Title: INTRAOCULAR PRESSURE ATTENUATION DEVICES AND METHODS

Abstract: Devices and methods described herein dampen transient intraocular pressure experienced by the eye through attenuation of intraocular pressure waves and, thus, reduce wall stresses in non-compliant eyes such that the optic nerve is protected from damage in ocular hypertensive or glaucoma patients, or during traumatic ocular procedures, and the refractive disorders of myopia, hyperopia, and/or presbyopia are moderated or reversed. A compressible attenuation device insertable within or in communication with the chambers of the eye preferably has an expanded volume within the range from about 0.1 cc to 7 cc. Embodiments include devices filled with a compressible medium comprising gases and structural components, having a septum plug for sealing and filling, formed as a cap extending from a base, and located within the eye, between the ocular tissues of the eye wall, or outside the eye, while in intimate communication with the interior of the eye for pressure attenuation.

FIG. 6D
Field

[001] The present invention relates generally to methods and apparatus for attenuating and/or baffling transient pressure waves in relatively incompressible materials in the eye, and in particular to the treatment of disorders of the eye caused by fluctuations of intraocular pressure (IOP).

Background

[002] Pressure waves are known to propagate through incompressible fluids in various organs of the body. These pressure waves may be caused by a number of events including events within the body, such as a beating heart, breathing in the lungs, peristalsis actions in the GI tract, movement of the muscles of the body, or events such as coughing, laughing, external trauma to the body, and movement of the body relative to gravity. As the elasticity of the surrounding tissues and organs—sometimes referred to as compliance—decreases, the propagation of these pressure waves increases. These pressure waves have many undesirable effects ranging from discomfort, to stress on the organs and tissue, to fluid leakage such as urinary incontinence, to renal failure, stroke, heart attack, visual impairment, refractive error and blindness.

[003] Pressure accumulators and wave diffusers are types of devices that can modulate pressure waves in various non-analogous settings. Accumulator technology is well known and used in hydraulic systems in aircraft, manufacturing equipment, and water supply and distribution since the 1940s. Common types of accumulators include bladder accumulators, piston accumulators, non-separator (air over fluid), and weight loaded type accumulators.

[004] Wave diffusers also affect the transmission of pressure waves in incompressible systems in various settings. The function of such diffusers is to interrupt the progress of a pressure wave and distribute the energy of the wave in so many directions so as to destroy the integrity of a uniform wave front and its resultant effects. Wave diffusers may be used to protect a specified area from the impact of a wave front.

[005] Ocular disorders are a widespread problem in the United States and throughout the world, affecting people of all ages. Visual impairment, including blindness, can be the result of many different disorders including relatively benign conditions such as myopia, hyperopia and presbyopia, in addition to more devastating conditions such as glaucoma, ocular hypertension, macular degeneration, retinal detachment and retinal tears. Many of these conditions can stem
from a lack of compliance in the eye that stimulates high and fluctuating pressures which in turn can damage key, vision-producing structures within the eye.

[006] Ever since the recognition by Bannister in the 16th century that certain forms of blindness were associated with a firm eye, ophthalmologists have been trying to measure and reduce IOP. IOP has been commonly used to evaluate the health of the human eye and has been linked to disorders such as glaucoma, retinal detachment, retinal tears, macular degeneration and refractive error. Reducing IOP has also been the intended therapy to treat many of these disorders.

[007] Historically, the most common method of measuring IOP has been pressing on the cornea of the eye (the anterior chamber) to judge the rigidity or compliance of the chamber. This approach eventually evolved into an instrument known as the Schiotz tonometer which was a metal plunger that was used to press the anterior chamber for several seconds and computed a pressure reading. In more recent times, the ophthalmologist measures IOP either by placing a plastic prism on the cornea or sending a puff of air onto the cornea. These tests compute pressure by measuring the amount of force required to deform the cornea of the eye. When the pressure required to deform the cornea is applied a certain amount equilibrates to the pressure inside of the eye, an intraocular pressure measurement is recorded. In essence, the tests are measuring the rigidity or compliance of the eye to compute IOP. A compliant cornea would be indicative of low or normal pressure; a rigid eye would be indicative of high pressure. "Normal" IOP is between 15-21 mmHg, but can vary greatly during different times of the day or as a result of varying corneal thickness. A measurement of more than 21 mmHg is not necessarily indicative of glaucoma; rather, it suggests that the patient has ocular hypertension. Evidence of nerve cell loss is needed for a definitive diagnosis.

[008] It should be noted that there are many problems that have been reported in the measurement of intraocular pressure using tonometry. First, it is known that pressure is dynamic and varies throughout the course of the day and at night. Straining, blinking and eye rubbing can cause increases in eye pressure, and other activities like drinking water, tightening a necktie and blowing into a musical instrument can cause dramatic increases in IOP, none of which is captured during an office visit. Similarly, anatomical differences, such as corneal thickness, can distort pressure readings. It is becoming increasingly accepted that traditional forms of measurement are inadequate and may not precisely identify what the cause of the ocular disorder is.

[009] A number of attempts have been made to reduce IOP and combat ocular disorders such as glaucoma, including the administration of drugs and surgical intervention. One such attempt
involves an attenuation device placed within the human eye as disclosed in Application Serial No. 11/737,054 filed April 18, 2007, herein incorporated by reference.

[010] Certain embodiments of one or more aspects of the invention provide improved pressure attenuation methods and devices that can optionally be refillable or rechargeable in-situ and exhibit reduced deflation or leakage over time.

Summary

[011] Embodiments described herein are directed to methods and apparatus for attenuating and/or baffling transient pressure waves in the eye, and, in particular, to the treatment of disorders of the eye exacerbated by fluctuations in intraocular pressure. The embodiments described herein include devices and methods that dampen transient intraocular pressure including pressure spikes experienced by the eye. During a high frequency transient pressure event, the eye becomes a relatively non-compliant environment due to a number of factors including the ocular skeletal structure, the compressive loads of contracting tissues bounding the eye, the decreased compliance of the musculature, nerve or connective tissue of the eye or vascular hypertension. The factors contributing to the reduced compliance of the eye are aging, anatomic abnormalities or trauma to the structures of the eye.

[012] The illustrative embodiments attenuate pressure waves and, thus, reduce wall stresses in a non-compliant eye such that the optic nerve is protected from damage in an ocular hypertensive or glaucoma patient. The attenuation of pressure waves also prevents the blood vessels in the back of the eye from bursting or leaking, as happens in age-related macular degeneration patients, prevents the retina from tearing at the back of the eye, and reduces or eliminates the stretching of refractive structures of the eye including the sclera, the cornea, the crystalline lens, the ciliary body and the capsular bag. By attenuating the pressure waves and reducing or eliminating the stretch of these tissues, the progression of refractive disorders such as myopia, hyperopia and presbyopia is halted and possibly reversed.

[013] In one embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled compressible member, such as an air cell or balloon. The attenuation device preferably includes a mechanical/structural plug preferably formed of silicone or the like, and preferably of a similar material as the thin-walled balloon. The plug is preferably insertable with an interference fit into a valve or port in the thin-walled balloon creating a septum. The mechanical/structural plug may advantageously provide a higher degree of seal integrity while allowing for a needle to be introduced into the interior of the balloon to fill the balloon.
[014] In another embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled balloon with a structural core that is compressible under pressure. The core may be a solid structure or, as in a preferred embodiment, a hollow thin walled structure with a plurality of cut-outs or holes thus resembling a wiffle ball structure. The structural core is preferably formed of silicone. A mechanical or structural core within a thin-walled balloon that is compliant will maintain its shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures.

[015] In another embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled balloon with a structural foam core that is compressible under pressure. A mechanical or structural foam core within a thin-walled balloon that is compliant will maintain its shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures.

[016] In a further embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled balloon with a core of small compliant pellets or spheres that are compressible under pressure. The pellets are preferably formed of silicone. A core of small compliant pellets or spheres within a thin-walled balloon that is compliant will maintain shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures.

[017] According to another embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled air cell or balloon. The attenuation device preferably includes a sealing plug preferably integrally formed with the wall of the balloon and disposed within the interior of the balloon. Once the balloon is in place within a chamber of the eye and inflated, a drawstring, such as a suture or the like, coupled to the plug is pulled drawing the plug into a valve or port formed in or coupled to the opposing wall of the balloon. The plug is maintained within the port, preferably in an interference fit relationship, creating a septum that gaseously seals the port. The plug advantageously provides a higher degree of seal integrity than an adhesive type septum.

[018] In a further embodiment there is provided a compressible attenuation device insertable within the chambers of the eye preferably in the form of a thin-walled balloon with an integral cage-type structure that is compressible under pressure. A structured cage formed from plastic or metal fibers, vanes or ribs within a thin-walled balloon that is compliant will maintain its shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures.
In another embodiment there is provided a compressible attenuation device implantable within the wall of the sclera of the globe of the eye preferably in the form of a plug that is compressible under pressure. The plug preferably includes a cylindrical base, a partial spherical cap extending axially from one end of the base and radially from the periphery of the base and a flange extending radially from the periphery of the base at an opposite end of the base. The plug is preferably formed from polymeric material and will maintain its shape and structure, and afford permanent and long term pressure attenuation when exposed to constant and variable pressures.

According to another embodiment there is provided a compressible attenuation device implantable within the wall of the sclera of the globe of the eye preferably comprising a thin membrane or patch that is moveable in response to pressure fluctuations. The attenuation device preferably includes a thin walled hollow body comprising a cylindrical base, a cap enclosing one end of the base and extending outwardly from the periphery of the base wall, and flange at an opposite end of the base and extending outwardly from the periphery of the base wall. The cap preferably includes a centrally located thin membrane or patch portion. The body is preferably formed from polymeric material and will maintain its shape and structure, and afford permanent and long term pressure attenuation when exposed to constant and variable pressures.

In another embodiment, there is provided an inflatable compressible attenuation device insertable within the chambers or walls of the eye preferably in the form of a thin-walled air cell or balloon with a refillable valve or port. Preferably, the refill port is contained outside the eye, for example, resting on the scleral tissue under the conjunctiva, with the remainder of the device contained inside the eye or within the wall tissues. Alternatively, the refill port could be positioned inside the eye tissues, aligned or positioned for easy access via a needle incision or paracentesis.

The refill port advantageously enables recharging of the device without re-operation. The eye can be anesthetized with local anesthetic and the port accessed with a cannula at the slit-lamp or exam table. After recharging the device, the port reseals such that the balloon integrity is maintained and it will hold gas for an extended period of time. The refill port can be used repeatedly, as needed, to provide maximum protection for the patient. This may be yearly, twice yearly, quarterly, or even monthly, for a duration of 3, 5, or 10 years.

In another embodiment, the refill port includes a base with a passageway in communication with the interior of the balloon or air cell, and implantable in the scleral wall of the eye. A port arm is coupled to the base and extends away from the base at an oblique angle.
The port arm includes a center channel in communication with the passageway of the base. The channel includes a re-sealable sealing mechanism such as, e.g., a septum plug, a flapper valve, a check valve or the like, that seals itself upon removal of the fill device such as cannula, syringe needle, or the like. With the base implanted in the scleral wall, the port arm extends upwardly at an angle away from the scleral wall for easy access. The port arm can remain hidden within or below the conjunctiva.

[024] In another embodiment, the attenuation device can be fabricated from two different wall materials, each with specific properties, without being attached or bonded to each other except at the fill point of the device. In this way, one material may be chosen for its gas barrier properties while the other material layer may be optimized for its moisture barrier properties. By not attaching or bonding the two materials, the attenuation of the device is not limited by the combined wall thickness, but is rather dictated only by the stiffer material layer.

[025] In another embodiment, the attenuation device can be positioned within the eye, within the outer tissue layers of the eye, or outside the eye. The primary consideration is to maintain communication between the attenuation device and the ocular environment, and the device may be located wherever is most desirable for the surgeon and patient.

[026] Further features and advantages of the present invention will become apparent to those of skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

**Brief Description of the Drawings**

[027] Figure 1A is a schematic cross-sectional view of the eye. The diagram shows the major structures within the eye, including the anterior chamber, the posterior chamber and the vitreous humor.

[028] Figure 1B is a schematic cross-sectional view of the eye which shows the flow of aqueous humor within the different chambers of the eye.

[029] Figure 2A illustrates intraocular pressures spikes that occur during continuous pressure monitoring of the eye. The spikes occur when an instrument is pressed on the anterior chamber of the eye at regular intervals.

[030] Figure 2B illustrates the dynamic intraocular pressure changes that occur over a 24 hour period.

[031] Figure 3A is a graph illustrating the effect on intraocular pressure of the presence of an implanted attenuation device.
[032] Figure 3B is a screenshot of the model eye test system when a 30 mmHg pressure pulse was applied to the chamber.

[033] Figure 3C is a screenshot of the test system with an air bubble as a simulated pressure attenuation device when a 30 mmHg pressure pulse was applied to the chamber.

[034] Figure 4A is a schematic view of a circular shaped attenuation device.

[035] Figure 4B is a side elevation view of the attenuation device of Figure 4A.

[036] Figure 4C is a detailed view of a septum plug and valve assembly for the attenuation device of Figure 4A.

[037] Figure 4D is a plan view of an exploded assembly of the septum plug and valve shown in Figure 4C.

[038] Figure 4E is a schematic view of a circular shaped attenuation device.

[039] Figure 4F is a detailed view of a septum plug and valve assembly for the attenuation device of Figure 4E.

[040] Figure 4G is a perspective view of the septum plug shown in Figures 4E and 4F.

[041] Figure 4H is a schematic view of an attenuation device with an integral plug.

[042] Figure 4I is a schematic view of the attenuation device of Figure 4H with the plug deployed in a sealing arrangement within a port.

[043] Figure 4J is a detailed view of the plug in Figure 4H.

[044] Figure 4K is a detailed view of the valve for the attenuation device of Figure 4H in the open position.

[045] Figure 4L is a detailed view of the septum plug and valve assembly for the attenuation device in the closed position.

[046] Figure 4M illustrates a cross-sectional view of the attenuation device implanted into the vitreous humor and anchored in position with a suture.

[047] Figure 4N is a schematic view of a re-fill port for a pressure attenuation device.

[048] Figure 4O is a side elevation view of the re-fill port of Figure 4N shown coupled to a pressure attenuation device positioned in the chamber of the eye.

[049] Figure 4P is a detail view of the re-fill port taken along line 4P in Figure 4Q.

[050] Figure 4Q is a cross-sectional view the re-fill port taken along line 4Q—4Q in Figure 4P.

[051] Figure 5A is a schematic view of a circular shaped attenuation device.
[052] Figure 5B is a perspective view of the attenuation device of Figure 5A with the compressible component having a plurality of cut-outs or holes.

[053] Figure 5C is a schematic view of a circular shaped attenuation device.

[054] Figure 5D is a side elevation view of the attenuation device of Figure 5C.

[055] Figure 5E is a schematic view of a circular shaped attenuation device.

[056] Figure 5F is a side elevation view of the attenuation device of Figure 5E.

[057] Figure 5G is a schematic perspective view of a spherically shaped attenuation device with cage-type structure.

[058] Figure 5H is a side elevation view of the attenuation device of Figure 5G.

[059] Figure 5I is a schematic perspective view of the attenuation device of Figures 5G and 5H rolled up and contained within an insertion device.

[060] Figure 5J illustrates a cross-sectional view of the attenuation device implanted into the vitreous humor and anchored in position with a suture.

[061] Figure 5K illustrates a cross-sectional view of an embodiment of an attenuation device where the inner wall is made of one material and the outer wall is made of another, separate material.

[062] Figure 6A is a schematic plan view of a scleral plug attenuation device.

[063] Figure 6B is a cross-sectional view of the attenuation device of Figure 6A.

[064] Figure 6C is a cross-sectional view of an alternative embodiment of the attenuation device shown in Figure 6B.

[065] Figure 6D illustrates a cross-sectional view of the attenuation device implanted and anchored into the wall of the sclera and extending into the vitreous humor.

[066] Figure 6E is a perspective view of a scleral patch attenuation device.

[067] Figure 6F is a cross-sectional view of the attenuation device of Figure 6E.

[068] Figure 6G illustrates a cross-sectional view of the attenuation device implanted and anchored into the wall of the sclera and extending into the vitreous humor.

[069] Figure 7A is a schematic view of a toroidal shaped attenuation device.

[070] Figure 7B is a side elevational cross-section view through one embodiment of the attenuation device of Figure 7A.

[071] Figure 7C is a side elevational cross-section view through one embodiment of the attenuation device of Figure 7D.
[072] Figure 7D is a schematic view of a toroidal shaped attenuation device.

[073] Figure 8A is a schematic view of a toroidal shaped attenuation device as in Figure 7A, with an integral baffle therein.

[074] Figure 8B is a side elevational cross-section view through one embodiment of the attenuation device of Figure 8A.

[075] Figure 9 is a schematic illustration of the attenuation device disrupting the unitary progression of a pressure wave front.

[076] Figures 10A thru 10E illustrate top-down views of different embodiments of attenuation devices that can be implanted in any chamber of the eye.

[077] Figures 10F thru 10H illustrate cross-sectional views of different embodiments of attenuation devices that can be implanted in the anterior chamber of the eye.

[078] Figures 11A thru C illustrate cross-sectional views of different embodiments of attenuation devices that can be implanted in the posterior chamber of the eye, anterior to the capsular bag and posterior to the iris.

[079] Figures 12A and B illustrate cross-sectional views of different embodiments of attenuation devices that can be implanted in the capsular bag of the posterior chamber of the eye.

[080] Figure 13A illustrates a cross-sectional view of one embodiment of an attenuation device that can be implanted in the vitreous humor and float freely in the vitreous humor.

[081] Figures 13B thru 13E illustrate cross-sectional views of different embodiments of attenuation devices that can be implanted into the vitreous humor.

[082] Figure 14 illustrates cross-sectional view of an embodiment of an attenuation device that can be implanted into the vitreous humor and anchored in position with a cap.

[083] Figure 15A illustrates a cross-sectional view of one embodiment of an attenuation device which is placed within the eye.

[084] Figure 15B illustrates a cross-sectional view of one embodiment of an attenuation device which is placed within the wall tissues of the eye, in the suprachoroidal space.

[085] Figure 15C illustrates a cross-sectional view of one embodiment of an attenuation device which is placed outside the eye, underneath the conjunctiva, in intimate communication with the inner ocular environment.

[086] Figure 16A is a side elevational schematic view of one embodiment of an attenuation device introducer.
Figure 16B is a side elevational schematic view of an alternative embodiment of an attenuation device introducer.

Figure 16C is a cross-section through the line 16C-16C in Figure 16.

Figure 17A is a schematic representation of the delivery system of Figure 16A trans-sclerally positioned within the eye.

Figure 17B is a schematic illustration as in Figure 17A, with the attenuation device inflated.

Detailed Description of the Preferred Embodiment

Embodiments provided herein are directed to pressure attenuation or baffling devices and further also to methods for attenuating and/or baffling transient pressure waves in relatively incompressible materials or fluids in organs of the body. Illustrative embodiments discussed below relate generally to the fields of ophthalmology, and in particular to the treatment of disorders of the eye exacerbated by fluctuations in intraocular pressure. However, as will be readily understood by those skilled in the art, and as described below, the present invention is not limited to the fields of ophthalmology and methods and apparatus of embodiments of the present invention may be used in other organs of the body as well to attenuate and/or baffle pressure transients or reversibly occupy intraorgan space. Other organs, tissues, fluids and bodily environments in which attenuators according to one or more aspects of the invention may be placed in, on, between, or in fluid or pressure communication with various organs, tissues, and fluids found in the body including those found in the following systems such as the digestive, endocrine, lymph, muscular, nervous, reproductive, respiratory, reproductive, and urinary system.

Certain embodiments described herein include devices and methods that dampen transient intraocular pressure including pressure spikes experienced by the eye. During a high frequency transient pressure event, the eye becomes a relatively non-compliant environment due to a number of factors including the ocular skeletal structure, the compressive loads of contracting tissues bounding the eye, the decreased compliance of the musculature, nerve or connective tissue of the eye or vascular hypertension. The factors contributing to the reduced compliance of the eye are aging, anatomic abnormalities or trauma to the structures of the eye. Various illustrative embodiments attenuate pressure waves in a non-compliant eye such that the optic nerve is protected from damage in an ocular hypertensive or glaucoma patient; attenuate pressure waves such that the blood vessels in the back of the eye are prevented from bursting or leaking, as happens in age-related macular degeneration patients; attenuate pressure waves such
that the retina is prevented from tearing at the back of the eye; and attenuate pressure waves
that stretch refractive structures of the eye which include the sclera, the cornea, the crystalline
lens, the ciliary body and the capsular bag. By attenuating the pressure waves and reducing or
eliminating the stretch of these tissues, the progression of refractive disorders such as myopia,
hyperopia and presbyopia is halted and possibly reversed.

[093] Pressure attenuators can dramatically lower the Intraocular pressure (IOP) inside the
eye, as well as attenuate the pressure fluctuations which occur. Certain embodiments function
either by gas or some mechanical system which becomes compressed or displaced (such as a
baffle) when the pressure is transiently elevated. In the case of a gas-based system, the gas may
tend to dissipate with time, as a function of the loads experienced as well as the intrinsic barrier
properties of the material of the compressible device.

[094] Various attenuation devices provided herein can be tethered or untethered in the eye
and can be adapted to remain in the eye for a period of the duration of the intra-operative
procedure up to a permanent implant, between several hours and several years, between one
week and one year, or between one and six months. Attenuation devices according to one or
more aspects of the invention may preferably be a small, thin-walled elastomeric compressible
member, such as an air cell or balloon. According to one or more methods attenuation devices
can be free-floating in the eye or bodily site or surgically affixed to the eye wall or bodily site
through the use of sutures, adhesives, staples, rivets, pincers, nails, screws and other accepted
methods or attached to the iris, cornea, sclera, trabecular meshwork, posterior lens capsule or
other anatomical structures within the eye or bodily site. In certain embodiments the attenuator
is friction fit within the organ space or bodily site. In other embodiments the device is
expanded from a reduced profile to conform to the implantation site and in another
embodiment the device is expanded such that it continually provides outward pressure in one or
more dimensions on the implantation site thereby fixing itself at the site.

[095] For those air cells or balloon requiring inflation upon introduction into the eye, a
septum is typically fabricated from an adhesive applied to the thin wall of the balloon to allow
the balloon to be filled with a needle and remain gas tight. Gas loss around an adhesive-formed
septum in a thin-walled balloon reduces the effectiveness and life of the attenuation device and
thus one or more embodiments provided herein are directed at reducing this loss.

[096] Certain attenuators of an air cell, balloon, or enclosure variety may over time tend to
experience gas loss through the thin elastomeric wall when exposed to constant or variable
pressures. Various embodiments are provided herein to prevent or minimize such gas loss
focused on the utilization or development of materials with acceptable vapor barrier properties
or coating of materials with less desirable vapor barrier properties to enhance the vapor barrier properties of the material. In other embodiments, these properties of optimal vapor barrier properties and moisture barrier properties may be accomplished with two entirely distinct and separate membranes, where one membrane is simply placed within the other membrane. In yet other embodiments, it may be necessary to refill the device periodically to ensure maximal attenuation. Alternatively utilizing a valve or opening mechanism which supports the recharging of the device and can prolong its lifetime of use and maximize the benefits to the patients. Additionally, other embodiments of the device may utilize a compressible material other than a gas, such as a gel, foam, or particles. Further embodiments of the device entail a compliant window or membrane which is affixed to the scleral wall of the eye to affect attenuation.

[097] There have been examples in the clinical literature demonstrating the effect that gas in the eye has on pressure. Tsilimbaris, et al showed in their study using Goldmann applanation tonometry (Current Eye Research 2002, Vol 24, No. 3, pp 202-205) that gas injected into the vitreous following vitrectomy surgery attenuated ocular wall pulsation. This attenuation effect correlated with the disappearance of the gas bubble—in other words, as the gas bubble disappeared the ocular pulse returned. While the bubble attenuated pulse it did not affect mean intra-ocular pressure. The article noted that increasing the elasticity of the eyeball could have important effects on macular degeneration as it is thought that reduced scleral elasticity can increase resistance to blood inflow—an important contributor to the pathogenesis of AMD. Other authors such as Lim (Archives of Ophthalmology, 1990, Volume 108 (5), pp 684-688) and Poliner (Archives of Ophthalmology, Volume 105, February 1987) have also noted the difficulty in ascertaining IOP in patients following gas injection in vitrectomy surgery. They note that the IOP is almost always underestimated by as much as 12 mmHg. This can be explained as the result of the compressibility of the gas bubble, and the absorption or attenuation of the force used to measure pressure. However, no one has shown or suggested that the attenuation effects of an air bubble could be used therapeutically to dampen pressure waves and treat ocular disorders.

[098] The use of a pressure attenuation device to attenuate dynamic pressure pulses in the eye was studied using computational modeling. Literature values for ocular tissue properties were used in a model eye of 5.5 mL volume. The effects of changing pressures in the eye were examined using a pressure loading method, where additional pressure was put into the eye of a fixed size. The effects of pressure attenuation were studied by affixing chambers of various compliances to this model to determine the overall influence of the device on the mean
intraocular pressure and the resulting wall stresses which occur at the position of the optic nerve.

[099] This study found that the wall stresses which result from these pressure pulses are extremely high, where a 30 mmHg baseline condition with 10 mmHg pressure spikes results in a wall stress at the optic nerve head of over 457 mmHg. A compliant device capable of attenuating 0.40 mL/kPa was able to reduce the peak wall stress by over 72 mmHg, or 16%. In an eye with a baseline pressure of 20 mmHg and with 10 mmHg pressure spikes, the wall stress at the optic nerve head is over 326 mmHg and a compliant device was able to reduce the peak wall stresses by over 62 mmHg, or 19%. The stresses at the optic nerve head are large because of the large ratio of eye radius to eye wall thickness, which is about 20:1. Therefore, with small deviations in pressure, such as by filling the eye with small volumes of fluid, the translated effect on the wall stress is high.

[0100] Thus, considering the problem of pressure and pressure spikes within the eye, evaluating the resulting pressure-induced forces at the point of the optic nerve head is essential to understand the magnitude of the problem. Small changes in measured intraocular pressures translate into large changes in wall stresses at the point of the optic nerve head, the site of the degeneration of the retinal ganglion cells. Therefore, designing attenuation devices which can reduce wall stresses to specified levels is an important design consideration. Devices which reduce wall stresses from peak values of over 450 mmHg and can reduce wall stress by 50 mmHg, 75 mmHg, 100 mmHg, or even 150 mmHg or more are desirable.

[0101] The eye 600 is comprised of three chambers of fluid as depicted in Figures IA and IB. There is the Anterior Chamber 601 between the cornea and iris, the Posterior Chamber 602 between the iris, zonule fibers and lens, and the Vitreous Chamber 603 between the crystalline lens and the retina. The Anterior and Posterior chambers are filled with aqueous humor, whereas the vitreous chamber is filled with a more viscous fluid, the vitreous humor. The aqueous humor and vitreous humor are virtually incompressible in the typical pressure ranges present within the human eye.

[0102] Compliance of the eye is defined as the ratio of the change in volume to the change in pressure, and the static compliance of the eye is measured during a typical tonometric evaluation. The static compliance index is measured by placing a mechanical force on the cornea and allowing the pressures to equilibrate for a time period of approximately 3-5 seconds. The static compliance index is calculated using standard applanation tonometry. Normal, compliant eyes will typically exhibit resting pressures from 10 mmHg to 21 mmHg during an office visit. Abnormal, rigid eyes will typically have pressures above 21 mmHg. The
steady state compliance of the eye is used to diagnose patients with problems such as damage to the optic nerves, macular and retinal problems, refractive problems, and damage to other critical structures of the eye.

[0103] In general, intraocular pressure spikes result from volumetric tissue displacement in response to gravity, muscular activity, vascular pulsation, rapid acceleration, blinking, straining, eye rubbing and other activities. The lack of compliance of the eye and the fluid contained in the eye with respect to events of high frequency, result in minimal fluidic pressure attenuation of the higher frequency pressure wave(s) and results in high intraocular pressures that are directly transmitted to the structures of the eye. Under steady state conditions, as shown in Figure IB, fluid passes (as indicated by the arrows) from the posterior chamber 602, to the anterior chamber 601, through the trabecular meshwork 605 and out Schlemm's canal 604, in effect, a volumetric pressure relief mechanism allowing a proportional volume of fluid to escape the eye, to lower the intraocular pressure to a tolerable level. However, this fluid flow relief mechanism is not "fast" enough to work for rapid pressure change as shown in Figure 2A where a continuous pressure monitor in the eye was used to monitor pressure spikes during periods when external pressure was applied to the eye. As demonstrated by the pressure spikes which can represent increases of more than 30 mmHg, the fluid flow in the eye does not adjust quickly enough to prevent these pressure changes. These pressure fluctuations occur throughout the course of the day as demonstrated in Figure 2B which uses a continuous pressure monitor to show the swings in pressure over the course of a 24 hour period, it should also be noted that these graphs show pressure in a normal, compliant eye. It is reasonable to expect that in a non-compliant eye, such as a glaucomatous eye, the intensity of the pressure spikes will be greater.

[0104] It is recognized herein that for the vast majority of patients suffering from problems of optical disorders, the cause and/or contributor to the dysfunction is a reduction of overall dynamic eye compliance rather than or in addition to steady state eye compliance. These patients may often have eyes that are compliant in steady state conditions (for example, normal tension glaucoma), but have become non dynamically compliant when subjected to external pressure events having a short duration of, for example, less than 10 seconds or in some cases less than 5 seconds, less than 2 seconds, less than 0.5 seconds, or less than .01 seconds. Reduction in dynamic compliance of the eye is often caused by some of the same conditions as reduction of steady state compliance including aging, use, distention, hypertension and trauma. The anatomical structure of the eye in relation to the eye socket, vascular structure and surrounding tissues causes external pressure to be exerted on the eye during talking, walking,
laughing, sitting, moving, turning, swallowing, sleeping, straining and blinking, as well as during traumatic ocular procedures.

[0105] Certain embodiments described herein provide for methods and devices for measuring and reporting the dynamic compliance of the eye. One method of determining dynamic compliance includes implanting a pressure transducer into the eye which continuously monitors changes in pressure, which as described below could be included with a pressure attenuator device. The transducer device could take up to 2000 readings per second and wirelessly transmit that information to an external source. Alternatively, an external device is contemplated with pressure measurements up to 2000 readings per second during extended pressure displacement.

[0106] Additional embodiments provide methods and devices for treating and/or compensating for reduced dynamic compliance of the eye. In one embodiment, a device having a compressible element is placed within the human eye, in a manner that allows the compressible element to act as a pressure accumulator or attenuator to attenuate transient pressure events. The term accumulator refers generally to devices that attenuate pressure, force, or energy in a given locale by absorbing and/or shifting away said pressure, force, or energy from said locale. The term attenuator refers generally to devices that attenuate pressure, force, or energy by dissipating or dampening said pressure, force, or energy.

[0107] Figure 3A illustrates the effect of an attenuation device on the intraocular pressure. Here, the intraocular pressure 352 with the attenuation device exhibits delayed rise and decay times and remains below the pressure of 21 mm Hg found in non-compliant eyes. This is in contrast to the intraocular pressure 354 which exceeds abnormally high pressure without an attenuation device.

[0108] Figures 3B-C illustrate pressure attenuation (i.e. pressure reduction) with an attenuation device. The data for these graphs were generated using a bench top eye simulation program. Here, the maximum spike pressure is 30 mmHg. The spike event duration is approximately 150 milliseconds, which is approximately equivalent to the duration of an ocular surface touch during a pressure measurement. With reference to Figure 3B, a test was conducted with a 5.5 mL rigid plastic container filled with saline. A regulated pressure of 30 mmHg was introduced into the container via a controlled solenoid valve. A pressure transducer detected the pressure rise. Here, the pressure rise time (Tr) of the container pressure 422 to reach 30 mmHg was approximately 80 milliseconds. With reference to Figure 3C, a similar test was conducted on a 5.5 mL rigid plastic container. Here, an air bubble simulating an attenuation device was placed inside the container filled with saline. During the spike event, the pressure inside the container
reached 18 mmHg versus 30 mniHg for the unattenuated sample, resulting in a 40% reduction of pressure vs. baseline.

[0109] In a preferred embodiment, an attenuation device is placed within the human eye. The attenuation device can be tethered or untethered in the eye and is intended to remain in the eye for a period of the duration of the intra-operative procedure up to a permanent implant, between several hours and several years, between one week and one year, or between one and six months. The attenuation device is preferably small with a relaxed (unstretched) volume of between .001 and 7 cc, more preferably between 0.1 and 5 cc and more preferably, between 0.1 and 3 cc. The attenuation device is a unitary component but can be comprised of two or more subcomponents. The attenuation device has a substantially uniform wall thickness of between 0.0001 inch to 0.25 inch, more preferably between 0.0005 inch and 0.005 inch, but could be designed to vary greatly, and still perform the intended function. As noted above, various attenuation devices describe herein such as those having air cells can be free-floating in the eye or surgically affixed to the eye wall through the use of sutures, staples, rivets, pincers, nails, screws and other accepted methods or attached to the iris, cornea, sclera, trabecular meshwork, posterior lens capsule or other anatomical structures within the eye. Other embodiments may also include attenuation devices with programmable, variable and adjustable buoyancy by using ballasting, specific inflation/deflation solutions, alternative materials of construction or by other means.

[0110] Referring to Figures and 4A-4D, an attenuation device 66 includes a valve 80 generally comprising a tubular body 82 defining a passageway 86 open to and in fluid communication with the interior 72 of the container 68 at aperture 88 and open to the exterior of the container 68 at aperture 85. In the illustrated embodiment in Figure 4B, the valve 80 is positioned across the seam 78, and may be held in place by the same bonding techniques utilized to form the seam 78. The port 80, however, may be formed integrally with either of the first or second components 74 and 76, or formed integrally with the container 68 if formed of unitary constructions. The valve 80 preferably includes one or more protuberances 84 extending inwardly from the tubular body 82. The one or more protuberances 84 preferably form an annular ring or lip and is preferably located at or adjacent to aperture 85.

[0111] A plug 90 or closure member is provided and acts as a septum sealing the container 68 against gas leakage through the valve 80. The plug 90 is preferably formed from the same or similar material as the valve 80 and container 68 such as silicone or the like. The plug 90 preferably comprises a cylindrical body 94 and semi-spherical cap 92, and a transition or neck region 96 that extends from the body 94 to the cap 92. The transition region 96 necks down to a
diameter smaller than the diameter of the cylindrical body 94 as it extends from the cylindrical body 94 to the cap 92 forming an annular trough in the plug 90.

[01 12] As illustrated in Figure 4C and 4D, the body 94 and transition region 96 of the plug 90 preferably has an interference fit with the tubular body 82 and lip 84 when inserted into the valve 80. As further illustrated, the Hp 84 and transition region 96 cooperate to retain the plug 90 in the valve 80.

[01 13] A filling device such as a syringe with a needle can be utilized to pierce the plug 90 and introduce compressible media into the interior cavity 72 of the container 68. Upon removal of the filling device, the plug 90 prevents or inhibits the escape of compressible media from the interior cavity 72 through the flow path 86.

[01 14] Once positioned within the eye, the interior cavity 72 is filled with the compressible media to produce a functional attenuation device 66. Fill pressures are contemplated to be between 0.1 and 150 mmHg, and more preferably between 1 and 100 mmHg and fill volumes are contemplated to be between 0.01 cc and 7 cc, and more preferably between 0.1 cc and 3 cc. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes. Pressures of less than 50 mmHg or even vacuums may be utilized if the structure of the attenuation device is sufficient to balance the negative pressure to produce a net force such that attenuation can occur. This may be accomplished, for example, in an embodiment where the attenuation device 66 is provided with a self-expandable support structure (e.g. nitinol wire frame), which provides a radially outwardly directed bias.

[01 15] The resiliency of the material of the attenuation device, and the pressure and volume of the inflation media are preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm’s canal or other drainage outlets in the eye.

[01 16] A high vapor pressure media could be used and include one or more of the following representative compounds, including heptafluoropropane, perfluoroctylbromide, perfluorohexane, perfluorodecalin, tetrafluoroethane, sulfur hexafluoride, hexafluoroethane, perfluoropropane, perfluorobutane, perfluoropentane, perfluorohexane, perfluoroheptane, perfluorooctane,
octafluoropropane, decafluoro-n-butane, perfluoroperhydrophenanthrene, or other similar compounds.

[01 17] Referring to Figures 4E, 4F and 4G, there is illustrated an alternative embodiment of a port 180 and plug 190 assembly. The valve 180 generally comprises a tubular body 182 defining a passageway 186 open to and in fluid communication with the interior 72 of the container 68 at aperture 188 and open to the exterior of the container 68 at aperture 185. The valve 180 preferably includes two or more annular protuberances or detents 184 and 183 extending inwardly from the tubular body 182 and forming an annular trough 187 in the tubular body 182 there between. The annular detent 184 preferably forms an annular lip located at or adjacent the aperture 185. The plug 190 or closure member is provided and acts as a septum sealing the container 68 against gas leakage through the valve 180. The plug 190 preferably comprises a cylindrical body 194 with two or more annular ridges or lips 193 and 195 extending outwardly from the body 194 forming a trough 197 there between.

[01 18] As illustrated in Figure 4F, the plug 190 and port 180 have an interference fit with the ridges and troughs of both components cooperating to retain the plug 190 in the valve 180.

[01 19] Referring to Figures 4H through 4M, there is illustrated an embodiment of an attenuation device 66 which comprises a moveable wall on an inflatable container 68, such as air cell or balloon, and an integral plug 90 to facilitate sealing the inflatable container 68. The inflatable container 68 is illustrated as having a generally oval profile, although other profiles may be utilized such as a circle, sphere and the like. The diameter of the inflatable container 68 may be varied within the range from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device. Many embodiments of the inflatable containers 68 will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the inflatable container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet inflatable containers 68 are utilized. The sum of the volumes of the multiple containers will equal the desired uncompressed displacement.

[01 20] The inflatable container 68 illustrated in Figures 4H-4M comprises a flexible wall 70 for separating the compressible contents of the attenuation device 66 from the external environment. The flexible wall 70 is preferably formed of unitary construction with a wall
thickness of about 0.0018 inches thick. The attenuation device is intended to be inflated to a volume less than 5 ml or generally within the range of about 0.3 to 2.5 ml.

[0121] The flexible wall 70 defines an interior cavity 72. As is discussed elsewhere herein, interior cavity 72 preferably comprises a compressible media, such as gas or foam. Other media or structures capable of reduction in volume through a mechanism other than strict compression may also be used. For example, a material capable of undergoing a phase change from a first, higher volume phase to a second, lower volume phase under the temperature and pressure ranges experienced in the eye may also be used.

[0122] In order to minimize trauma during delivery of the attenuation device 66, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration to a second, enlarged cross-sectional configuration. The attenuation device 66 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once positioned within the eye to accomplish the pressure attenuation function. Preferably, a cross-sectional configuration of the attenuation device 66 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by stretching a deflated inflatable container 68 about a longitudinal axis of an introducer device 46, while the interior cavity 72 is evacuated.

[0123] Once positioned within the eye, the interior cavity 72 is filled with the compressible media to produce a functional attenuation device 66. Fill pressures are contemplated to be between 0.1 and 150 mmHg, and more preferably between 1 and 100 mmHg and fill volumes are contemplated to be between .01 cc and 7 cc, and more preferably between 0.1 cc and 3 cc. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes.

[0124] The resiliency of the material of the attenuation device, and the pressure and volume of the inflation media are preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm's canal or other drainage outlets in the eye.

[0125] To facilitate sealing the interior cavity 72 following placement and inflation of the attenuation device 66 within a chamber of the eye, the inflatable container 68 is preferably provided with the integral plug 90, which is capable of sealing the valve or port 80 with an
interference fit. In the illustrated embodiment, the valve 80 and plug 90 are preferably integrally formed with the container 68 in opposing walls. As illustrated in Figure 4I and 4M, when the plug 90 is in a sealing arrangement with the valve 80, the interior 72 of the container 68 is divided into two chambers. As illustrated in Figure 4M, this configuration advantageously conforms to the contour of the interior chambers of the eye.

[0126] Referring to Figures 4H, 4K and 4L, the valve 80 generally comprises a tubular body 82 defining a passageway 86 open to and in fluid communication with the interior 72 of the container 68 at aperture 88 and open to the exterior of the container 68 at aperture 85. The valve 80 preferably includes one or more annular troughs 84 formed in the wall of the tubular body 82. The plug 90 or closure member, as illustrated in Figure 4L, preferably acts as a septum sealing the container 68 against gas leakage through the valve 80. The plug 90 is preferably formed from the same or similar material as the valve 80 and the wall 70 of the container 68 such as silicone or the like. The plug 90 as illustrated in Figure 4J preferably comprises a cylindrical body 96 extending from the wall 70 of the container 68, a tapering insertion end 92, and an annular detent, protuberance or ridge 94 that extends outwardly from the body 96. The ridge 94 interacts with the trough 84 of the valve 80 to retain the plug 90 in the valve 80 once engaged.

[0127] An insertion device or tube 46 is utilized to insert the attenuation device 66 into a chamber of the eye, fill the device 66 and then seal device by pulling on a suture 93 secured with an anchor 91 to the back of the plug 90 to draw the plug into engagement with the valve 80.

[0128] Turning to Figures 4N and 4O, to facilitate filling the interior cavity 72 of the inflatable container 68 following placement of the attenuation device 66 within the eye 600, the inflatable container 68 is preferably provided with a re-filling valve or port 80. As depicted in more detail in Figures 4P and 4Q, the refill port 80 includes a base 82 with a passageway 83 in communication with the interior 72 of the inflatable container 68, and implantable in the scleral wall 634 of the eye 600. A port arm 84 is coupled to the base 82 and extends away from the base 82 at an oblique angle θ. The port arm 84 includes a center channel 86 in communication with the passageway 83 of the base 82. The channel 86 includes a re-sealable sealing mechanism 88 depicted in Figure 4Q as a flapper valve that seals itself upon removal of the fill device such as cannula, syringe needle, or the like. Other valves or sealing devices such as, e.g., a septum plug, a check valve or the like, could be used. With the base 82 implanted in the scleral wall 634, the port arm 84 extends upwardly at an angle away from the scleral wall 634.
for easy access. The port arm 84 can remain hidden within or below the conjunctiva (not shown).

[0129] The refill port 80 advantageously enables recharging of the attenuation device 66 without re-operation. The eye 600 can be anesthetized with local anesthetic and the port 80 accessed with a cannula or syringe needle at the slit-lamp or exam table. After recharging the attenuation device 66, the port 80 sealing mechanism 88 reseals such that the attenuation device 66 integrity is maintained and it will hold gas for an extended period of time. The refill port 80 can be used repeatedly, as needed, to provide maximum protection for the patient. This may be yearly, twice yearly, quarterly, or even monthly, for a duration of 3, 5, or 10 years.

[0130] A filling device such as a syringe with a needle can be utilized to pierce the plug 190 and introduce compressible media into the interior cavity 72. Upon removal of the filling device, the plug 190 prevents or inhibits the escape of compressible media from the interior cavity 72 through the flow path 186.

[0131] Referring to Figures 5A and 5B, there is illustrated an embodiment of an attenuation device 66 which comprises a moveable wall such as a compressible container or balloon 68. The container 68 is illustrated as having a generally spherical profile, although other profiles may be utilized such as circular, toroidal, cylindrical or the like. The diameter of the container 68 may be varied within the range from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device. Many embodiments of the containers 68 will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet containers 68 are utilized. The sum of the volumes of the multiple containers will equal the desired uncompressed displacement.

[0132] The container 68 illustrated in Figures 5A and 5B comprise a flexible wall 70 for separating the compressible contents of the attenuation device 66 from the external environment. The flexible wall 70 may be formed of unitary construction or may comprise a first component and second component bonded together such as by a seam. Preferably, the flexible wall 70 is about 0.0018 inches thick and forms an approximately 1 cm diameter sphere. The attenuation device is intended to have an un-compressed or relaxed volume less than 5 ml or generally within the range of about 0.3 to 2.5 ml.
The flexible wall 70 defines an interior cavity 72. The interior cavity 72 preferably comprises a compressible component 73 in the form of a structural core preferably formed from silicone. The core 73 may be a solid structure or, as illustrated in a preferred embodiment, comprise a hollow thin walled body 74 with a plurality of cut-outs or holes 75 thus resembling a wiffle ball structure. The structural core 73 within a thin-walled balloon 68 that is compliant will maintain shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures. Other media or structures capable of reduction in volume through a mechanism other than strict compression may also be used. For example, a material capable of undergoing a phase change from a first, higher volume phase to a second, lower volume phase under the temperature and pressure ranges experienced in the eye may also be used.

In order to minimize trauma during delivery of the attenuation device 66, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration to a second, enlarged cross-sectional configuration. The attenuation device 66 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once positioned within the eye to accomplish the pressure attenuation function. Preferably, a cross-sectional configuration of the attenuation device 66 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by rolling the container 68 about a longitudinal axis, while the interior 72 is evacuated.

Once positioned within the eye, the container 68 is released and allowed to expand to its relaxed volume. A compressible media such as gas may be added to the interior cavity 72. Fill pressures are contemplated to be about 0.1 to 150 mmHg, and fill volumes sufficient to enable the core 73 to move freely within the interior 72 of the container 68. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes.

The resiliency of the core 73 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm's canal or other drainage outlets in the eye.
To facilitate filling the interior cavity following placement of the attenuation device within the eye, the container is preferably provided with a valve or port having a closure mechanism such as a plug or other septum as described and illustrated above.

Referring to Figures 5C and 5D, there is illustrated an embodiment of an attenuation device which comprises a moveable wall such as a compressible container or balloon. The container is illustrated as having a generally circular top profile and pancake side profile, although other profiles may be utilized such as a sphere and the like. The diameter of the container may be varied within the range from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device. Many embodiments of the containers will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the container are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet containers are utilized. The sum of the volumes of the multiple containers will equal the desired uncompressed displacement.

The container illustrated in Figures 5C and 5D comprise a flexible wall for separating the compressible contents of the attenuation device from the external environment. The flexible wall preferably comprises a first component and second component bonded together such as by a seam, but may be formed of unitary construction. Preferably, the first and second components, which preferably comprise sheets that are about 0.001 inches thick, are bonded together to form an approximately 1 cm diameter circle in top view. The attenuation device is intended to have an un-compressed or relaxed volume less than 5 ml or generally within the range of about 0.3 to 2.5 ml. In the illustrated embodiment, the first component and second component are essentially identical, such that the seam is formed on the outer periphery of the container. The seam may be accomplished in any of a variety of manners known in the medical device bonding arts, such as heat bonding, adhesive bonding, solvent bonding, RF or laser welding, or others known in the art.

The flexible wall formed by a bonded first component and second component define an interior cavity. The interior cavity preferably comprises a compressible component such as mechanical or structural foam. A mechanical or structural foam core within a thin-walled balloon that is compliant will maintain shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable
pressures. Other media or structures capable of reduction in volume through a mechanism other than strict compression may also be used. For example, a material capable of undergoing a phase change from a first, higher volume phase to a second, lower volume phase under the temperature and pressure ranges experienced in the eye may also be used.

[0141] In order to minimize trauma during delivery of the attenuation device 66, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration to a second, enlarged cross-sectional configuration. The attenuation device 66 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once positioned within the eye to accomplish the pressure attenuation function. Preferably, a greatest cross-sectional configuration of the attenuation device 66 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by rolling the container 68 about a longitudinal axis.

[0142] Once positioned within the eye, the container 68 is released and allowed to expand to its relaxed volume. A compressible media such as gas may be added to the interior cavity 72. Fill pressures are contemplated to be about 0.1 to 150 mmHg, and fill volumes sufficient to enable the foam core 73 to move freely within the interior 72 of the container 68. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes.

[0143] The resiliency of the foam core 73 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm’s canal or other drainage outlets in the eye.

[0144] To facilitate filling the interior cavity 72 following placement of the attenuation device 66 within the eye, the container 68 is preferably provided with a valve or port 80 having a closure mechanism such as a plug or other septum as described and illustrated above.

[0145] Referring to Figures 5E and 5F, there is illustrated an embodiment of an attenuation device 66 which comprises a moveable wall such as a compressible container or balloon 68. The container 68 is illustrated as having a generally circular top profile and pancake side profile, although other profiles may be utilized such as a sphere and the like. The diameter of the container 68 may be varied within the range from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device. Many embodiments
of the containers 68 will have a diameter within the range from about 0.5 mm to about 25 mm with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet containers 68 are utilized. The sum of the volumes of the multiple containers will equal the desired uncompressed displacement.

[0146] The container 68 illustrated in Figures 5E and 5F comprise a flexible wall 70 for separating the compressible contents of the attenuation device 66 from the external environment. The flexible wall 70 preferably comprises a first component 74 and second component 76 bonded together such as by a seam 78, but may be formed of unitary construction. Preferably, the first and second components 74 and 76, which preferably comprise sheets that are about 0.0018 inches thick, are bonded together to form an approximately 1 cm diameter circle in top view. The attenuation device is intended to have an un-compressed or relaxed volume less than 5 ml or generally within the range of about 0.3 to 2.5 ml. In the illustrated embodiment, the first component 74 and second component 76 are essentially identical, such that the seam 78 is formed on the outer periphery of the container 68. Seam 78 may be accomplished in any of a variety of manners known in the medical device bonding arts, such as heat bonding, adhesive bonding, solvent bonding, RF or laser welding, or others known in the art.

[0147] The flexible wall 70 formed by a bonded first component 74 and second component 76 define an interior cavity 72. The interior cavity 72 preferably comprises a compressible component 73 comprising a core of compliant pellets or spheres preferably formed of silicone. A core of small compliant pellets or spheres within a thin-walled balloon that is compliant will maintain shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures. Other media or structures capable of reduction in volume through a mechanism other than strict compression may also be used. For example, a material capable of undergoing a phase change from a first, higher volume phase to a second, lower volume phase under the temperature and pressure ranges experienced in the eye may also be used.

[0148] In order to minimize trauma during delivery of the attenuation device 66, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration to a second, enlarged cross-sectional configuration. The attenuation device 66 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second
configuration once positioned within the eye to accomplish the pressure attenuation function. Preferably, a greatest cross-sectional configuration of the attenuation device 66 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by rolling the container 68 about a longitudinal axis.

[0149] Once positioned within the eye, the container 68 is released and allowed to expand to its relaxed volume. A compressible media such as gas may be added to the interior cavity 72. Fill pressures are contemplated to be about 0.1 to 150 mmHg, and fill volumes sufficient to enable the pellets 73 to move freely within the interior 72 of the container 68. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes.

[0150] The resiliency of the core of pellets 73 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm’s canal or other drainage outlets in the eye.

[0151] To facilitate filling the interior cavity 72 following placement of the attenuation device 66 within the eye, the container 68 is preferably provided with a valve or port 80 having a closure mechanism such as a plug or other septum as described and illustrated above.

[0152] Referring to Figures 5G and 5H, there is illustrated an embodiment of an attenuation device 66 which comprises a moveable wall such as a compressible container or balloon 68. The container 68 is illustrated as having a generally spherical profile, although other profiles may be utilized such as circular, toroidal, cylindrical and the like. The diameter of the container 68 may be varied within the range from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device. Many embodiments of the containers 68 will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the container 68 are selected to produce an attenuation device having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet containers 68 are utilized. The sum of the volumes of the multiple containers will equal the desired uncompressed displacement.
The container 68 illustrated in Figures 5G and 5H comprises a flexible wall 70 for separating the compressible contents of the attenuation device 66 from the external environment. The flexible wall 70 may be formed of unitary construction or may comprise a first component and second component bonded together such as by a seam. Preferably, the flexible wall 70 is about 0.0018 inches thick and forms an approximately 1 cm diameter sphere. The attenuation device is intended to have an un-compressed or relaxed volume less than 5 ml or generally within the range of about 0.3 to 2.5 ml.

The flexible wall 70 defines an interior cavity 72. The interior cavity 72 preferably comprises a compressible component 73 in the form of a cage-type structured preferably formed from plastic, silicone, metal or the like. The compressible cage-type structure 73, as illustrated, comprises a plurality of elongate cylindrical, tubular, rectangular or flat fibers, ribs or vanes 74 that are coupled together at one end 76 and retained within a collar 75 at the other end. A structured cage 73 formed from plastic or metal fibers, ribs or vanes 74 within a thin-walled balloon 68 that is compliant will maintain shape and structure, and provide pressure attenuation and long term device stability when exposed to constant and variable pressures. Other media or structures capable of reduction in volume through a mechanism other than strict compression may also be used. For example, a material capable of undergoing a phase change from a first, higher volume phase to a second, lower volume phase under the temperature and pressure ranges experienced in the eye may also be used.

In order to minimize trauma during delivery of the attenuation device 66, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration, as illustrated in Figure 51, to a second, enlarged cross-sectional configuration as illustrated in Figures 5G and 5H. The attenuation device 66 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once positioned within the eye to accomplish the pressure attenuation function. Preferably, a cross-sectional configuration of the attenuation device 66 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by stretching the container 68 along a longitudinal axis and retaining it within an introducer device 46.

Once positioned within the eye, container 68 is released and allowed to expand to its relaxed volume. A compressible media such as gas may be added to the interior cavity 72. Fill pressures are contemplated to be about 0.1 to 150 mmHg, and fill volumes sufficient to enable the cage-type structure 73 to move freely within the interior 72 of the container 68. In general, the fill pressure and volume are preferably no more than necessary to keep the attenuation
device 66 inflated or partially inflated in the absence of pressure spikes. Excessive pressure and volume within the attenuation device 66 may shorten the dynamic range of the attenuation device 66, thereby lessening the sensitivity to attenuate pressure spikes. Pressures of less than 50 mmHg or even vacuums may be utilized if the structure of the attenuation device is sufficient to balance the negative pressure to produce a net force such that attenuation can occur.

[0157] The resiliency of the cage-type structure 73 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm's canal or other drainage outlets in the eye.

[0158] To facilitate filling the interior cavity 72 following placement of the attenuation device 66 within the eye, the container 68 is preferably provided with a valve or port 80 having a closure mechanism such as a plug or other septum.

[0159] Figure 5J depicts the attenuation device 66 deployed within the vitreous 603 in its expanded configuration.

[0160] Figure 5K illustrates an embodiment of the device 66 which includes an inner membrane 71A and an outer membrane 71B, where one membrane material is chosen for its optimal vapor barrier properties and the other membrane material is chosen for its moisture barrier properties. The two membranes are not attached or bonded to each other, except at the valve or port 80 for the device 66, in order to avoid reducing the compliance of the membrane.

[0161] Referring to Figures 6A and 6B, there is illustrated an embodiment of an attenuation device 60 which comprises a compressible body or cap 62. The cap 62 is illustrated as having a generally partial, spherical or dome type profile, although other profiles may be utilized such as circular or toroidal, disc type or cylindrical and the like. The diameter of the cap 62 may be varied within the range of from about 0.5 mm to about 25 mm, in an application involving the implantation of only a single attenuation device 60. In embodiments involving the implantation of more than one attenuation device 60 of the cap 62 will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. In general, the specific dimensions and configuration of the cap 62 are selected to produce an attenuation device 60 having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two, three or more discreet
attenuation devices 60 are utilized. The sum of the volumes of the multiple caps 62 will equal the desired uncompressed displacement.

[0162] The attenuation device 60, as depicted in Figures 6A and 6B, comprises a partially spherical or dome type cap 62 axially extending from a base or stem 64 that is preferably cylindrical and radially extending from the periphery of the base 64, and a flange 61 extending about the opposite end of the base 64 from the cap 62. With the base 64 having a smaller diameter than the cap 62 and flange 61, the cap 62, base 64, and flange 61 define or form an annular recess 68 adapted to receive scleral wall tissue upon implantation of the scleral plug 60 into the wall of the sclera of the eye. Once implanted, the flange 61 prevents the plug 60 from advancing further into the vitreous humor and the cap 62 prevents the plug 60 from becoming dislodged from the wall of the sclera. As depicted, the cap 62, base 64, and flange 61 are solid and preferably formed from a polymeric material.

[0163] In an alternate embodiment, attenuation device 60, illustrated in Figure 6C, comprises a hollow cap 62 having a flexible wall 70 for separating the compressible contents of the cap 62 from the external environment. Preferably, the flexible wall 70 is about 0.0018 inches thick. The cap 62 of the attenuation device 60 is intended to have an un-compressed or relaxed volume less than 5 ml or generally within the range of about 0.1 to 2.5 ml. The flexible wall 70 defines an interior cavity 72. The interior cavity 72 preferably comprises a compressible media such as gas.

[0164] In order to minimize trauma during delivery of the attenuation device 60, the attenuation device is preferably expandable from a first, reduced cross-sectional configuration, to a second, enlarged cross-sectional configuration as illustrated in Figures 6C. The cap 62 of the attenuation device 60 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once implanted in the wall of the sclera of the eye to accomplish the pressure attenuation function. Preferably, a cross-sectional configuration of the attenuation device 60 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by stretching or rolling the attenuation device 60 along a longitudinal axis and retaining it within an introducer device. Once positioned, the attenuation device 60 is released and allowed to expand to its relaxed volume.

[0165] The resiliency of the attenuation device 60 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm's canal or other drainage outlets in the eye.
[0166] Figure 6D depicts the attenuation device 60 implanted in the wall of the sclera 634 and extending within the vitreous 603 in its expanded configuration. As shown, tissue of the scleral wall is received in the recess defined by the cap 62, base 64 and flange 61, and the cap 62 and flange 61 abut the sclera 634 and retain the attenuation device in its implanted position.

[0167] Referring to Figures 6E and 6F, there is illustrated a preferred embodiment of an attenuation device 60 in the form of a hollow thin walled body 70 comprising a cylindrical base 64 and a cap 62 enclosing one end of the base. The cap 62 is illustrated as having a generally partial spherical or dome type profile, although other profiles may be utilized such as circular, disc type or cylindrical and the like. The diameter of the cap 62 may be varied within the range of from about 0.5 mm to about 25 mm in an application involving the implantation of only a single attenuation device 60. In embodiments involving the implantation of more than one attenuation device 60, the cap 62 will have a diameter within the range from about 0.5 mm to about 25 mm, with a total volume within the ranges recited above. The cap 62 preferably includes a centrally located thin membrane or patch portion 63 that is moveable in response to pressure fluctuations. In general, the specific dimensions and configuration of the cap 62 are selected to produce an attenuation device 60 having a desired volume and a desired dynamic compression range, and may be varied from spherical to relatively flat as will be apparent to those of skill in the art based upon the disclosure herein. In certain embodiments, two or three or more discreet attenuation devices 60 are utilized. The sum of the volumes of the multiple caps 62 will equal the desired uncompressed displacement.

[0168] The attenuation device 60, as depicted in Figures 6E and 6F, comprises a partially spherical or dome type cap 62 enclosing one end of the hollow base 64 and extending outwardly beyond the periphery of the base wall, and an annular flange 61 extending outwardly from the periphery of the base wall at the opposite end of the base 64 from the cap 62. With the base 64 having a smaller diameter than the cap 62 and flange 61, the cap 62, base 64, and flange 66 define or form an annular recess 68 adapted to receive scleral wall tissue upon implantation of the scleral patch attenuation device 60 into the wall of the sclera of the eye. Once implanted, the flange 61 prevents the scleral patch device 60 from advancing further into the vitreous humor and the cap 62 prevents the scleral patch device 60 from becoming dislodged from the wall of the sclera. As depicted, the cap 62, base 64, and flange 66 are preferably formed from a polymeric material.

[0169] Preferably, the thin wall 70 is about 0.0018 inches thick and defines an interior cavity 72. In order to prevent inadvertent or intentional piercing of the patch 63 and entry into the
vitreous humor, a protective cover or shield formed from an acrylic material or the like is positional and implantable in the sclera over the flange 66 end of the attenuation device 60. 

[0170] In order to minimize trauma during delivery, the attenuation device 60 is preferably expandable from a first, reduced cross-sectional configuration, to a second, enlarged cross-sectional configuration as illustrated in Figures 6E and 6F. The cap 62 of the attenuation device 60 may thus be trans-sclerally deployed into the eye in its first configuration, and enlarged to its second configuration once the device 60 is implanted in the wall of the sclera of the eye to accomplish the pressure attenuation function. Preferably, a cross-sectional configuration of the attenuation device 60 when in the first configuration is no greater than about 10 mm, and, preferably, no greater than about 3 mm. This may be accomplished, for example, by stretching or rolling the attenuation device 60 along a longitudinal axis and retaining it within an introducer device. Once positioned, the attenuation device 60 is released and allowed to expand to its relaxed volume.

[0171] The resiliency of the patch 63 is preferably matched to produce a compression cycle time which is fast enough to allow the attenuation device to respond to increases in pressure while not having a clinically detrimental effect on normal fluid outflow through Schlemm’s canal or other drainage outlets in the eye.

[0172] Figure 6G depicts the attenuation device 60 implanted in the wall of the sclera 634 and extending within the vitreous 603 in its expanded configuration. As shown, tissue of the scleral wall is received in the recess defined by the cap 62, base 64 and flange 61, and the cap 62 and flange 61 abut the sclera 634 and retain the attenuation device in its implanted position.

[0173] Referring to Figures 7A and 7B, there is illustrated a top plan view of another embodiment of an attenuation device 166. The attenuation device 180 comprises an inflatable body 68. An outer seam 78 may be provided with a valve 80 such as the valve 80, 180 and septum plug 90, 190. In this embodiment, an inner seam 182 defines a central region 184. The outer seam 78 and inner seam 182 define a generally toroidal or spherical shaped inflatable body 68. The central region 184 may comprise either a membrane or a central opening, depending upon the desired performance characteristics. The center hole may assist in the placement and location of the attenuation device within the eye, permit additional baffling of the pressure waves within the eye, minimize the attachment to structures within the eye by surface tension between the attenuation device and the wall of the eye, and allow for aqueous humor flow through the hole in the event that the attenuation device is in or near the angle of the anterior chamber or near the various drainage ports of the eye, such as the trabecular meshwork, Schlemm’s canal, and the uveoscleral channels.
The central region 184 in Figure 7A may also contain a lens that corrects for refractive error, including myopia, hyperopia or presbyopia. The lens may be made of a rigid, non-compliant material or a material that is able to flex to provide accommodation. The central region may also contain a lens that is ocularly neutral or has the same index of refraction as the vitreous and/or aqueous humour thereby not altering the pathway of light to the retina.

An alternative shape to the attenuation device 166 is provided in Figures 7C and 7D. The attenuation device 166 comprises an inflatable body 68 that is provided with a valve 80 along its inner diameter and may include a structural core such as a solid core, a hollow thin walled core, a structural or mechanical foam core or a core of small compliant pellets generally as described above.

In another embodiment, illustrated in Figures 8A and 8B, the central region 184 comprises a baffle 186. The baffle 186 comprises a membrane 188 having a plurality of apertures 190 therein. In the illustrated embodiment, approximately nine round apertures 190 are provided, each having a diameter of about 0.04 inches. Generally at least about 9 apertures 190 are provided, and many embodiments include anywhere from about 1 to about 1000 apertures. The optimal number of apertures 190 and sum of the area of the apertures 190 compared to the total area of the baffle 186 may be optimized depending upon the desired performance characteristics. Apertures may have any of a variety of configurations, such as round holes, irregular openings, slits or others.

The wave diffuser function of the baffle 186 is schematically illustrated in Figure 9. A wave front 192 may be generated by any of a wide variety of events, such as blinking, eye rubbing, coughing, sneezing, laughing, physical movement, muscle spasms or others as is understood. Since aqueous humor comprises essentially non-compressible fluid, and due to the low dynamic compliance of the eye the wave front 192 will propagate rapidly through the eye to impact structures such as the optic nerve, the retina, the cornea or blood vessels with the eye. Apparent transient pressure spikes as high as 30 mmHg or greater can be experienced during normal activities.

If the attenuation device 166, having a baffle 186 is positioned within the eye, the baffle 186 functions to disrupt the unitary progression of the wave front 192. The prediffusion wave front 192 is thus interrupted into a plurality of post-diffusion wave fronts 194 by the baffle 186. Although the sum of the resulting post-diffusion wave fronts 194 is essentially equal to the prediffusion wave front 192, the greater dispersion of force accomplished by the baffle 186 is believed to reduce the apparent magnitude of the wave front 192 as experienced by structural tissue within the eye.
[0179] As will be apparent in view of the foregoing, the baffle 186 may be constructed in any of a variety of manners and still accomplish the intended result. Thus, although the attenuation device 166 illustrated in Figures 7A through 9 comprise a generally toroidal-shaped inflatable container, any of a variety of other support structures may be utilized to maintain the baffle 186 in a useable configuration. The support 196 can comprise an inflatable tube, a resilient material such as nitinol wire, or other support structure as may be desired.

[0180] Figure 10A consists of an attenuation device 606 that has anchors 614 located on either side of the device. Figure 10B demonstrates a device 606 that has a circumference of less than 360 degrees. Figure 10C shows a device where the circumference of the air-filled portion may be less than 360 degrees and connected to a positioning ring 615 that extends the circumference to 360 degrees. Figure 10D shows a double sided attenuator device 606 with no connections between the air chambers and filling valves on each side 616. There may also be a single sided air chamber. Figure 10E would be a double sided air chamber with members 617 that connect, fluidically or otherwise, the air chambers. These embodiments may be in any shape and are not limited to circular shapes.

[0181] Figures 10F through 10H shows a cross-section of the attenuation device when positioned in the anterior chamber of the eye. The placement of such a device takes advantage of standard delivery techniques used in the placement of phakic IOLs. The devices will typically be inserted through incisions less than 6 mm, more preferably between 0.5 and 3 mm. Figure 10F shows a free-floating air cell 618 in which no portion of the device enters into the optical path. It is angled in such a way as to minimize contact with the iris 621. Figure 10G shows an attenuator device 619 in which no part of the device enters into the optical path and which lays flat on the iris 621. Another embodiment of both 10F and 10G could include a lens which contains no power or which enhances vision. Figure 10H shows an attenuator device that is anchored to the iris 621 in ways known to the art, for instance with pincers, staples, rivets, sutures, clips, nails, screws and other means of attachment (Willis, US 7,008,451 or Worst US 5,192,319). The air cell 620 in such an embodiment preferably surrounds the lens 624 which could have no optical power or correct for refractive error.

[0182] Figures 11A through 11C shows embodiments where the attenuation devices are located in the posterior chamber of the eye, posterior to the iris 621 and anterior to the capsular bag 625. Figure 11A shows a free-floating attenuation device in which no part of the device 622 enters into the optical path. Figure 11B shows a free-floating attenuation device 623 in which no part of the device enters into the optical path and in which there are anchors 627 anchored into the ciliary bodies 626. The anchors 627 comprise sutures, staples, or haptics,
which press outward into the ciliary bodies, or other forms of anchoring known to those skilled in the art. Figure 11C shows a free-floating attenuation device 628 in which a lens 624 covers the optical path. Such a lens may have no optical power or correct for refractive error.

[0183] Figures 12A and B show embodiments where the attenuation device 629 is placed into the capsular bag 625 in the posterior chamber following a standard phacoemulsification technique and an insertion technique similar to that of intraocular lens placement for cataract surgery. Figure 12A shows a cross-section of the device in which the haptics of the lens 624 are the air cells 629 of the attenuation device extending outward to the wall of the capsular bag. The lens portion 624 of the device may provide accommodation, and allow for the appropriate correction of refractive error. Figure 12B shows a device that is placed into the capsular bag 625 in the posterior chamber and consists of a standard IOL 624 with haptics 627, and posterior to that an attenuation device 628 that can be connected or unconnected to the IOL.

[0184] Figure 13A shows a cross-section of an attenuation device 632 placed into the vitreous humor 603. In this embodiment the attenuator 632 is placed just posterior to the capsular bag 625 without interrupting the optical path. In another embodiment, the attenuation device is placed without creating a void in the vitreous humor. In another embodiment the device is placed after creating the appropriate void in the vitreous humor via a vitrectomy.

[0185] Figure 13B shows a cross-section of an attenuation device 635 which is free floating in the vitreous, and angled upward at about 45 degrees. It does not enter the optical path. Shapes of the device may be similar to those demonstrated on Figure 10A through 10E. The device is inserted into the vitreous via the same approach used in a trans-pars plana vitrectomy. The device 635 may reside just posterior to the capsular bag 625 as shown in Figure 13B or in other locations more posterior in the vitreous chamber 603, including but not limited to near the optic nerve. Figure 13C shows a cross-section of a device 635 that is anchored to the wall 634 of the vitreous humor 603. The anchor 636 could either be a valve mechanism to the attenuator 635 or simply a distinct anchor that secures the device. Figure 13C also incorporates a lens 624 which may be either a zero optical power lens or visually enhancing lens.

[0186] Figures 13D and 13E show different configurations and anchors of attenuation devices that have been placed into the vitreous humor. Figure 13D shows a one-sided attenuator 635 anchored or connected to the ciliary bodies 633 by means of a suture, staple, clip or other anchors 636 known to those skilled in the art. Figure 13E shows a one-sided attenuator 635 anchored or connected to the wall 634 of the vitreous humor by means of either a valve mechanism or a distinct anchor 637.
If the pressure attenuator needs to be anchored, one embodiment, as depicted in Figure 10A and Figure 14 could include attaching a cap 638 to the attenuator which affixes to the device, but sits outside the sclera and under the conjunctiva. A portion of the attenuator passes through the insertion site and a cap screws or snaps onto the device. The cap could be made of metal, such as stainless steel, titanium, various alloys, nitinol, cobalt chromium or any kind of polymer, resorbable or non-resorbable. The part of the device that the cap snaps onto could be metal, such as those listed above, or polymer. The cap prevents that attenuator from migrating into the vitreous and could facilitate removal or re-filling. Other methods of anchoring could include sutures, rivets, cords, staples or other anchors known to those knowledgeable in the industry.

Alternatively, the attenuation device could include a thin, pliable safety tether long enough to extend from the attenuation device and exit from the eye. The tether can be constructed of accepted materials such as those used in the manufacture of sutures, catheters and may also possess anti-microbial properties. In one embodiment, the distal end of the tether may be terminated with a lightweight pendant of sufficient bulk to prevent ingress of the entire tether into the eye. During normal use, the pendant may be temporarily affixed to the sclera. The tether may be used to remove or deconstruct the attenuation device.

Placement of the device into the vitreous is similar to other devices that are placed into the vitreous 603, see, e.g., U.S. Patent No. 6,719,750. A pressure stabilizing or attenuating device may be inserted into the vitreous chamber 603 and could include the following steps:

- Creating an incision in the conjunctiva
- Inserting a cannula— .25 mm - 5 mm, more preferably 0.5 mm to 3.0 mm, more preferably 1.0 to 2.0 mm —that goes through the sclera into the vitreous.
- Removing an appropriate volume of vitreous humour, if necessary, from about 0 cc to 3.0 cc, more preferably .25 cc to 1.5 cc or more preferably about 1 cc. Alternatively, vitreous humour may be withdrawn through a 20-25 gauge needle.
- Inserting a delivery sheath into vitreous through the puncture site and dilating the access site to accommodate a 15-20 gauge sheath.
- Inserting a delivery tube into the sheath and into vitreous chamber. Delivery tube shall be between about 0.5 mm and 5 mm, more preferably between about 1 and 3 mm.
• Inflating the pressure attenuator to a volume from .01 cc to 5 cc, more preferably from .25 cc to 1.5 cc.
• Pulling the suture and drawing the plug into a sealing arrangement with the valve.
• Securing the suture to the exterior of the sclera.

[0190] Figures 15A through 15C describe some of the placement options for the device. Figure 15A illustrates an intravitreal placement of the device 635. In Figure 15B, the attenuation device 635 is placed between the tissues of the ocular wall, beneath the sclera, defined as the suprachoroidal space. In Figure 15C, the attenuation device 635 is placed external to the eye, on top of the sclera, beneath the conjunctiva, provided it is in intimate communication with the internal ocular environment. In this illustration the device 635 is in intimate contact with the anterior chamber 601 of the eye 600.

[0191] One embodiment provided herein relates to the delivery of the attenuator device. Delivery of an attenuation device is typically accomplished via a suitably sized introducer or possibly through the working channel of an ophthalmoscope. However, in certain instances the columnar strength of an attenuation device may make it difficult to be pushed through such channels. A further requirement of any delivery system is that it be atraumatic, and not pose a threat of tissue damage. The embodiments described below address such issues, and offer improvements for accomplishing delivery of such attenuation devices as disclosed in U.S. Patent No. 6,682,473, titled Devices And Methods For Attenuation Of Pressure Waves In The Body.

[0192] The attenuation device is normally folded on itself along its diameter in order to present a low profile for insertion into, for example, a patient's eye trans-sclerally. In this configuration the attenuation device has insufficient column strength to withstand the forces of insertion without buckling. If the attenuation device buckles it cannot be inserted. Following insertion the attenuation device is inflated via an inflation tube to which it is pre-mounted. After inflating the inflation tube is detached and the attenuation device is freed. By way of illustration, various embodiments are described in the exemplary context of trans-sclerally insertion of a delivery system into a patient's eye.

[0193] Referring to Figure 16A, there is illustrated one delivery system for deploying the attenuation device into the treatment site within the eye. In general, the delivery system 40 is designed to advance an attenuation device 66 (not illustrated) trans-sclerally into the eye while in a first, reduced cross-sectional configuration, and to thereafter inflate or enlarge or permit the
expansion of the attenuation device to a second, implanted orientation. The particular
configuration and functionality of the delivery system 40 will therefore be governed in large
part by the particular design of the attenuation device 66. Thus, as will be apparent to those of
skill in the art in view of the disclosure herein, various modifications and adaptations may
become desirable to the particular delivery system disclosed herein, depending upon the
construction of the corresponding attenuation device.

[0194] The delivery system 40 comprises an elongate tubular body 42 having a proximal end
44 and a distal end 46. Tubular body 42 is dimensioned to trans-sclerally access the eye. Thus,
the tubular body 42 preferably has an outside diameter of no more than about 5 mm, and,
preferably, no more than about 3 mm. The length of the tubular body 42 may be varied,
depending upon the desired proximal extension of the delivery system 42 from the eye during
deployment. In general, an axial length of tubular body 42 within the range of from about 1" to
about 10" is currently contemplated.

[0195] The tubular body 42 is provided with at least one central lumen 48 extending axially
there through. Central lumen 48 axially slideably receives a filling tube 50, for filling the
attenuation device 66. Filling tube 50 comprises a tubular body 52 having a proximal end 54
and a distal end 58. An inflation lumen 60 extends throughout the length of the tubular body
52, and is in fluid communication with a proximal hub 56. Hub 56 comprises a connector such
as a standard leuer connector for coupling to a source of inflation media.

[0196] The tubular body 52 has an axial length which is sufficiently longer than the axial
length of tubular body 42 to allow the proximal hub 56 to remain accessible to the clinician and
accomplish the functions of deploying and filling the attenuation device 66. In one
embodiment, an outer tubular sheath (not illustrated) is slideably carried over the tubular body
42, and is spaced radially apart from the tubular body 52 to define an annular cavity for
receiving a rolled attenuation device 66 therein. In this manner, the deflated attenuation device
can be rolled around a distal portion of the tubular body 52 and carried within the tubular
sheath during trans-scleral placement. Once the delivery system 40 has been properly
positioned, proximal retraction of the outer sheath with respect to the tubular body 52 exposes
the deflated attenuation device 66. A source of inflation media is coupled to the proximal hub
56, and media is introduced distally through central lumen 59 to inflate the attenuation device
66. Following inflation of the attenuation device 66, the delivery system 40 is disengaged from
the attenuation device 66, such as by retracting the filling tube 50 with respect to the tubular
body 42. A distal stop surface 47 on tubular body 42 prevents proximal movement of the
an attenuation device 66 as the filling tube 50 is proximally retracted. Delivery system 40 is thereafter removed from the patient, leaving the inflated attenuation device 66 within the eye.

[0197] Biocompatible lubricating substances may be used to facilitate the placement of the attenuation device/fill tube within the lumen of the introducer. The distal tip of the introducer has been modified to allow a minimally traumatic presentation of the attenuation device to the eye tissue. Biocompatible lubricating substances may be used to facilitate the insertion of the attenuation device into the eye.

[0198] In one embodiment, the attenuation device incorporates biocompatible coatings or fillers to minimize irritation to the eye wall and/or to inhibit the formation of mineral deposits (encrustation). The materials can be coated onto the surface or incorporated within the wall of the attenuation device.

[0199] With reference to Figures 16B and 16C, there is illustrated a modified version of the delivery system 40. In this embodiment, a control 55 is connected by way of a proximal extension 53 to the tubular body 52. The control 55 may be in any of a variety of forms, such as a knob or a pistol grip. The control 55 may be grasped by the clinician, and utilized to axially advance or retract the filling tube 50 within the tubular body 42. The proximal hub 56 is connected to the tubular body 52 by way of a bifurcation 51. As will be appreciated by those of skill in the art, the central lumen 59 extends through the bifurcation 51 and to the proximal hub 56. Proximal extension 53 may comprise a blocked tubular element or a solid element. An inflation source 54 such as a syringe filled with a predetermined volume of air or other media may be connected to the proximal hub 56.

[0200] For patient comfort, the introducer is suitably sized to easily pass through the sclera into the eye (approximately 0.5 to 4 mm diameter). Visual feedback is provided to the clinician by means of insertion depth indicators along the longitudinal length of the introducer. The introducer may also have an adjustable depth stop that allows the clinician to pre-set the desired insertion depth. Once the delivery system has been inserted into the eye to the desired depth the introducer is then kept in a fixed position and the attenuation device mounted on the distal end of the fill tube is then extended in the lumen of the eye. The attenuation device is then filled with the indicated volume of gas from the attached syringe or similar device. See Figures 17A and 17B. Once properly inflated, the attenuation device is released from the fill tube using the tip of the introducer as an opposing force disengaging the attenuation device valve from the fill tube. The fill tube is then retracted completely into the lumen of the introducer and the entire delivery system is then withdrawn from the patient. The attenuation device is left in place for the clinically indicated period of time.
[0201] Suitable materials for the production of the attenuation devices include but are not limited to foldable or compressible materials, such as silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyesters, polyamides, polyolefins, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof. It is preferred that attenuation device be of a bicomposite material design whereby optic and haptic elements are manufactured from a compressible or foldable material such as but not limited to a silicone or acrylic materials such as but not limited to copolymers of ethyl acrylate/ethyl methacrylate/trifluoroethyl methacrylate, phenylethyl acrylate/phenylethyl methacrylate, and other copolymers of acrylic esters suitable for a foldable refractive optic. Alternatively, the optic may be manufactured from a compressible or foldable material such as but not limited to a silicone or acrylic material, and the haptics and fixation clamps may be manufactured from a relatively more rigid material such as but not limited to a relatively more rigid hydrogel, PMMA or polyimide.

Various acrylic copolymers are preferred for the manufacture of the optic portion of IOL due to its high refractive index of approximately 1.47-1.55, which is greater than that of the aqueous humor of the eye, i.e., 1.33.

[0202] The attenuation devices can be dip molded or extruded in a plurality of biocompatible materials. Furthermore, the attenuation devices can be fabricated from a variety of multi-layer composites or produced by a number of different manufacturing processes. Here, the designs of the attenuation devices are characterized by minimization and control of the gas and moisture vapor permeabilities in and out of the attenuation device.

[0203] The gas and moisture vapor permeabilities of any given material will vary depending on the conditions surrounding the material. For example, an attenuation device comprised of a certain material can have different gas and/or moisture permeabilities within the eye than at standard temperature and pressure. In addition to exposure to aqueous humor or vitreous humour, the intraocular environment includes exposure to pressure variations in the range of from about 10.0 mmHg to about 50 mmHg at rest or equilibrium, with transient pressure spikes ranging from 0.5 mmHg to as high as 30 mmHg or more. The body temperature is normally about 98 degrees F or greater, and the attenuation device resides in 100% humidity. Long term efficacy of the attenuation device may be compromised if there exists any fluid or vapor exchange through the wall of the attenuation device in situ. The relative impermeability of the wall under normal intraocular conditions is preferably accomplished without losing the compliancy of the attenuation device which allows it to compress within the eye as is described elsewhere herein.
In general, the wall of the attenuation device will comprise at least one gas barrier layer and at least one moisture barrier layer. Any of a variety of gas barrier materials (e.g. polyvinylidene chloride, ethyl vinyl alcohol, fluoropolymers, etc.), available in thin film constructions, may be implemented into the attenuation device design. These materials are generally relatively stiff, have high moisture vapor permeability, and have low impact strength. Consequently, layering the film with flexible, high moisture barrier, high impact strength polymers is desirable. A variety of relatively flexible materials, having high moisture barrier characteristic and optionally high impact strength that can be formed into thin film sheets include but are not limited to: polyamide, polyethylene, polypropylene, polyurethane, polyamide/polyester copolymer, polystyrene/polybutadiene copolymer, etc. In one embodiment, at least one layer on, or the entire attenuation device comprises a blend of a barrier material and a flexible high impact strength material (e.g. polyxirethane/polyvinylidene chloride, polyethylene/ethyl vinyl alcohol, etc.).

The attenuation device typically has two or more layers or barriers. For example, the attenuation device can have a gas barrier layer and a moisture barrier layer. An additional layer may be included to enhance the structural integrity of the attenuation device. In one embodiment, the attenuation device has an outer layer comprising a gas barrier and an inner layer comprising a moisture barrier. In another embodiment, the attenuation device has an outer layer comprising a moisture barrier and an inner layer comprising a gas barrier.

The attenuation device can have three, four, five, or more layers. In one embodiment, the attenuation device has a gas barrier layer, a moisture barrier layer, and one or more layers composed of at least one high impact strength material. In another embodiment, the attenuation device has multiple gas barrier layers arranged in a nonconsecutive arrangement. In yet another embodiment, the attenuation device has multiple moisture barrier layers arranged in a nonconsecutive arrangement. With respect to those embodiments having multiple, nonconsecutive barrier layers, the other layers of the attenuation device can include high impact strength material layers and/or other types of barrier layers.

The overall thickness of the wall is preferably minimized, and will often be no more than about 0.03 inches. Preferably, the wall will be no more than about 0.006 inches, and, in some implementations, is no more than about 0.001 inches thick. An outer layer may comprise a soft, conformable material such as polyurethane, EVA, PE, polypropylene, silicone or others, having a thickness within the range of from about 0.0025 inches to about 0.025 inches. The adjacent barrier layer may comprise EVOH, PVDC or other materials in a thin film such as from about 5 microns to about 25 or 30 microns thick. If the attenuation device is fabricated by
bonding two sides together, a bonding or tie layer may be provided on the barrier layer. Tie layers comprising polyurethane, EVA or others may be used, having a thickness of preferably no greater than about 0.001 inches. Layers of less than about 0.0008 are preferred, and layer thicknesses on the order of from about 0.0003 to about 0.0005 inches are contemplated.

[0208] The layers of the attenuation device can be formed in any number of ways known to those skilled in the art, including, but not limited to, lamination, coextrusion, dip molding, spray molding, or the like, etc. As discussed above, the layers of the attenuation device can be formed from various materials. With respect to those attenuation devices that are formed by laminating two or more layers together, various different laminating techniques known to those skilled in art can be used, including, but not limited to, heating, solvents, adhesives, tie layers or the like.

[0209] The material may not need to be elastomeric at all for the attenuation device to function. However, the materials chosen for use in embodiments of described herein are to be sufficiently flexible in the thickness ranges dictated by the selected designs. When the attenuation device is subjected to external pressures, the attenuation device's material is able to transmit the pressure to the contained air or pressure management construct and respond sacrificially as one of the most compliant members of the eye.

[0210] Having thus described certain embodiments of the present invention, various alterations, modifications and improvements will be apparent to those of ordinary skill in the art. Such alterations, variations and improvements are intended to be within the spirit and scope of the present invention. Accordingly, the foregoing description is by way of example and is not intended to be limiting. In addition, any dimensions that appear in the foregoing description and/or the figures are intended to be exemplary and should not be construed to be limiting on the scope of the present invention described herein. It should further be understood, however, that the invention is not to be limited to the particular forms or methods disclosed. but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.
WHAT IS CLAIMED IS:

1. An attenuation device, comprising: a flexible housing comprising an outer wall and defining a chamber therein, wherein the chamber having an expanded volume within a range from about 0.1 cc to about 7 cc and being positionable within a patient’s eye;

   a valve in fluid communication with the chamber; and

   septum plug sealingly positioned within the valve;

   wherein the valve includes one or more protuberances inwardly extending and retaining the septum plug in the valve.

2. The attenuation device of claim 1 wherein the septum plug includes a body, a cap and a transition region, wherein the one or more protuberances cooperate with the body and transition region to retain the septum plug in the valve.

3. The attenuation device of claim 2 wherein the valve includes a first aperture opening into the interior of the chamber and a second aperture opening to the exterior of the chamber, and wherein the one or more protuberances form an annular lip adjacent the second aperture.

4. The attenuation device of claim 1 wherein the one or more protuberances include two or more annular detents extending inwardly, and wherein the septum plug includes a body and two or more annular ridges extending from the body, wherein the two or more detents cooperate with the two or more annular ridges to retain the septum plug in the valve.

5. The attenuation device of claim 4 wherein the valve includes a first aperture opening into the interior of the chamber and a second aperture opening to the exterior of the chamber, and wherein the one of the two or more detents form an annular lip adjacent the second aperture.

6. The attenuation device of claim 1 further comprising at least one high vapor pressure media having a vapor pressure approximately equal to an intraocular pressure of the patient's eye and a permeability of less than 1 ml/day at body temperature through the outer wall.

7. An attenuation device, comprising: a flexible housing comprising an outer wall and defining a chamber therein, wherein the chamber having an expanded volume within a range from about 0.1 cc to about 7 cc and being positionable within a patient's eye; and

   a re-filling valve in fluid communication with the chamber; wherein the valve includes a base implantable in the sclera of the patient's eye and a port arm extending upwardly from the
base at an angle away from the scleral wall; wherein the port is hideable within or below the conjunctiva of the patient's eye.

8. The attenuation device of claim 7 wherein the port arm includes a first passageway in fluid communication with a second passageway in the base, the second passageway being in fluid communication with the interior of the chamber.

9. The attenuation device of claim 8 wherein the first passageway include a re-sealable sealing mechanism.

10. The attenuation device of claim 9 wherein the sealing mechanism comprises a flapper valve, a septum plug, or a check valve.

11. An attenuation device, comprising:

   a flexible housing positionable within a patient's eye and comprising an outer wall and defining a chamber therein, and; and

   a compressible medium disposed within the chamber, wherein the compressible medium includes a compressible structural component.

12. The attenuation device of claim 11 wherein the structural component comprises a thin wall forming a hollow core structure.

13. The attenuation device of claim 12 wherein the structural component comprises a plurality of cut-outs formed in the wall.

14. The attenuation device of claims 11 through 13 wherein the structural component is formed of silicone.

15. The attenuation device of claim 11 wherein the structural component comprises a structural foam core.

16. The attenuation device of claim 11 wherein the structural component comprises a core having a plurality of pellets.

17. The attenuation device of claim 16 wherein the pellets are formed of silicone.

18. The attenuation device of claim 11 wherein the structural component comprises a compressible cage structure.

19. The attenuation device of claims 11 through 18 wherein the compressible medium further includes a gas.

20. The attenuation device of claim 19 wherein the chamber having an expanded volume within a range from about 0.1cc to about 7cc.

21. An attenuation device, comprising:
a base implantable within the scleral wall of an eye; and

a compressible cap extending from the base and being positionable into a chamber of the eye.

22. The device of claim 21 wherein the cap is solid.

23. The device of claim 21 wherein the cap includes a thin outer wall defining a hollow chamber.

24. The device of claim 21 wherein the base is hollow and the cap encloses one end of the hollow base and extending outwardly beyond the periphery of a base wall.

25. The device of claim 24, wherein the cap includes a centrally located patch moveable in response to pressure fluctuations within the eye.

26. The device of claim 25, wherein the patch comprises a thin membrane.

27. The device of claim 26, further comprising a protective shield enclosing an end of the hollow base opposite the cap.

28. The device of claims 21 through 25 wherein the cap having an expanded volume within a range from about .Olcc to about 7cc.

29. The device of claims 21 through 27 further comprising a flange extending from the base at an opposite end than the cap, wherein the cap and flange have larger diameters than the base and act to prevent dislodgement of the base from the scleral wall.

30. The device of claim 29 wherein the cap is dome shaped.

31. An attenuation device, comprising: a flexible housing comprising an outer wall and a separate inner wall, defining a chamber therein, wherein the chamber having an expanded volume within a range from about .Olcc to about 7cc and being positionable within a patient's eye; with the outer wall and the inner wall being independent of one another, joined only at a fill point.

32. The device of claim 31 wherein one layer is selected to provide a vapor barrier and one layer is selected to provide a moisture barrier.

33. The device of claims 1 through 20 and claims 31 and 32, wherein the device is positionable beneath the scleral wall tissues of a patient's eye.

34. The device of claims 1 through 20 and claims 31 and 32, wherein the device is positionable within the wall tissues of a patient's eye in the suprachoroidal space.
35. The device of claims 1 through 20 and claims 31 and 32, wherein the device is positionable outside a patient's eye, on top of the sclera, but in communication within a patient's eye.

36. A method of treating a patient, comprising the steps of: introducing a cap of an attenuation device into the chamber of a patient's eye while in a first configuration, the attenuation device including a base extending from the cap, wherein the attenuation device being transformable under its own bias from a first, introduction configuration to a second, expanded configuration, wherein the cap having a volume within a range from about 7cc to about 10%; transforming the attenuation device within the eye to the second configuration; and attenuating a pressure change within the eye by reversibly changing the volume of the cap in response to the pressure change.

37. The method of claim 36, wherein the step of introducing the attenuation device step comprises transclerally introducing the cap into the vitreous of the eye and implanting the base into the scleral wall of the eye.

38. The method of claim 37, wherein the step of introducing the attenuation device step further comprises capturing scleral wall tissue between the cap and a flange positioned at opposing ends of the base and anchoring the attenuation device in place.

39. The method of claim 38, wherein the cap is solid.

40. The method of claim 38 wherein the cap includes a thin outer wall defining a hollow chamber.

41. The method of claim 38 wherein the base is hollow and the cap encloses one end of the hollow base and extending outwardly beyond the periphery of a base wall.

42. The method of claim 41, wherein the cap includes a centrally located patch moveable in response to pressure fluctuations within the eye.

43. The method of claim 42, wherein the patch comprises a thin membrane.

44. The method of claim 43, further comprising a protective shield enclosing an end of the hollow base opposite the cap.

45. The method of claim 36, wherein the attenuating step comprises reducing the volume of the cap by at least about 5%.

46. The method of claim 36, wherein the attenuating step comprises reducing the volume of the cap by at least about 10%.
47. The method of claim 36, wherein the attenuating step comprises reducing the volume of the cap by at least about 25%.

48. The method of claim 36, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 21 mm Hg without the presence of the attenuation device to a pressure of no more than about 20 mm Hg.

49. The method of claim 39, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 30 mm Hg without the presence of the attenuation device to a pressure of no more than about 25 mm Hg.

50. The method of claim 36, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 40 mm Hg without the presence of the attenuation device to a pressure of no more than about 30 mm Hg.

51. A method of treating a patient, comprising the steps of: introducing an attenuation device into the chamber of a patient's eye while in a first configuration, the attenuation device comprising an outer wall defining a chamber therein and a compressible medium disposed within the chamber, wherein the compressible medium includes a compressible structural component, and wherein the attenuation device being transformable under its own bias from a first, introduction configuration to a second, expanded configuration having a volume within a range from about 1.0 cc to about 7 cc; transforming the attenuation device within the eye to the second configuration; and attenuating a pressure change within the eye by reversibly changing the volume of the attenuation device in response to the pressure change.

52. The method of claim 51, wherein the step of introducing the attenuation device step comprises transclerally introducing the device into the vitreous of the eye.

53. The method of claim 51, wherein the structural component comprises a thin wall forming a hollow core structure.

54. The method of claim 53, wherein the structural component comprises a plurality of cut-outs formed in the wall.

55. The method of claim 51, wherein the structural component comprises a structural foam core.

56. The method of claim 51, wherein the structural component comprises a core of silicone pellets.

57. The method of claim 51, wherein the structural component comprises a compressible cage structure.

58. The method of claim 51, wherein the compressible medium further includes a gas.
59. The method of claim 51, wherein the attenuating step comprises reducing the volume of the device by at least about 5%.

60. The method of claim 51, wherein the attenuating step comprises reducing the volume of the device by at least about 10%.

61. The method of claim 51, wherein the attenuating step comprises reducing the volume of the device by at least about 25%.

62. The method of claim 51, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 21 mm Hg without the presence of the attenuation device to a pressure of no more than about 20 mm Hg.

63. The method of claim 51, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 30 mm Hg without the presence of the attenuation device to a pressure of no more than about 25 mm Hg.

64. The method of claim 51, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 40 mm Hg without the presence of the attenuation device to a pressure of no more than about 30 mm Hg.
received by the International Bureau on 03 June 2009 (03.06.09)

1. An attenuation device, comprising: a flexible housing comprising
an outer wall and defining a chamber therein, wherein the chamber having an expanded
volume within a range from about .01 cc to about 7 cc and being positionable within a patient's
eye;

   a valve in fluid communication with the chamber; and

   septum plug sealingly positioned within the valve;

   wherein the valve includes one or more protuberances inwardly extending and retaining
the septum plug in the valve.

2. The attenuation device of claim 1 wherein the septum plug includes a body, a cap and a
transition region wherein the one or more protuberances cooperate with the body and transition
region to retain the septum plug in the valve,

3. The attenuation device of claim 2 wherein the valve includes a first aperture opening
into the interior of the chamber and a second aperture opening to the exterior of the chamber,
and wherein the one or more protuberances form an annular lip adjacent the second aperture.

4. The attenuation device of claim 1 wherein the one or more protuberances include two
or more annular detents extending inwardly, and wherein the septum plug includes a body and
two or more annular ridges extending from the body, wherein the two or more detents
cooperate with the two or more annular ridges to retain the septum plug in the valve.

5. The attenuation device of claim 4 wherein the valve includes a first aperture opening
into the interior of the chamber and a second aperture opening to the exterior of the chamber,
and wherein the one of the two or more detents form an annular Hp adjacent the second
aperture.

6. The attenuation device of claim 1 further comprising at least one high vapor pressure
media having a vapor pressure approximately equal to an intraocular pressure of the patient's
eye and a permeability of less than 1 ml/day at body temperature through the outer wall.

7. An attenuation device, comprising: a flexible housing comprising
an outer wall and defining a chamber therein, wherein the chamber having an expanded
volume within a range from about .01 cc to about 7 cc and being positionable within a patient's
eye; and

   a re-filling valve in fluid communication with the chamber; wherein the valve includes
a base implantable in the sclera of the patient's eye and a port arm extending upwardly from the
base at an angle away from the scleral wall; wherein the port is hideable within or below the conjunctiva of the patient's eye,

8. The attenuation device of claim 7 wherein the port arm includes a first passageway in fluid communication with a second passageway in the base, the second passageway being in fluid communication with the interior of the chamber.

9. The attenuation device of claim 8 wherein the first passageway include a re-sealable sealing mechanism,

10. The attenuation device of claim 9 wherein the sealing mechanism comprises a flapper valve, a septum plug, or a check valve.

11. An attenuation device, comprising:

   a flexible housing positionable within a patient's eye and comprising an outer wall and defining a chamber therein, and

   a compressible medium disposed within the chamber, wherein the compressible medium includes a compressible structural component,

12. The attenuation device of claim 11 wherein the structural component comprises a thin wall forming a hollow core structure.

13. The attenuation device of claim 12 wherein the structural component comprises a plurality of cut-outs formed in the wall.

14. The attenuation device of claims 11, 12 or 13 wherein the structural component is formed of silicone.

15. The attenuation device of claim 11 wherein the structural component comprises a structural foam core.

16. The attenuation device of claim 11 wherein the structural component comprises a core having a plurality of pellets.

17. The attenuation device of claim 16 wherein the pellets are formed of silicone.

18. The attenuation device of claim 11 wherein the structural component comprises a compressible cage structure.

19. The attenuation device of claims 11, 12, 13, 15, 16, 17 or 18 wherein the compressible medium further includes a gas,

20. The attenuation device of claim 14 wherein the compressible medium further includes a gas.
21. The attenuation device of claim 19 wherein the chamber having an expanded volume within a range from about 0.1cc to about 7cc.

22. An attenuation device, comprising:
   a base implantable within the scleral wall of an eye; and
   a compressible cap extending from the base and being positionable into a chamber of the eye.

23. The device of claim 22 wherein the cap is solid.

24. The device of claim 22 wherein the cap includes a thin outer wall defining a hollow chamber.

25. The device of claim 22 wherein the base is hollow and the cap encloses one end of the hollow base and extending outwardly beyond the periphery of a base wall.

26. The device of claim 25, wherein the cap includes a centrally located patch moveable in response to pressure fluctuations within the eye.

27. The device of claim 26, wherein the patch comprises a thin membrane.

28. The device of claim 27, further comprising a protective shield enclosing an end of the hollow base opposite the cap.

29. The device of claims 22, 23, 24, 25 or 26 wherein the cap having an expanded volume within a range from about 0.1cc to about 7cc.

30. The device of claims 22, 23, 24, 25, 26, 27 or 28 further comprising a flange extending from the base at an opposite end than the cap, wherein the cap and flange have larger diameters than the base and act to prevent dislodgement of the base from the scleral wall.

31. The device of claim 29 wherein the cap is dome shaped.

32. An attenuation device, comprising: a flexible housing comprising an outer wall and a separate inner wall, defining a chamber therein, wherein the chamber having an expanded volume within a range from about 0.1cc to about 7cc and being positionable within a patient's eye; with the outer wall and the inner wall being independent of one another, joined only at a fill point.

33. The device of claim 31 wherein one layer is selected to provide a vapox barrier and one layer is selected to provide a moisture barrier.

34. The device of claims 1 through 13, 15, 16, 17, 18, 21, 32 or 33, wherein the device is positionable beneath the scleral wall tissues of a patient's eye.
35. The device of claim 14, wherein the device is positionable beneath the scleral wall tissues of a patient's eye.

36. The device of claim 19, wherein the device is positionable beneath the scleral wall tissues of a patient's eye.

37. The device of claim 20, wherein the device is positionable beneath the scleral wall tissues of a patient's eye.

38. The device of claims 1 through 13, 15, 16, 17, 18, 21, 32 or 33, wherein the device is positionable within the wall tissues of a patient's eye in the suprachoroidal space.

39. The device of claims 1 through 13, 15 through 18, 21, 32 or 33, wherein the device is positionable within the wall tissues of a patient's eye in the suprachoroidal space, depend from claim 19.

40. The device of claims 1 through 13, 15 through 18, 21, 32 or 33, wherein the device is positionable within the wall tissues of a patient's eye in the suprachoroidal space, depend from claim 20.

41. The device of claims 1 through 13, 15 through 18, 21, 31 or 32, wherein the device is positionable outside a patient's eye, on top of the sclera, but in communication within a patient's eye.

42. The device of claim 14, wherein the device is positionable outside a patient's eye, on top of the sclera, but in communication within a patient's eye.

43. The device of claim 19, wherein the device is positionable outside a patient's eye, on top of the sclera, but in communication within a patient's eye.

44. The device of claim 20, wherein the device is positionable outside a patient's eye, on top of the sclera, but in communication within a patient's eye.

45. A method of treating a patient, comprising the steps of: introducing a cap of an attenuation device into the chamber of a patient's eye while in a first configuration, the attenuation device including a base extending from the cap, wherein the attenuation device being transformable under its own bias from a first, introduction configuration to a second, expanded configuration, wherein the cap having a volume within a range from about 7cc to about 10cc; transforming the attenuation device within the eye to the second configuration; and attenuating a pressure change within the eye by reversibly changing the volume of the cap in response to the pressure change.
46. The method of claim 45, wherein the step of introducing the attenuation device step comprises transclerally introducing the cap into the vitreous of the eye and implanting the base into the scleral wall of the eye.

47. The method of claim 46, wherein the step of introducing the attenuation device step further comprises capturing scleral wall tissue between the cap and a flange positioned at opposing ends of the base and anchoring the attenuation device in place.

48. The method of claim 47, wherein the cap is solid.

49. The method of claim 47 wherein the cap includes a thin outer wall defining a hollow chamber.

50. The method of claim 47 wherein the base is hollow and the cap encloses one end of the hollow base and extending outwardly beyond the periphery of a base wall.

51. The method of claim 50, wherein the cap includes a centrally located patch moveable in response to pressure fluctuations within the eye.

52. The method of claim 51, wherein the patch comprises a thin membrane.

53. The method of claim 52, further comprising a protective shield enclosing an end of the hollow base opposite the cap.

54. The method of claim 45, wherein the attenuating step comprises reducing the volume of the cap by at least about 5%.

55. The method of claim 45, wherein the attenuating step comprises reducing the volume of the cap by at least about 10%.

56. The method of claim 45, wherein the attenuating step comprises reducing the volume of the cap by at least about 25%.

57. The method of claim 45, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 21 mm Hg without the presence of the attenuation device to a pressure of no more than about 20 mm Hg.

58. The method of claim 48, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 30 mm Hg without the presence of the attenuation device to a pressure of no more than about 25 mm Hg.

59. The method of claim 45, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 40 mm Hg without the presence of the attenuation device to a pressure of no more than about 30 mm Hg.
60. A method of treating a patient, comprising the steps of: introducing an attenuation device into the chamber of a patient's eye while in a first configuration, the attenuation device comprising an outer wall defining a chamber therein and a compressible medium disposed within the chamber, wherein the compressible medium includes a compressible structural component, and wherein the attenuation device being transformable under its own bias from a first, introduction configuration to a second, expanded configuration having a volume within a range from about .01 cc to about 7 cc; transforming the attenuation device within the eye to the second configuration; and attenuating a pressure change within the eye by reversibly changing the volume of the attenuation device in response to the pressure change.

61. The method of claim 60, wherein the step of introducing the attenuation device step comprises transclerally introducing the device into the vitreous of the eye.

62. The method of claim 60, wherein the structural component comprises a thin wall forming a hollow core structure.

63. The method of claim 62, wherein the structural component comprises a plurality of cut-outs formed in the wall.

64. The method of claim 60, wherein the structural component comprises a structural foam core.

65. The method of claim 60, wherein the structural component comprises a core of silicone pellets.

66. The method of claim 60, wherein the structural component comprises a compressible cage structure.

67. The method of claim 60, wherein the compressible medium further includes a gas.

68. The method of claim 60, wherein the attenuating step comprises reducing the volume of the device by at least about 5%.

69. The method of claim 60, wherein the attenuating step comprises reducing the volume of the device by at least about 10%.

70. The method of claim 60, wherein the attenuating step comprises reducing the volume of the device by at least about 25%.

71. The method of claim 60, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 21 mm Hg without the presence of the attenuation device to a pressure of no more than about 20 mm Hg.
72. The method of claim 60, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 30mm Hg without the presence of the attenuation device to a pressure of no more than about 25mm Hg.

73. The method of claim 60, wherein the step of attenuating a pressure change includes attenuating an intraocular pressure spike that would have been at least about 40mm Hg without the presence of the attenuation device to a pressure of no more than about 30mm Hg.
FIG. 1A
FIG. 1B
INTERNATIONAL SEARCH REPORT

A CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 31/00 (2009.01)
USPC - 600/521
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61M 31/00 (2009.01)
USPC - 600/521

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/399, 604/500, 48, 19, 8, 623/4 I

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB) Google Scholar
Search Terms: pressure, attenuation, glaucoma, sclera, cap, head, base, valve, body, transition, protuberances, annular, ridges

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
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<tbody>
<tr>
<td>X</td>
<td>US 2008/0027304 A1 (Pardo et al) 31 January 2008 (31 01 2008) entire document, especially para [0026] to [0028], [01 18] to [0126], [01 32], [01 35], [01 54], [01 59], [01 60], [01 61], [01 71], [0172], [0180], [0181], [0186], [0196], [0199], [0210], [0312], [0313], Fig 6A-B, 7A, 8A-B, 15, 218, 28D</td>
<td>11-15, 18, 31-32, 51-55, 57-64</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,945,951 A (Beam er) 07 August 1990 (07 08 1990) col 2, Ins 26-68, Fig 1, 3</td>
<td>1-6</td>
</tr>
<tr>
<td>Y</td>
<td>US 5,234,454 A (Bangs) 10 August 1993 (10 08 1993) col 4, Ins 53-56, Fig 2, elements 19, 21</td>
<td>7-10</td>
</tr>
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<td>Y</td>
<td>US 7,291,125 B2 (Coroneo) 06 November 2007 (06 11 2007) col 6, Ins 32-47, Fig 3</td>
<td>21-28, 29(21-27), 30(21 - 27), 36-50</td>
</tr>
<tr>
<td>Y</td>
<td>US 6,544,208 B2 (Ethier et al) 08 April 2003 (08 04 2003) col 6, Ins 23-48, Fig 6</td>
<td>27, 29(27), 30(27), 44</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C

* Special categories of cited documents
  'A' document defining the general state of the art which is not considered to be of particular relevance
  'E' earlier application or patent but published on or after the international filing date
  'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  'O' document referring to an oral disclosure, use, exhibition or other means
  'P' document published prior to the international filing date but later than the priority date claimed

'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

'X' document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

'Y' document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a skilled person in the art

'&' document member of the same patent family

Date of the actual completion of the international search
26 March 2009 (26 03 2009)

Date of mailing of the international search report
09 APR 2009

Name and mailing address of the ISA/US
Mail Stop PCT, Attn ISA/US, Commissioner for Patents
P O Box 1450, Alexandria, Virginia 22313-1450
Facsimile No 571-273-3201

Authorized officer
Lee W Young

PCT Helpdesk 571-273-4300
PCT OSP 571-273 7774

Form PCT/ISA/2.10 (second sheet) (April 2007)
**INTERNATIONAL SEARCH REPORT**

**Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **D** Claims Nos.  because they relate to subject matter not required to be searched by this Authority, namely:

2. **[ ]** Claims Nos.  because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **[ ]** Claims Nos. 19-20, 33-35 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6(4)(a)

**Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. **[ ]** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **[ ]** As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. **[ ]** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.

4. **[ ]** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

**Remark on Protest**

- **[ ]** The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- **[ ]** The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- **[ ]** No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (Ap.1 2007)