-month rabbits, shards of implant material were present in 1 rabbit, and there

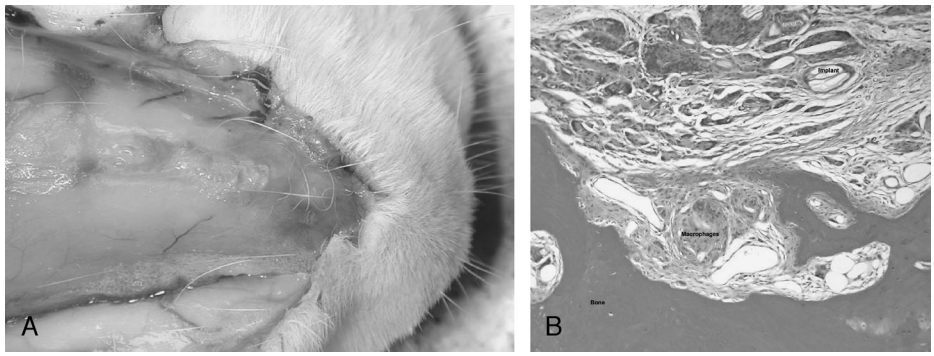

Fig 9 At 18 months, prominence at 1 screw site present on nasal bone (A). Histology of nose demonstrating shards of implant and the presence of foamy macrophages at 18 months (B).

was no evidence of implant material in 5 rabbits. In the rabbit with remnants of implant material, connective tissue and macrophages were present. In the parietal bone, there was no evidence of implant material in any of the specimens. Normal bone and periosteum were present. In the nasal bone, shards of implant material were present in 3 rabbits and were rimmed with fibrous tissue containing macrophages. At 1 site, there was a palpable screw with macrophages present in the full thickness of the bone. Some implant material was present on the surface of the bone, suggesting that there may still be a remnant of the plate or screw. (Fig 9B). The hole was lined by connective tissue, foamy macrophages, and a few shards of implant materials. One of the bone segments had an irregular surface with bone spicules extending into the overlying connective tissue. A pocket of macrophages, giant cells, and shards of implant materials were on the surface of the bone surrounded by connective tissue. In 3 rabbits, there was no evidence of implant material, and the nasal bone seemed normal.

DISCUSSION

The goal of this study was to investigate the biodegradation of the baby Inion fast absorbing plates and screws. Optimal biodegradation should be within 1 year to avoid interference with bone growth in children, and there should be minimal or absent foreign body reaction.

In the 9-month evaluations of the frontal bone, where the plate was fixed directly to bone, no remnants of plates and screws were present in 3 of 6 animals. In some animals, there was a depression at the site where the plate was situated. This can be caused by bone formation around the plate or compression forces from the plate that were present. There was no clinical evidence of inflammation in any of the specimens. In the parietal bone defect at 9 months, we found almost complete biodegradation of plate to a paste in 2 rabbits and small fragment of plate left in 4 rabbits. There seemed to be hypervascularity clinically, but it was not confirmed on histology. In the nasal bone fracture at 9 months, significant biodegradation had occurred. In some rabbits, there was almost complete resorption of biodegradable material. In some of the animals, there was encapsulation and a still significant amount of plate present. The largest fragment of plate was 5×2 mm, with the remaining plates converted to a paste-like material. In the subcutaneous tissue of the occipital area, no remnant of any plate was found in the subcutaneous tissue in any of the rabbits at any stage of evaluation.

On histology, in 1 specimen at 9 months, it was noted that 1 of the larger trabeculae had cartilage at the center. This is consistent with other wound-healing studies in rodents that showed that cranial defects and sutures occasionally develop secondary or adventitious cartilage, probably from excessive biomechanical stress or forces in the area of the wound site or suture.[15,16] There were also pockets containing shards of implant material and foamy macrophages in between the cords of bone and fibrous tissue.

At 12 months, there was complete biodegradation of all the plates and screws in the parietal bone in all rabbits. There was also good bone formation in all animals on the right side of the parietal bone, where no plate was applied. In the frontal bone, there was almost complete biodegradation of all plates. In the nasal bone, there was residual paste-like material or small remnant of plate in all rabbits in this group.

The significance of the 12-month evaluation was that there was no gross evidence of plates and screws,

and only a paste was present. The significant aspect of it was that the amount of material still present at 12 months was sufficiently small that if it was to occur in humans, it would not interfere with growth of the skull or face.

Evaluation of the later time points showed minimal remnants of plate present in the frontal bone in 1 rabbit at 15 months. In the parietal bone, there was complete biodegradation of plate and screws in all rabbits. In the nasal bone, there was still some biodegradable material present. At 18 months, the bone and periosteum had not returned completely to normal in the frontal and parietal bones in all animals. In the nasal bone, 1 prominence was present where a screw had been present and was still palpable at 18 months. Histology confirmed that there were still shards of implant material present, and bone had formed over this material. Histology on all the 9-month rabbits demonstrated macrophages with multinucleated giant cells present but no evidence of excessive inflammation. There was no evidence of cyst formation. At every time period when the specimens were examined, there were macrophages present at surgical sites in some of the specimens. The macrophages, giant cells, and fibrous rims are reactions to the materials.

The plates appear osteoinductive by presence of new bone noted adjacent to plates and screws. At 18 months, there did not seem to be excess bone formation in any animals.

As seen in the current study and reported elsewhere, biodegradable materials do result in tissue reactions. Early work with a biodegradeable crystalline material took a long time to degrade and resulted in a late inflammatory response.[12] Adverse reactions can occur during immediate degradation of a material/implants (e.g., the first implants made of pure PGA) or when the polymer reaches its polymer-specific degradation peak (even a very slow-degrading material such as L-lactide copolymers [PLLA]) especially if there is poor vascularity at the implantation site or there is only a thin soft tissue layer covering the implants.[13] There must be a differentiation between crystalline and amorphous materials when evaluating the inflammatory response. An inflammatory response can occur if the degradation rate is faster than the body's ability to handle the degradation products. This can even occur at the final stages of degradation, whether late in crystalline polymers or early in hydrophilic fast-degrading materials such as PGA. To minimize amount of tissue reactions, a gradual degradation rate is preferred. The process of biodegradation of a polymer implant begins with the polymer chains being broken into smaller fragments by hydrolysis. The molecular weight of the implant decreases first. Thereafter, the mechanical strength of the implant decreases, allowing subsequent mechanical fragmentation and absorption of the implant to begin. Actual mass loss of the implant occurs, then through the release of soluble degradation products, phagocytosis by macrophages and histiocytes, intracellular degradation, and finally, metabolic elimination through the citric acid (Krebs) cycle to carbon dioxide and water occur, which are expelled from the body via respiration and urine. There is a danger of adverse tissue reaction if the rate of implant degradation produces more debris particles than the tissue is able to tolerate. This risk is greatest when the gross geometry of the implant is rapidly lost.[13,17] All biodegradable implants induce a subclinical (i.e., nonsymptomatic) but histopathologically recognizable nonspecific foreign body type of tissue response. According to Rokkanen et al,[18] it seems to be a phenomenon inherent in the degradation and absorption processes of these polymers in the tissues. This is expected and normal as long as it does not cause any clinical symptoms. Usually, the degradation process begins with diffusion-controlled hydrolytic phase, in which the molecular chains are cut into smaller fragments by random bulk hydrolysis of ester bonds.[14] The molecular weight of implants initially decreases, followed by a decrease in the mechanical strength of the implant, allowing subsequent mechanical fragmentation and absorption of the implant. Actual mass loss of the implant occurs through release of soluble degradation products, phagocytosis by macrophages and histiocytes, intracellular degradation, and finally, metabolic elimination via the Krebs citric acid cycle to carbon dioxide and water, which are then secreted from the body via respiration and urine.[17,19]

Regarding the phagocytic and clearing capacity of the tissues, the most demanding phase is the decomposition stage, when the gross geometry of the implant is rapidly lost. At this time, the production rate of polymeric debris particles may exceed the critical limits of tissue tolerance.[13] This can occur in case of very fast (or sudden) degradation of the material/implants (e.g., implants made of polyglycolic acid) or when the polymer reaches its polymer-specific degradation peak, especially if there is poor vascularity at the implantation site or there is only a thin soft tissue layer covering the implants.[13] Local accumulation of released monomers may lower the local pH of the tissue,[14] which in turn can lead to increased osmotic pressure resulting in a temporary osteolytic expansion of the implant cavity or to a local sterile fluid accumulation. The patient notices this

reaction as swelling and pain.[13] Many of the biodegradable plates and screws available for clinical use have never been evaluated for reaction to biodegradation in animals. Results from the current study revealed that Inion CPS Baby biodegradable plates and screws had a relatively short resorption time (9 mo) and a normal, minimal inflammatory sequelae in an adult rabbit model. These findings suggest that these plates may be used safely in fixing the pediatric craniofacial skeleton.

SUMMARY

Effective degradation of biodegradable plates occurs when there is complete disappearance of the plates and screws. At the 9- and 12-month time point in this study, there were still small fragments of biodegradable plates and screws grossly visible. Clinically significant degradation occurs when the plates and screws have effectively biodegraded to no longer hold the bone on the ends of the plate together. At 12, 15, and 18 months, there was minimal biodegradable material present. Consequently, it was concluded that effective biodegradation of the plates and screws had occurred by 12 months, suggesting that baby Inion plates are appropriate for use in rigid fixation of the pediatric craniofacial skeleton.

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