Use of self-expanding, hydrophilic osmotic expanders (hydrogel) in the reconstruction of congenital clinical anophthalmos

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Purpose of review

Rehabilitation of the congenitally anophthalmic orbit is frustrating to both the parents and physician. Traditional methods involve using progressively enlarging static acrylic conformers to expand the conjunctival socket, followed by placement of conventional static spherical orbital implants, dermis-fat grafts, or inflatable balloon expanders for orbital enlargement. Limitations of these methods typically result in less-than-optimal cosmetic outcomes, with retardation of bony orbital and overlying soft tissue growth adversely affecting midfacial growth and symmetry. Recent advances in tissue expansion technology may offer additional, novel alternatives to conventional therapies.

Recent findings

Hydrogel tissue expanders were recently adapted for use in congenital anophthalmia. The expanders are placed in their dry, contracted states, and expand gradually to their full size via osmosis of surrounding tissue fluid, with up to a 10-fold increase in volume. Offering the benefit of predictable and controllable self-expansion, hydrogel expanders may offer yet another alternative or adjunctive therapy to the early rehabilitation of the contracted socket. Separate appliances are used for conjunctival and orbital reconstruction. Initial results appear promising. Tempering the enthusiasm for their use, however–particularly in terms of implanted orbital expanders–is the recent spate of long-term complications reported from previous uses of hydrogels as scleral buckling material.

Summary

Self-expanding hydrogel tissue expanders appear to offer an intriguing reconstructive alternative to the frustrating condition of congenital anophthalmia. Long-term safety of the material as an orbital implant has not yet been demonstrated, but early results are promising.

Keywords

congenital clinical anophthalmia and microphthalmia, orbital expansion and reconstruction, conjunctival reconstruction, microblepharon, micro-orbita, hydrogel tissue expanders

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Introduction

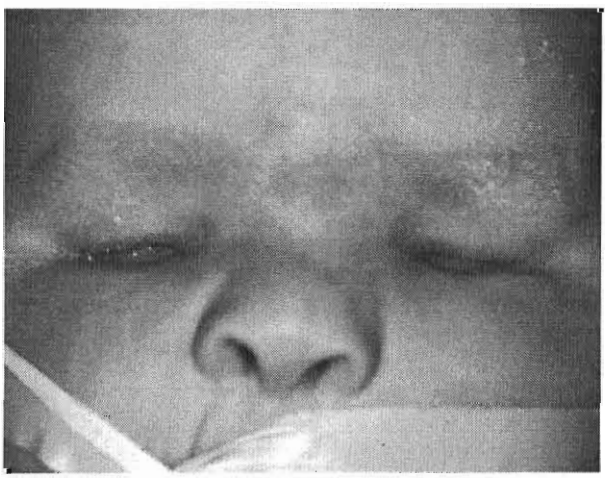
Although decidedly uncommon, congenital anophthalmia and microphthalmia are among the most frequently encountered ocular malformations [1–3]. True congenital anophthalmia is an exceedingly rare condition wherein the optic vesicle fails to develop *in utero*. More commonly, one finds some vestige of ocular tissues that failed to develop properly early on, termed extreme microphthalmos, abortive microphthalmos, or blind microphthalmos. Practically, of course, this distinction is largely academic and matters little to the patient, the parent, or the physician, as the clinical picture is the same regardless of etiology, that being a shrunken bony orbital skeleton (micro-orbitism) and contracted overlying soft tissues (microblepharon). The clinical condition is often referred to as clinical congenital anophthalmia. Reconstruction must begin promptly after birth (within weeks), and requires an intense commitment of time, energy, and resources by the parents, the physician, and the ocularist [4,5]. Reconstruction of these tiny orbits poses significant challenges, as retardation of bony orbital growth leads to retarded growth of the entire hemiface (or midface, in the case of bilateral anophthalmia) and secondary hypoplasia of the maxilla and mandible [6]. The resulting asymmetry is cosmetically and functionally disappointing, despite the best of intentions and efforts. Reconstruction is aimed at expansion first of the conjunctival sac, and subsequently the bony orbit [7,8]. Traditional methods include the initial use of progressively bigger static acrylic conformers to enlarge the conjunctival socket and lids, followed by the placement of conventional solid spherical orbital implants, dermis-fat grafts, or inflatable tissue expanders for orbital expan-

sion. Craniofacial surgery for surgical orbital enlargement may be required at a later stage. Recently, self-expanding hydrogel tissue expansion technology has been applied to this condition [9,10•,11], a development that has been received with equal amounts of enthusiasm and caution. Although used successfully in Europe for several years, the devices have only recently become available in the United States [9–15]. This article will briefly review traditional methods of reconstruction as well as the evolving role of hydrogel expanders in the early treatment of clinical congenital anophthalmia.

Clinical characteristics of congenital anophthalmia

Studies report the incidence of congenital anophthalmia as approximately 0.2 to 0.6 per 10,000 births [1,2]. Clinical anophthalmia can result from primary genetic disorders, maternal exposure to environmental teratogens, or in association with other developmental abnormalities [1–3]. Lacking the globe not only retards growth of the socket and overlying soft tissues, but retards the development of the entire hemiface, affecting the growth of the maxilla, maxillary sinus, and mandible [6]. The distance between the lid fissure and brow is also reduced, creating a compressed appearance of the midface [4] (Fig. 1). The hypoplasia is most marked when the child is congenitally anophthalmic, but less dramatic retardation can also result when a normal eye is removed in early infancy. Although the lids are normally developed structurally, the fissures are severely phimotic both horizontally and vertically. Additionally, the conjunctival sac and fornices are severely contracted and shrunken, in contradistinction to acquired anophthalmia, in which the lids and conjunctiva are more age-proportionally appropriate [4,8].

Figure 1. Congenital clinical anophthalmos



Newborn girl with bilateral congenital clinical anophthalmos. In addition to hollow, sunken orbits, she also demonstrates the microblepharon and midfacial hypoplasia that are characteristic of this condition. (Photo courtesy of Dr. Asa D. Morton, MD, San Diego, CA).

Current therapies: lid expansion

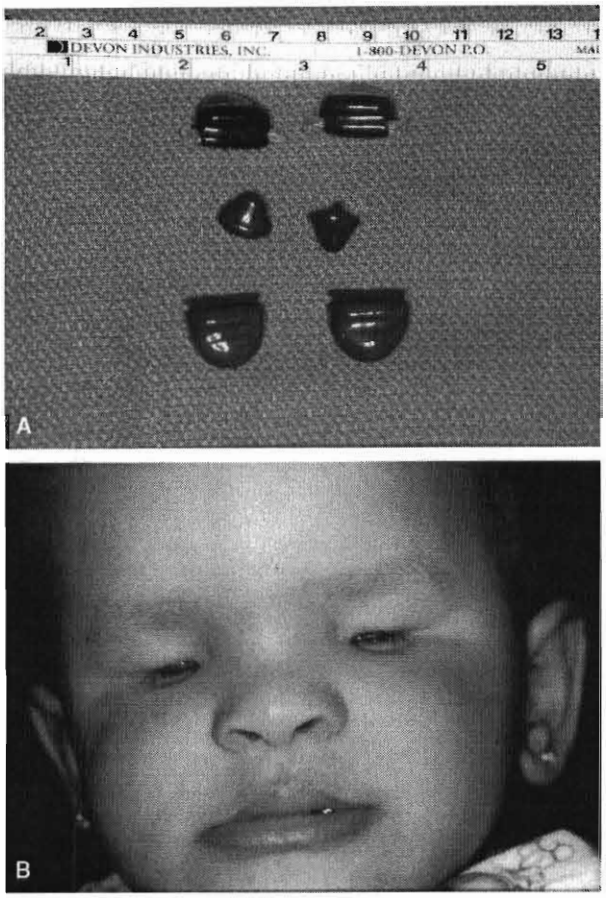
Reconstruction efforts are focused in several directions simultaneously: 1) expansion of the lid dimensions, both horizontally and vertically; 2) expansion of the conjunctival sac and formation of normal fornices; and 3) expansion of the bony orbit [8]. Initial efforts are necessarily directed at expansion of the lid fissure, because the severe phimosis effectively denies access to the orbit. It is axiomatic that soft tissue drapes to the underlying musculoskeletal structures: loss of bone or deep soft tissue leads to contraction and shrinkage of the overlying tissues, while mass effects lead to distention and expansion of those same overlying tissues—this is, of course, the genesis of the microblepharon in this condition, and the principle by which tissue expanders work in the first place. Traditionally, the lids and conjunctiva are expanded with a series of progressively enlarging acrylic conformers (Fig. 2). This effort requires significant dedication and time investment on the parts of the family, the physician, and the ocularist, because the management requires frequent office visits and multiple examinations under anesthesia.

While the lids are expanded via anteriorly directed pressure, the conjunctiva and fornix are expanded via posterior and radially directed pressure, and therein lies several rubs: each conformer has to be incrementally larger than the previous, but not so much larger that it is painful or impossible to place in the cul de sac. However, if it is too easily placed, it may be too small to have dramatic effect on lid dimensions. At the same time, the conformer has to be bulky enough to exert sufficient posterior pressure to induce conjunctival expansion, but not so bulky as to extrude from socket, while still exerting enough anterior pressure to effect lid growth: what one gains in posterior pressure is often lost in anterior pressure, and *vice versa*. For that reason, some surgeons elect to insert bulky appliances under anesthesia and place temporary suture tarsorrhaphies (which can sometimes cheesewire through the lids over time) [16,17]. Additionally, progressively enlarging conformers are nonetheless static, and will force the soft tissues to mold to their shapes. Therefore, the conjunctival space often adopts a dumbbell, spherical, or acorn-shape, with inadequate forniceal depth [8,16]. Clearly, current therapies leave much to be desired.

Current therapies: orbital expansion

Once the lids are opened adequately to afford orbital access, the bony skeleton is addressed. Again, traditionally, conventional solid orbital spheres are used, although the contracted bony orbit severely limits the size of implant able to be placed, ending in uniformly disappointing results. Again, the trade-off appears: small implants

Figure 2. Therapy for anophthalmos with enlarging conformers, and results



(**A**) Traditional therapy initially includes a series of progressively enlarging conformers. In this figure, the middle conformers represent the patient's initial socket impressions, which were subsequently replaced by the upper, and then the lower series of conformers (Photo courtesy of Dr. Asa D. Morton, MD, San Diego, CA). (**B**) After several months, the orbits still show marked growth delay that is characteristic of clinical anophthalmia. Note the persistent lid phimosis and compression of all midfacial dimensions.

yield negligible results; large implants risk extrusion. Repeated implant exchanges require numerous anesthesias and surgical traumas until the skull has matured [13].

Because of this, some surgeons use inflatable balloon tissue expanders, implanted via bicoronal flap and surgical orbitotomy [4,11,13,14]. The balloon is inflated with saline via an exteriorized injection/inflation port placed distally from the orbit. The balloon is inflated routinely, either in the office or at home [11–13]. Inflation pressures can sometimes reach 150 to 200 mm Hg, which can be uncomfortable for the patient and the parents (and ultimately the physician) [11,16,17]. To minimize inflation pressure spikes, one group of researchers developed a pulsatile orbital expander that transmits steady carotid pulsations to the orbit [18]. These devices all carry risks of tissue ischemia, infection, and extrusion [11]. Perhaps not surprisingly, although inflatable orbital expanders are effective, ophthalmologists do not commonly use them.

The ideal expander

An ideal expander would have several characteristics: it would be easily placed through a small access site; would gradually enlarge over a relatively short time, yet be well tolerated over the long term; would avoid uncomfortable inflation spikes; would be resistant to infection, extrusion, or inflator complications; and would require minimal intervention, manipulation, or revision.

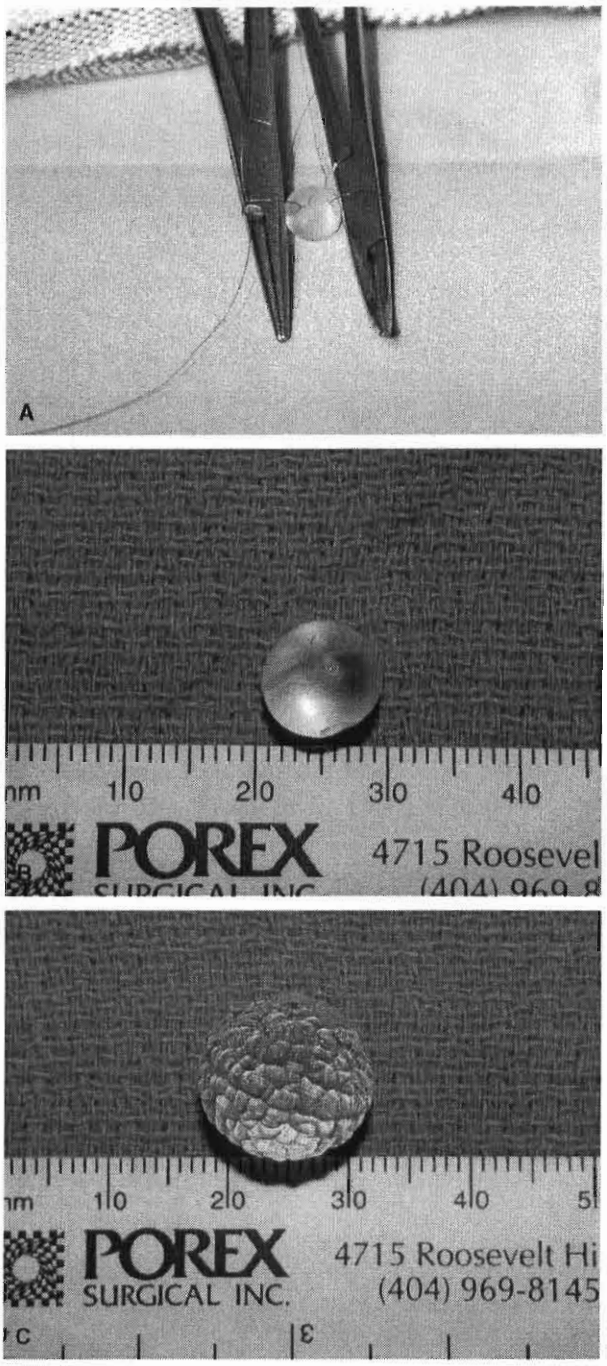
Katowitz *et al.* [7,8] showed promising results in this regard using dermis-fat grafts as orbital implants. Being a vascular tissue that grows with the child, dermis-fat grafts can exert enough orbital pressure and volume to expand both the lids and socket. In some cases, the growth was so exuberant that the dermis-fat grafts had to be debulked to avoid overexpansion. Best success was achieved when the dermis-fat graft was placed before 3 years of age [7,8]. Because of the familiarity of the procedure and the low risks of complications, this procedure is gaining broad acceptance.

Reedy *et al.* [19] attempted to determine the optimal orbital pressure required of an orbital expander to stimulate normal orbital growth. In a well-crafted and controlled study on newborn Yorkshire piglets, they demonstrated that near normal orbital pressures (20 mm Hg in this study) resulted in near normal orbital volumes, that less than normal pressures resulted in reduced orbital growth, and that greater than normal pressures resulted in larger orbital volumes. Normal adult human orbital pressures have been separately shown to be approximately 3 to 6 mm Hg [20–22], so direct application of Reedy's pressures to the human may not be valid. On the other hand, it may be that the smaller infant orbit is more equivalent to that of the piglet and requires a higher pressure for normal growth.

Hydrogel orbital expanders

After several years of use in Europe, a new hydrogel orbital expander—which appears to meet many of the requirements of the ideal expander—has been recently introduced and marketed in the United States (Osmed GmbH, Illmenau, Germany, distributed in the United States by IOP, Inc., Costa Mesa, CA). Hydrogels are highly hydrophilic polymers that expand by osmotically imbibing water (or in the case of implanted expanders, tissue fluids). They are commonly used to make soft contact lenses and some intraocular lenses [9,10•,11,14,15,23,24]. The amount and rate of expansion can be engineered and very precisely controlled. These characteristics, coupled with the ability to craft the anhydrous material into any desired shape and size [23,24], make it an attractive material to consider in reconstructing congenital anophthalmic sock-

Figure 3. Osmotic hydrogel expanders



(**A**) Hemispheric shape is for lid and conjunctival expansion. Demonstration of surgical technique of loose retention sutures to allow for expansion of the device while in the conjunctival sac. (Photo courtesy of Dr. John D. Ng, MD, Portland, OR). (**B**) Spherical shapes are for orbital implantation and expansion. The figure demonstrates the 5-mL sphere in its contracted, anhydrous shape. (**C**) Within a few hours of hydration (in this instance, in water), expansion is already well under way.

ets and orbits. Over the last several years, a variety of hydrogel materials have been used in general plastic and orbital surgery for tissue expansion [9–15,23–25••,26], as well as for retinal scleral buckling elements [27]. The current product is a copolymer of vinyl pyrrolidone and methylmethacrylate [23–25••], whereas prior ophthalmic and retinal hydrogels were crosslinks of different materials [11–13,27].

Two ophthalmic appliances are available: one, a hemisphere designed for conjunctival expansion; and the other, a sphere intended for bony orbital expansion (Fig. 3). Both are inserted in the dry, shrunken, anhydrous state, and expand gradually over several weeks to their fully inflated sizes, roughly a 10-fold increase in volume. The hemisphere is placed into the conjunctival sac, much as a regular conformer, and held in place with fornix reconstruction sutures tied externally (loosely, to allow for expansion). One surmises that these sutures not only help hold the conformer in place against extrusion, but also enhance radial expansion of the conjunctival fornices. Normal tear secretion gradually swells the conformer to maximum size within a few weeks, as it exerts a constant hydrostatic pressure of 20 to 30 mm Hg. A suture tarsorrhaphy is recommended to help maximize anterior and posterior pressure while minimizing the likelihood of extrusion as the conformer expands. Maximum expansion is achieved within 30 days, although the conformer can be retained for 2 to 3 months [11]. Once maximum socket expansion is realized, a conventional prosthesis can be placed [11].

The orbital expander is spherical. Its anhydrous size is roughly one tenth the expanded volume. Surgically, it can be placed intraorbitally through a small lateral soft-tissue incision, avoiding the need for the central conjunctival incision that is required for conventional spheres and dermis-fat grafts, thereby decreasing the chances for anterior wound breakdown and extrusion. Similarly, this avoids the need for bicoronal flap and lateral orbitotomy as required for balloon expander insertion and removal. Additionally, because the hydrogel implants are self-inflating, there is no need for subfascial tracts or remote injection ports, with less risk of inflator-related complications [11]. The orbital expander exerts a constant pressure of about 20 to 25 mm Hg. As mentioned previously, whether that pressure is appropriate for human infants is, at this writing, a matter of conjecture. Regardless, it appears that even the actively expanding sphere is better tolerated than the high-pressure spikes associated with inflatable balloons [9,10•,11,14,16,17].

Potential drawbacks

As with any new material or technique, there can be potential for unintended or unexpected consequences in the long term. The fly in this particular soup is the recent spate of reports of complications of prior hydrogel appli-

cations in the orbit, to whit, retinal buckling elements made of MIRAgel (MIRA, Waltham, MA) and its precursor, MAI, popular products introduced in the late 1970s [27,28•,29••,30•,31••–38]. Reputed advantages of these products were the following: less likelihood for extrusion or erosion because of the material's softness and elasticity; less likelihood of buckle infections because of its lack of dead-air spaces and the fact that it could be saturated in antibiotic solution (which it would gradually release thereafter); the degree of swelling could be controlled by controlling hydration; and, it stimulated the formation of a surrounding pseudocapsule [27,28•,29••,30•]. In fact, most of these claims were borne out clinically, at least in the short-term [29••,35]. Unfortunately, over the long term (10+ years), complications of late hydrogel breakdown were recognized, attributed to uncontrolled swelling of the material beyond its initial size [28•,29••,31••,33]. In fact, the long time lapse between implantation and development of complications may lead to initial misdiagnosis of the condition, particularly if the patient presents to a clinician unfamiliar with either the prior surgery performed, or the material used [31••]. Indeed, since withdrawal of MIRAgel from the market in the mid 1990s, many novice ophthalmologists are no longer historically familiar with the material at all. There are now reports of buckle extrusions, intraocular erosion and migration, progressive limitation of motility, intraorbital fibrosis and mass effect, pain, foreign body granuloma formation, and inflammatory orbital pseudotumor [27,28•,29••,30•,31••,32–38]. Attempts at removing the material are frustrating, because the hydrogel becomes very friable with age, becomes semisolid, and fragments easily between the forceps. Some advocate using cryo or curettage to help remove the pieces [29••,30•,32].

It is this point that gives us pause when it comes to contemplating placing the hydrogel orbital sphere for an extended period, and tempers our eagerness to clamor aboard the wagon quickly. Admittedly, the current hydrogel polymers are different from MAI/ MIRAgel—different base compounds, different cross-linking, different polymerization characteristics—and hydrogel intraocular lenses appear to be tolerated differently from MAI/ MIRAgel [9,10•,11–15,21–24]. Additionally, the rate of extrusion of the MAI/ MIRAgel elements is significantly lower than for silicone buckling elements [28•,29••]. Nevertheless, one wonders what the effect of any hydrogel implant would be in the extreme long term—how well tolerated will the material be over the course of an 80-year lifetime? Obviously, as with any new idea or invention, time will tell. Perhaps a reasonable approach would be to use the hydrogel orbital expander as an initial, temporary step towards reconstruction, allowing it to remain for 5 to 7 years before replacing it with another hydrogel implant, a conventional implant, or a dermis-fat graft.

We could not find any reports of orbital implants being removed. Other hydrogel tissue expanders are covered in a soft, silicone wrap that helps maintain the shape and to control the expansion of the material [25••,26]: the orbital implant is not so encased. When similar hydrogel expanders were removed from elsewhere on the body, there was no comment on the difficulty of removal or of fragmentation of the material, but in those cases, the tissue expanders were removed within weeks of implantation. Nonetheless, despite the chemical differences between the Osmed and MAI/ MIRAgel implants, one cannot help but assume that they would share some characteristics, especially of long-term fragility and friability. Time will tell. However, the concept of a self-expanding orbital implant that can be placed early in the course of clinical congenital anophthalmia is certainly appealing.

Conclusion

Reconstructing congenitally anophthalmic sockets and orbits poses significant difficulties and obstacles that often result in universal frustration and disappointment for all concerned. Current expansion modalities all suffer from significant limitations. Although use of dermis-fat grafts continues to gain popularity among ophthalmologists, a new generation of self-inflating hydrogel tissue expanders is now available that significantly expands our options. The potential for controlled, gentle expansion of the lids, conjunctiva, and orbit with these devices is intriguing and exciting. Prior experience with hydrogel retinal implants should temper initial enthusiasm for long-term use of the implanted orbital expander, but initial reports are encouraging.

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