Magnetically Integrated Microporous Implant

Safety and Efficacy of Secondary Posting

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Objective: To evaluate the surgical technique and morbidity related to secondary posting of a previously implanted 12-mm microporous high-density polyethylene implant (MEDPOR) and the enhanced motility associated with magnetic coupling of the prosthesis and the implant in a rabbit model.

Methods: Eight New Zealand rabbits underwent primary evisceration surgery with implantation of a 12-mm microporous high-density polyethylene implant. At 6 weeks, a 4 × 6-mm stainless steel, titanium-coated post was secondarily inserted in 6 rabbit eyes using a bilevel incision. Four weeks after the second surgery, 3 rabbits were fitted with a magnet-embedded prosthesis. Motility was measured by evaluating lateral prosthetic excursion during direct observation. At 3, 6, and 12 months the implants and surrounding tissues were harvested for histopathologic examination.

Results: Secondary placement of the post within the implant was accomplished without difficulty. No signs of erosion, dehiscence, or extrusion were found after a 12-month follow-up in any of the study eyes. Clinical grading documented increased movement of the magnetically coupled prostheses compared with nonmagnetically integrated control eyes.

Conclusion: This study establishes the safety of secondary posting and the efficacy of magnetically integrated microporous high-density polyethylene implants in the rabbit model.

Clinical Relevance: This technique may offer an alternative to patients with previously implanted microporous high-density polyethylene implants seeking enhanced cosmesis and prosthetic motility.

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The first description of enucleation as a treatment of ocular disease was reported in the 16th century. Over the years the surgical technique has been greatly modified and enhanced and the use of orbital implants was introduced to achieve improved cosmesis.

The ideal orbital implant should offer excellent cosmesis and motility while minimizing potential risks such as extrusion, infection, and other complications. The search for the ideal implant has resulted in the development of a variety of materials (homologous, heterologous, and alloplastic) and configurations. Porous high-density polyethylene implants have become widely used for volume replacement as spherical orbital implants for the treatment of anophthalmia. Polyethylene is a stable hydrocarbon polymer that is easily molded into different shapes. Porous spherical implants possess certain qualities that make them unique: they are nontoxic, nonallergenic, biocompatible, and provide a scaffold for ingrowth of fibrovascular tissue. These properties offer the theoretical advantages of improved adherence to host tissue, reducing the risk of implant extrusion or migration and secondary infection. Prosthetic motility may also be improved because of enhanced extraocular muscle attachment to the implant.

Microporous implants can accommodate drilling of a tunnel to insert a coupling peg or post that allows the fitting of an ocular prosthesis. Enhancement of ocular motility is achieved with the integrated ocular prosthesis. However, the integration of the implant with a prosthesis by means of a coupling peg has led to high complication rates.

We previously reported the orbital tolerance of a buried polyethylene micro-
porous implant, fitted with an integrated stainless steel post, and the enhanced motility associated with magnetically coupling an ocular prosthesis with the implant in a rabbit model. In this study, integration of the post and magnetic coupling was successfully accomplished with no complications and good motility was achieved in all animals. These results form the basis of the current study. The purpose of the present study is to investigate the safety and efficacy and to document the surgical technique of secondary posting of previously implanted microporous high-density polyethylene implants as well as to evaluate the enhanced motility associated with magnetically coupling a buried microporous high-density polyethylene implant with an ocular prosthesis in a rabbit model.

METHODS

All experiments in this study were conducted under the auspices of the Animal Care and Use Committee of the University of Miami School of Medicine, Miami, Fla. Experiments adhered to the guidelines of the Association for Research in Vision and Ophthalmology Statement for the Use of Animals in Ophthalmic and Vision Research.

Eight New Zealand white rabbits, weighing between 4 and 5 kg, underwent primary evisceration of the right eye with implantation of a 12-mm spherical microporous high-density polyethylene implant (MEDPOR; Porex Corp, College Park, Ga). All animals were anesthetized using intramuscular injections of ketamine hydrochloride, acepromazine, and xylazine hydrochloride. They also received topical proparacaine hydrochloride. After evisceration, the 12-mm spherical microporous high-density polyethylene implant was placed inside the scleral shell and the edges were approximated and sutured with a 5-0 polygllactin 910 suture. The deep and superficial Tenon tissues and conjunctiva were closed in a layered fashion with a 6-0 polyglactin 910 suture. A small ophthalmic conformer was inserted and an occlusive dressing was applied. The rabbits were monitored postoperatively for signs of infection and to ensure proper wound healing.

Six weeks after evisceration, under appropriate anesthesia and monitoring, secondary placement of a stainless steel, titanium-coated post was performed in 6 animals using a billevel incision (Figure 1). After inserting a lid speculum in the operated on right eye, a 3-mm conjunctival incision was made 3 mm above the midline; a second 5-mm incision was made through superficial and deep Tenon tissues 3 mm below the midline (incisions above and below the center at the horizontal meridian). A third incision was made through the sclera at the center midline and tissues were dissected until an area of about 5 × 5 mm of the 12-mm spherical microporous high-density polyethylene implant was visible. A 4 × 6-mm threaded, stainless steel, titanium-coated post (Figure 2) was secured into the implant and embedded flush with the anterior surface of the implant. The orbital structures were irrigated with 60 mg/mL of gentamicin sulfate. The sclera and Tenon tissues were closed with a 5-0 polygllactin 910 suture and the conjunctiva was closed with a running 7-0 polygllactin 910 suture.

Custom-fitted rabbit ocular prostheses were manufactured integrating two 1-mm circular medical-grade rare earth magnets (Figure 3). A spacing interval of 1 mm was maintained and the magnets were embedded 0.5 mm lateral to the midline (right and left of center at the horizontal meridian). The prostheses were vaulted to achieve a 0.3-mm elevation from the central conjunctiva, thereby eliminating direct central apposition of the conjunctiva and prosthesis. An identically designed prosthesis without incorporation of the magnets was used for the control eyes.

Four weeks after the secondary implantation of the posts, 3 rabbits were fitted with a magnet-embedded, porcelain prosthesis and 3 control rabbits were fitted with a prosthesis without incorporation of the magnets. Magnetic field strength (force) was determined using a hanging ball technique at varying distances determined to approximate the clinical relation between the prosthetic and the implant.

Serial examinations of the eye sockets were performed and clinical photographs were taken. Animals were clinically evaluated for prosthetic motility using the implant with a magnetically integrated prosthesis. Control motility was determined by placement of the nonmagnetic prosthetic. Animals were encouraged into extended field gaze using targeted visual stimuli. Motility was graded, in a masked fashion, as good (<2 mm), fair (1-2 mm), or poor (>2 mm), evaluating lateral prosthetic excursion during direct observation. Measurements were graded by the distance in millimeters of the prosthetic limbus from the evaluated eyelid margin (medial and lateral).

Rabbits with secondary implantation of the post were killed 3, 6, and 12 months after the second surgery. The 2 remaining rabbits were killed—one at 3 months and the other at 6 months after the initial evisceration surgery. The implant and surrounding tissues were harvested for histopathologic examination and comparison between study groups.

RESULTS

Secondary insertion of a stainless steel, titanium-coated post within the 12-mm microporous high-density polyethylene implant using the bilevel incision technique was accomplished without difficulty or compromise of the implant in all rabbit eyes. All 12-mm microporous high-density polyethylene implants exhibited fibrovascular ingrowth at the time of the second surgery.

Gross clinical evaluation at monthly intervals during a 12-month follow-up period after the second surgery showed no signs of extrusion of the implant or post displacement, dehiscence of the conjunctiva, or infection (Figure 4). The stainless steel, titanium-coated posts were well tolerated. Orbital histopathologic features of the specimens obtained at 3, 6, and 12 months' follow-up disclosed no evidence of conjunctival erosion, inflammation, or other signs of orbital toxic reactions. Muscle attachment to sclera and orbital fat was not compromised.

Clinical grading of all eyes with a magnetically integrated prosthesis documented fair to good motility. All nonmagnetically integrated control eyes were graded as having poor motility. Although this series documented enhanced motility in all eyes with a magnetically integrated prosthesis, the small sample size precludes meaningful statistical analysis. Magnetic force studies documented a coupling force of 77 N, which clinically represents a moderately strong attraction force.

COMMENT

A variety of prosthetic coupling systems have been investigated throughout the years with the goal of achieving excellent cosmosis, good long-term motility, and minimizing complications. Transconjunctival integration or “pegging” of the microporous high-density polyethylene implants improves both the motility and the stability of the prosthetic eye in most cases.
However, complication rates have been documented to be as high as 48%. A recent approach to transconjunctival integration or pegging has used titanium alloy motility coupling posts. Prosthetic motility has been found to be acceptable and this coupling system offers an efficient surgical option in selected cases. As with all transconjunctival implants, complications have been reported in short-term follow-up and longer follow-up is needed to assess long-term complication rates. Magnetically integrated implants have been studied in the distant past by several investigators, but the appearance of late complications, such as exposure.

Figure 1. Surgical technique. Panel A, The 12-mm microporous high-density polyethylene implant is grasped and held in place with an implant stabilizer. A bivel incision is made. Panel B, A tunnel is drilled on the midline of the implant. A third incision was made through the sclera at the center midline and tissues were dissected. Panel C, The post is secured and embedded flush with the anterior surface of the 12-mm microporous high-density polyethylene implant. Layered closure of the sclera and Tenon tissues is seen.
and extrusion, led to the discontinuation of this approach. More recently, our laboratory demonstrated that advanced magnetic coupling of an integrated microporous high-density polyethylene implant with a buried stainless steel post generates clinically effective force profiles with the magnetic prosthesis. The design, materials, and placement of the surgical-grade magnets within the prosthesis played an important role in the successful outcomes and absence of complications.

In the present study, secondary insertion of a stainless steel, titanium-coated post into a previously implanted 12-mm microporous high-density polyethylene implant was performed without technical difficulty. No intraoperative complications were noted in any of the treated animals. The bivel incision technique was associated with rapid socket healing and rehabilitation without postoperative complications such as epithelial breakdown, exposure, or extrusion. Magnetic coupling of the secondary post implanted microporous high-density polyethylene implant with the magnet-embedded prosthesis generated clinically effective force profiles and enhancement of motility, as we have previously reported with an implant integrated with a buried stainless steel post.

A unique advantage of this coupling system is that it does not involve transconjunctival integration as do the pegging systems. Magnetic coupling between the prosthesis and the postimplanted microporous high-density polyethylene implant is achieved without interruption of the overlying Tenon and conjunctival tissues. Moreover, the vaulted design of the magnet-embedded prosthesis precludes direct apposition of the prosthesis with the buried post which, therefore, may avoid the risks of conjunctival dehiscence, infection, erosion, and extrusion commonly seen with other coupling systems. Longer follow-up is needed to assess long-term complication rates.

The outcomes are promising and this technique may offer an alternative to patients with previously implanted microporous high-density polyethylene implants seeking enhanced cosmesis and prosthetic motility. Weighing the benefits of improved motility and cosmesis with the small risks of infection and extrusion implicit in the performance of a second surgical procedure, it would seem reasonable to consider this approach. A disadvantage to the use of this 12-mm microporous high-density polyethylene implant with a buried stainless steel, titanium-coated post will be the elimination of magnetic resonance imaging studies for these patients.

This study establishes the new surgical technique, underscoring the feasibility, safety, and efficacy of secondary posting in the rabbit model. Cosmetic enhancement of motility is documented using this magnetically integrated model. These results provide the basis for further clinical investigation of the potential of this technique in improving long-term motility and cosmesis of ocular prostheses on patients with previously implanted microporous high-density polyethylene implants.

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REFERENCES


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