Design of a Magnetically Integrated Microporous Implant

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Objective: To determine the orbital tolerance of a microporous implant fitted with an integrated stainless steel post and the enhanced motility associated with magnetic coupling of the prosthetic and the implant in a rabbit model.

Methods: Six New Zealand white rabbits underwent primary enucleation with implantation of a 12-mm microporous polyethylene implant with a 2 × 3-mm stainless steel post embedded flush with the anterior surface. At 1 month, the rabbits were fitted with an external prosthesis containing two 1-mm circular rare earth dental magnets embedded at 0.5 mm off the midline (right and left of center at the horizon). Magnetic coupling forces were determined with a hanging block technique.

Results: No evidence of toxicity was observed in association with this integrated ocular implant. Magnetic coupling forces were noted maximally at 0.47 N. Clinical grading of motility documented enhancement in lateral excursion when compared with nonintegrated controls.

Conclusion: Magnetically integrated microporous implants achieve excellent enhancement of motility without evidence of complications in this rabbit model.

Clinical Relevance: This study establishes a framework for the clinical evaluation of a magnetically integrated implant that may enhance prosthetic motility without requiring direct mechanical coupling of the implant to the prosthesis.


BARTISCH FIRST described enucleation as a treatment of ocular disease in 1583. The current surgical approach was introduced in 1841 by Farrell and Bonnet, and in 1884, Mules placed the first orbital implant. In 1946, Ruedemann proposed the use of partially exposed, integrated implants with the attachment of the extraocular muscles to the implant to allow for better prosthetic motility. Complete tissue enclosure of the implant began in the 1950s, minimizing socket complications but limiting prosthetic motility. Troutman, in 1949, introduced a magnetic integrated implant. Magnetic implants were then evaluated by several investigators. Late complications associated with the magnetically integrated implants, including exposure and extrusion, led to the discontinuation of this reconstructive approach. The use of a microporous magnetic coupling system was postulated to eliminate the complications associated with prior magnetic implants. The ideal orbital implant would offer excellent motility and cosmesis and few complications. To achieve this goal, various materials have been advocated, including cartilage, bone, fat, cork, rubber, gold, silver, silk, wool, aluminum, ivory, acrylics, silicone, quartz, glass, titanium, and, recently, porous materials, such as polyethylene and hydroxyapatite.

Tissue-covered, quasi-integrated implants derived from acrylic irregularly shaped spheres include the Allen implant (in which extraocular muscles are passed through tunnels) and the Iowa and Universal implants (in which extraocular muscles are passed through grooves within the implant).

Porous spherical implants are most widely used at the Bascom Palmer Eye Institute, Miami, Fla, and other institutions. Porous polyethylene is made from synthetic, high-density polyethylene powder that is easily molded into virtually any shape. Hydroxyapatite, derived from reef-building coral of the genus Porites, was introduced in 1985 by Perry as a microporous implant material. Microporous implants allow for fibrovascular ingrowth and offer the...
MATERIALS AND 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.

Microporous polyethylene implants (MEDPOR; Porex Corp, College Park, Ga) were custom modified to integrate a medical-grade 2 × 3-mm stainless steel post embedded flush with the microporous sphere (Figure 1). Custom-fitted rabbit ocular prosthetics were manufactured integrating two 1-mm circular medical-grade rare earth magnets (Figure 2). 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) (Figure 2). The prosthetics 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 as a control.

Magnetic field strength (force) was determined using a hanging ball technique.27 Briefly, the hanging ball technique measures the magnetic force by determining the amount of movement of a 0.32-cm steel ball as a test object placed at varying distances from the magnet test object. Field strength was determined in a single and combined magnet application at varying distances determined to approximate the clinical relation between the prothetic and the implant.

Six animals underwent implantation of the custom-modified microporous implants (Figure 1). All animals were anesthetized with intramuscular injections of ketamine hydrochloride and xylazine hydrochloride, retrobulbar bupivacaine hydrochloride, and topical proparacaine hydrochloride. Under appropriate anesthesia and monitoring, primary enucleation of the right globe was performed using a previously reported technique.28 A custom 12-mm microporous implant with an integrated steel post was implanted to maintain the orientation of the post along the horizontal and vertical center of the socket (Figure 1). The recti muscles were reapproximated to the wrapped implant to maintain gross anatomic positioning. The deep and superficial Tenon tissues were closed with 5-0 polyglactin 910 sutures, and the conjunctiva was closed with a 7-0 polyglactin 910 suture. A small ophthalmic conformer was inserted, and an occlusive dressing was applied. The sockets were serially examined, and clinical photographs were obtained (Figure 3). At 6 weeks after enucleation, the magnetically integrated, custom-fitted prosthesis was placed in all animals (Figure 4). Animals were clinically evaluated for prothetic motility using the eyes with a magnetically integrated prosthesis and the control eyes with a nonmagnetically integrated prosthesis. Control motility was determined by placement of the nonmagnetic prosthesis. Motility was graded, in a masked fashion, as good, fair, or poor, evaluating lateral prothetic excursion during direct observation (poor indicates <1 mm; fair, 1-2 mm; and good, >2 mm).

RESULTS

Integration of the steel post within the microporous implant was accomplished without difficulty or compromise of the implant (Figure 1). Placement of the medical-grade magnets within the custom prosthesis did not impair the socket placement of the prosthesis (Figures 2 and 4). Clinical and histopathologic evaluation of treated sockets, during a 20-month follow-up, disclosed no evidence of infection, inflammation, extrusion, or complication (Figure 3). Orbital histopathologic features at 6

Figure 1. Left, A medical-grade 2 × 3-mm stainless steel post integrated into a microporous implant. Right, A 2 × 3-mm stainless steel post.

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and 12 weeks after placement of the prosthesis disclosed no evidence of conjunctival thinning or orbital complication. Magnetic movement forces achieved adequate field strengths to enable magnetic coupling of the buried implant and custom prosthesis (Table). All eyes with the magnetically integrated prosthesis were graded as having good motility, while all eyes with placement of the control, nonmagnetic prosthesis were graded as having poor motility.

**COMMENT**

Magnetic coupling of a buried, steel post–implanted, microporous implant appears to generate clinically effective force profiles for interaction with the modified magnetic prosthesis. No data are available to determine the ideal placement of the magnets within clinical practice. Data suggest that within the rabbit model, the spacing interval of 1 mm (0.5 mm lateral to the midline) for the 2 prosthetic magnets and a prosthetic vault of 0.5 mm will allow for enhanced movement of the prosthesis.

The design and production of these integrated devices are possible using medical-grade production items, including the microporous implant, steel post, and surgical-grade magnets. No intraoperative or postoperative complications were noted in any treated animal. Rapid socket healing and rehabilitation were associated with this surgical technique.

This technique appears to achieve the benefits of an invasively integrated implant-prosthetic combination without the associated concerns of socket-related complications, including epithelial breakdown, exposure, extrusion, or infection. Data suggest that these rates may be as high as 28% or greater for microporous implants undergoing “pegging” of the implant. These rates are concerning in light of the recently reported pediatric and adult complication rates in nonpegged microporous implants of less than 1.5%.

This study establishes the feasibility and efficacy of this magnetically coupled implant within this animal model. Advances in materials, surgical technique, and ocular prosthetic fitting allow for a reconsideration of a magnetically coupled implant. True evaluation of enhanced cosmesis will require clinical study in humans undergoing enucleation and implant placement.

A caveat to the use of this implant will be the restriction of magnetic resonance imaging studies for these patients. Fortunately, computed tomographic scanning analysis continues to allow for adequate orbital and central nervous system imaging in most patients.
REFERENCES


A look at the past . . .

De Wecker proposes that the treatment of squint should differ according as one wishes to obtain binocular vision or merely a cosmetic effect. From statistics of 3002 cases of squint he endeavors to find the proportion in which binocular vision is restored. The cases of alternating strabismus with good vision in each eye are the most favorable.

The periodic squint of hyperopes with good vision in both eyes is cured and binocular vision is restored by using correcting glasses, or there may be spontaneous recovery. When the vision of the squinting eye is less than 1/4, one cannot count upon obtaining binocular vision. This is also the case in periodic squint of myopes, surgical interference here being necessary and often difficult to carry out successfully. In the most frequent form of squint, permanent unilateral squint, binocular vision is secured in only about one fourth of the cases. It is, furthermore, unnecessary to bother these patients with visual exercises in case the squinting eye has very poor vision.