EXPERIMENTAL OBSERVATIONS ON THE USE OF RUBBER IN THE TREATMENT OF CRANIOSYNOSTOSIS

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The surgical treatment of craniosynostosis by the wrapping of inert foreign material around the edges of linear craniectomies parallel to fused cranial suture lines was first reported by Simmons and Peyton in 1947, who used tantalum foil in 2 infants. Prior to this, Lannelongue in France in 1890, and Lane in the United States in 1892, had advocated the use of simple linear craniectomies. However, their method of treatment rapidly became unpopular because of indefinite indications for the operation. In 1927 and again in 1943, Faber and Towne re-introduced the use of linear craniectomy in craniosynostosis.

In 1948 Ingraham et al. carried out extensive experimental studies on the use of fibrin film, oxidized cellulose gauze (Oxycel), tantalum, methyl methacrylate (Lucite), and polyethylene (Polythene). They studied the tissue reaction to these substances when placed between the margins of artificially created channels in the cranial vaults of dogs and monkeys with survivals from 32 to 315 days. Control linear craniectomies were placed on the opposite side of the cranium in each animal. Bony fusion was found in all control saw cuts examined after 100 days. They concluded that polyethylene, because of its flexibility, transparency, and availability in various sizes of tubing and film, was particularly adaptable for introduction into the gap of artificially made sutures in the cranium in order to inhibit bony healing. They observed that its tolerance by the tissues was equal to that of tantalum or Lucite. They found that fibrin film and Oxycel failed to inhibit bony union across the saw cuts. Tantalum and Lucite were found to be inert and to inhibit bony fusion. However, the weight and opacity of the tantalum to roentgen rays and the rigidity, brittleness and difficulty in molding of the Lucite made the use of these substances difficult.

Following the study by Ingraham et al., there were no unfavorable reports regarding the use of polyethylene in the treatment of craniosynostosis until 1956 when Anderson and Johnson noted a reaction to polyethylene film in 2 patients, necessitating its postoperative removal. They were compelled to search for a new method to prevent bony regrowth across a linear craniectomy. They described the use of a thorough application of Zenker's acetic fixative or of a 7 per cent tincture of iodine on the surgically exposed
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It has been the general experience in this clinic that polyethylene material which has been embedded in human tissues has a tendency to become brittle and to crack. Experimental studies by Oppenheimer et al.\textsuperscript{13,14} and Bering et al.\textsuperscript{4} have revealed that numerous implanted plastic materials, including pure polyethylene, have induced the development of sarcomas in rats and mice in from 400 to 650 days. These observations noted above have prompted us to consider the use of a soft, pliable, resilient, relatively inert material such as rubber in the treatment of craniosynostosis. This report is concerned with observations on the use of rubber material in chronic animal experiments.

MATERIALS AND METHODS

Fourteen mature cats weighing approximately 2 to 4 kg. were used. Anesthesia was obtained with pentobarbital sodium (U.S.P.) in a solution of 10 per cent alcohol injected either intravenously or intraperitoneally in the approximate dosage of 25 mg. per kg. of body weight. The hair of the scalp was clipped with small animal clippers. The operative procedures were carried out with aseptic technique and were essentially the same as described by Ingraham et al.\textsuperscript{10} The cranium was exposed through a midline sagittal incision. The pericranium was elevated from the mid frontoparietal areas. Two bi-frontoparietal and bi-parietal burr holes 1 cm. in size were made approximately 2 mm. from the midline. The bi-frontoparietal burr holes usually bisected the coronal sutures and were about 2 to 2.5 cm. anterior to the bi-parietal burr holes. The burr holes were connected unilaterally with Gigli saw cuts, the edges of which were trimmed to right angles, leaving bilateral linear craniectomy defects averaging approximately 2 mm. in width. No bone wax was used in these experiments. Bleeding from the bone was allowed to stop spontaneously.

One linear craniectomy was used as the control and was left untouched following its completion. On the side in which the tested material was used, 2 holes were made with a 1-mm. dental drill, approximately 2 mm. from the lateral edge of the saw cut at each end of the cut. Three types of rubber material were used: 1) latex surgical tubing;\textsuperscript{*} 2) Penrose rubber drains;\textsuperscript{t} and 3) condom rubber.\textsuperscript{t}

The material to be tested was then wrapped around the lateral edge of the linear craniectomy and held in place with No. 40 stainless steel wire sutures passed through the dental drill holes. The dura mater was not opened. The galea and the skin were closed with interrupted 0000 black silk sutures. There were no operative deaths. One cat in which Penrose rubber had been implanted died 11 days postoperatively with a purulent wound infection. It was autopsied and studied although it was not used in the final consideration of these results.

\textsuperscript{*} Manufactured by Rubber-Latex Products, Inc., Cuyahoga Falls, Ohio, U.S.A. No. 200, size ½ inch I.D., Wall Amber. The manufacturer states that the tubing "contains approximately 95 per cent pure latex rubber, the balance being made up of small quantities of zinc oxide, sulphur, wax and an aliphatic amine."

\textsuperscript{t} Manufactured by Sterling Rubber Co., Ltd., Guelph, Canada. The rubber is a centrifuged, clarified, prevulcanized, natural latex. The manufacturer lists a 2 per cent chemical content made up of the following ingredients: "Sulphur, Accelerator 552, zinc oxide, Antioxidant 2246, El-Sixty, soap stabilizer, Butyl Zimate, casein stabilizer, ammonia, and caustic potash."

\textsuperscript{t} Manufactured by Julius Schmidt, Inc., New York. The rubber is a natural latex containing only a trace of free sulphur. It was generously supplied by the manufacturer in a powder-free state for use in this experiment.