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# Drainage devices in glaucoma surgery

## Urządzenia do drenażu w chirurgii jaskry

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**Summary:** Glaucoma drainage devices, also termed aqueous shunts (AS), are widely used in the USA. Indications for AS include excessive conjunctival scarring diminishing the success of another filtration surgeries, abnormalities of the iridocorneal angle, neovascular glaucoma<sup>1</sup>, presence of corneal grafts, and inflammatory glaucoma. Qualified success has been achieved for many years in 50 to 100 % of the treated eyes, depending on the patient selection. An AS consists of a silicone tube that is inserted into the anterior chamber and a plate (explant) made of silicone or polypropylene. The latter is positioned between the recti muscles. Within some weeks the surrounding tissue forms a fibrous bleb around the plate. This serves as a permanent filtration reservoir. The most serious complication is postoperative hypotonia, that can lead to serious choroidal detachment, suprachoroidal hemorrhage, anterior chamber flattening, and corneal decompensation. To avoid this complication some devices, e.g. the Ahmed Glaucoma valve and the Krupin valve, have integrated mechanisms to sustain a residual intraocular pressure. With other devices such as the Molteno and the Baerveldt devices the tube has to be temporarily ligated until a scar area forms around the explant. On the other hand, fibrous infiltration of the wall of the bleb often leads to a reversible rise in intraocular pressure about one to four months after surgery which can be treated by massaging the bulb, needling the bleb, or injection of antimetabolites. There are no obvious differences between the different AS regarding the success of pressure control. With appreciation of indications and therapy of complications, AS are an useful option in the management of complicated glaucoma, where conventional filtration surgery is considered to carry a high risk of failure.

**Słowa kluczowe:** jaskra, urządzenia przetokowe, operacje jaskry.

**Key words:** glaucoma, aqueous shunts, glaucoma surgery.

<sup>1</sup>According to our concept AS is here contraindicated, because the related secondary hypotonia can induce rubeosis iridis progression [104].

### Background

Trabeculectomy is currently the standard procedure in glaucoma surgery. In some unfavourable conditions, however, it can fail because of scar formation in the filtering bleb. Cyclodestructive procedures like cyclophotocoagulation or aqueous shunts (AS) are options in this case [40] (table I, II).

Since 1900 various implants have been used to improve the aqueous humour outflow under the conjunctiva, including horsehair [100], silk [125] or metal [11, 101, 113, 118]. These implants work as pure 'stents', that is these implants are without an own lumen, but only prevent the scarring of the sclera opening. Implants with lumen were introduced in the fifties to lead the aqueous humour directly under the conjunctiva [12, 31, 71]. A summary is given by Lim [65]. Scarring of the filtration bleb could not, however, be prevented by such implants. Molteno in New Zealand attempted to solve the scarring problem in 1969 [80, 81], when he introduced a new AS composed of a silicon tube leading to a thin acrylic plate to be fit on the sclera and enlarge the filtration area (fig. 1). Since

then, AS are used besides in New Zealand especially in USA to treat refractory glaucoma [18, 82, 83]. They are also often applied in Asia, in Japan, Korea and China as well as in Saudi-Arabia [3, 54, 59, 124]. From Europe there are only a few publications [1, 41, 46, 98]. In some conditions like conjunctiva scarring and intraocular inflammation AS achieved better lowering of intraocular pressure (IOP), compared with classical filtration operations such as trabeculectomy and goniotrepanation. In USA AS are used as an extension to primary filtration surgery in neovascular glaucoma, glaucoma uveitis, after penetrating keratoplasty, after scleral buckling, and after pars plana vitrectomy [18].

'Miniature Glaucoma-Implant Ex Press™' is a new stent development with lumen but without drainage plate and consists of a 3mm long, 400µm thick metal needle with barb, endplate, and a lumen of 20 to 50 µm. After viscoelastic injection into the anterior chamber, the needle is pushed into the anterior chamber through an opening of the conjunctiva at the limbus and fixed at the sclera through the barb and the endplate. This quick surgery is suggested

Name of the Implant	year	tube			plate			valve mechanism
		material	diameter (mm)		material	thickness (mm)	surface (mm <sup>2</sup> )	
			internal	external				
Molteno	1979	silicon	0.34	0.64	polypropylene	1.65	single:135 double: 265	optional „pressure ridge“
v. Denffer	1986	silicon	0.25	0.64	silicon	0.3	simple: 107 triple: 322	none
Joseph	1986	silicon	0.30	0.64	silicon band	1.00	765	slit
Baerveldt glaucoma implant	1990	silicon	0.30	0.63	silicon	0.84	250 350 425	none
Krupin valve with disc	1990	silicon	0.38	0.58	silicon	1.75	180	slit
White glaucoma pump shunt	1992	silicon	0.30	0.64	silicon			15-25µl compressible reservoir with two valves
Ahmed glaucoma valve	1993	silicon	0.30	0.63	polypropylene	1.90	S-2: 184 S-3: 96	silicon membranes with Venturi effect
OptiMed Model-1014	1995	silicon	0.30	0.56	silicon		140	microtubuli

Tab.I. AS implants.

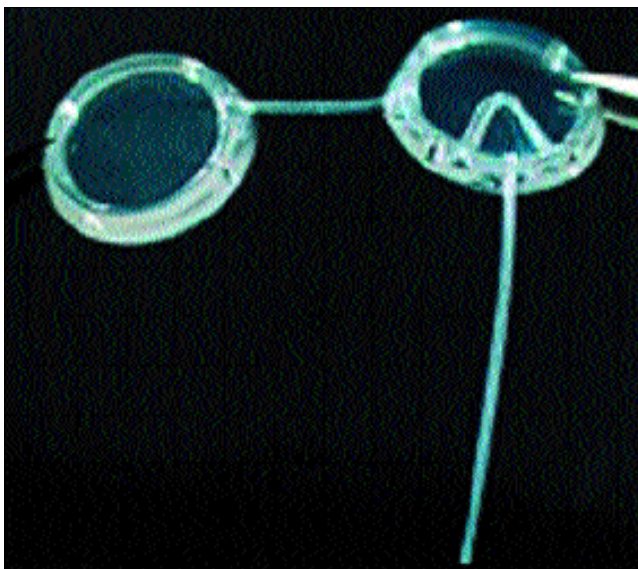


Fig. 1. Molteno drainage system, double-plate model: the ridge to reduce the outflow is visible (arrow).

as an alternative to trabeculectomy. Up to now there has been only one clinical study with a mean follow up of 31 weeks. The success rate was 76% (without medicaments) after 6 months [52]. Problems are associated with hypotonia (10%), as well as with conjunctival erosions, with implant extrusion and insufficient IOP lowering making further surgical procedures necessary. A long observation time is needed to show whether this new „stent“ is also useful in refractory glaucoma.

### Structure and function

AS are usually made of a silicon tube („drainage tube“) connected to a variably shaped plate („explant“) of polypropylene or silicon. Some AS have an IOP- or flow-restricting valve to limit the outflow of aqueous humour.

Silicon tubes used for aqueous humour outflow have an internal diameter between 0.25 and 0.38 mm inserted either in the anterior chamber or in the posterior chamber. The tube in the anterior chamber is implanted by tangential incision through the sclera with an injection needle with the same diameter for waterproof closing of the scleral tissues. The tube close to the corneoscleral limbus can be covered by a scleral flap or an allogenic scleral graft to avoid bulbar conjunctiva erosion.

The drainage plate („explant“) forms the filtration area and is positioned at the equator between the recti muscles in the space below the vagina bulbi. Both temporal quadrants are preferred, because of the large distance to the optic nerve. Some implants are large and extend therefore from the limbus almost to the optic nerve [64]. The aqueous humour flows through the tube to the drainage plate. After implantation a fibrous capsule develops around the explant within a few weeks. This chamber serves as subconjunctival reservoir, from which the aqueous humour passes by passive diffusion via the surrounding orbital tissue to the episcleral blood- and lymph vessels. The size and thickness of this fibrous capsule are the IOP-limiting factor, not the flow resistance in the silicon tube. For sufficient outflow the surface of this capsule has to be large enough, limited by the fact that a large explant may affect the muscles, resulting in motility disorders. To create a sufficiently large reservoir, up to three plates are connected with each other and implanted in different quadrants in the Molteno- and von Denffer implants (fig. 2).

Implant	Author	Year	Diagnoses	Eye numbers	follow up average	Success			
						Success definition: no further pressure-lowering surgery, no phthisis or loss of vision	at end of the follow up		„total success“ according to Kaplan-Meier to the time projected
							without medicaments („complete success“).	with or without medicam. („total success“)	
Molteno SP and DP	Mills [78]	1996	Refractory glaucoma 25% NVG 15% Uveitis	77	44 mo (6-107 mo)	IOP<23mmHg	23%	57%	
Molteno SP	Mermoud [76]	1993	NVG	60	24.7	IOP<22mmHg	17%	37%	52.9% at 2y 10.3% at 5y
Molteno SP:	Heuer [44]	1992	Refractory at glaucoma aphakie/ pseudophakie	50	14.9 mo	5<IOP<22	10%	50%	46% at 2y
DP:				52	16.4 mo		12%	75%	71% at 2y
Molteno SP:	Minckler [79]	1988	Refractory glaucoma	79	17.6 mo (6-39 mo)	IOP<22mmHg	7%	47%	
Molteno SP:	Downes [27]	1988	Refractory glaucoma	96	30 mo (6-87 mo)	IOP<21mmHg	31%	58%	
Molteno SP:	Munoz [86]	1991	Children under 12y with refr. glaucoma	53	18 mo (6-36 mo)	IOP<22mmHg		68%	
Molteno SP and DP:	Molteno [82]	2001	Primary glauc. with additional risk factors	130	4.4 y (1-12y)	IOP<22mmHg	62% nach 5 y.	100%	100% at 7y
Baerveldt 200,250, 350,500:	Siegner [109]	1995	Refractory glaucoma, 33% NVG, 15% congen., 11% Uveitis	103	13.6 mo (4-37 mo)	5<IOP<22	45%	72%	60.3% at 2y
Baerveldt 350:	Lloyd [66]	1994	Refractory glaucoma, no NVG	37	15.5 mo (7-23)	5<IOP<22	15%	84%	93% at 1.5y
500:				36	14.1 mo (6-24)		38%	83%	88% at 1.5y
Baerveldt 350:	Krishna [56]	2001	Refractory glaucoma	65	At least 24mo	IOP<22mmHg and 30% Red.			71% at 2y
Krupin Valve with disk	Krupin study group [116]	1994	Refractory glaucoma	50	25.4 mo (16-36 mo)	IOP<20mmHg	47%	80%	
Ahmed	Ayyala [8]	1998	Refractory glaucoma	85	6-36 mo	4<IOP<22	11.8%	43.5%	77% at 1y
Ahmed	Topouzis [117]	1999	Refractory glaucoma	60	30.5 mo (2.1-63.5)	5<IOP<22		78.5%	76% at 3y
Ahmed	Huang [48]	1999	Refractory glaucoma	159	13.4 mo (4-44 mo)	5<IOP<22	21%	84%	75% at 2y
Ahmed	Wilson [124]	2000	Primary glaucoma	55	9.7 mo (6-13 mo)	IOP<21mmHg and 15% Red.	65%		88.1% at 1y
Ahmed	Andreanos [1]	2001	Refractory glaucoma 52% NVG	142	32.4 mo (6-48 mo)	IOP<22mmHg		56.3%	
mostly Baerveldt 350	Arroyave [2]	2001	At the same as or after KPL	72	At least 1y	5<IOP<21	49%	91.6%	
						clear graft		56.9%	
Baerveldt/ Ahmed	Kwon [58]	2001	Before, at the same taime as, or after KPL	55	34 mo (8-74 mo)	5<IOP<22mmHg		82%	78% at 74mo
						clear graft		56%	40% at 89mo

SP = single plate, DP = double plate, NVG = sek. glaucoma bei Neovascularisation, mo = month, y = year, IOP = intraocular pressure, Red. = Reduction

Tab. II. Success rate of AS implantation.

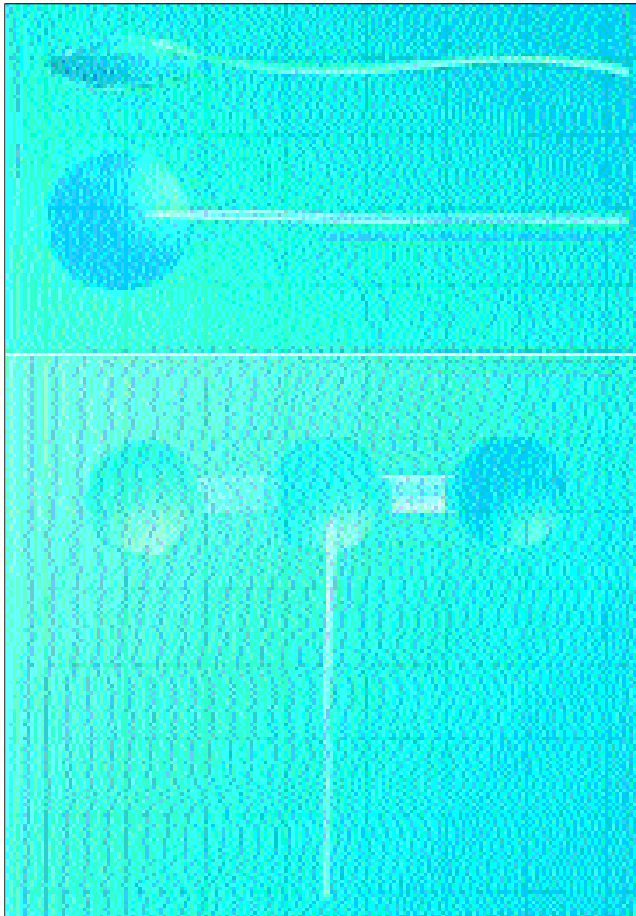


Fig. 2. Von Denffer silicon drainage system; above: model Mono; below: model Trio.

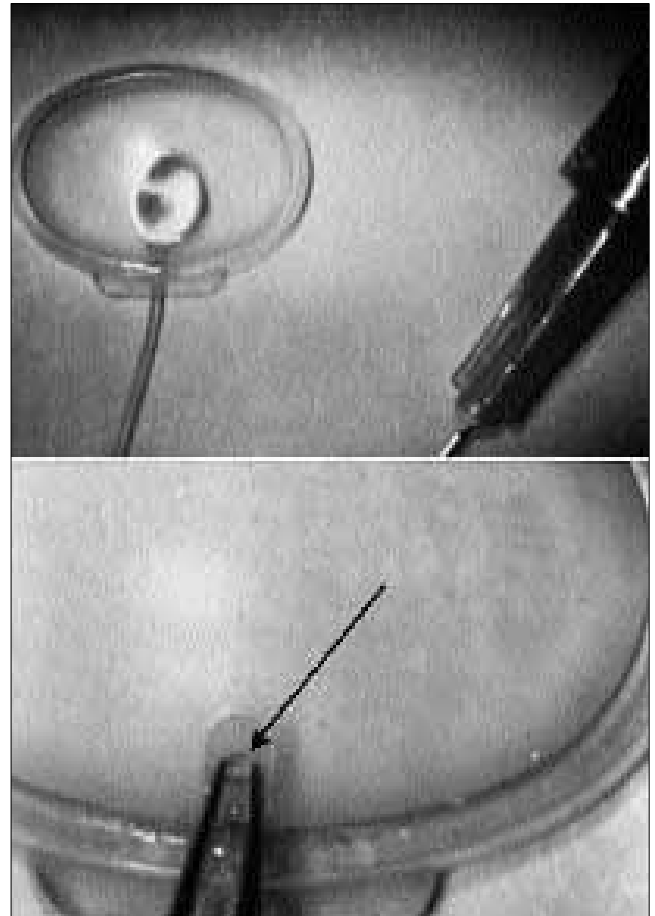


Fig. 3. Krupin valve; above: implant after flushing with BSS, liquid coming out in the valve area; below: the slits opening in tube system (arrow).

Schocket [103] implanted a silicon tube together with an encircling band. The encircling band serves as the space for the filtration area. The silicon tube can be implanted into the fibrous capsule of an already existing encircling band. This procedure is called the ACTSEB method (anterior chamber tube shunt to an encircling band).

In the first weeks after implantation, before the formation of the capsule, the unlimited outflow can lead to hypotonia, with the danger of severe complications such as flattening anterior chamber, choroid detachment, or choroid haemorrhage. Different implant mechanisms have been integrated to avoid these complications and to limit the overdrainage in this critical phase. In the „Krupin Eye valve with disk“ the end of the silastic tube was sealed with silastic cement. Horizontal and vertical slits in the sealed tube functioned as an unidirectional valve with an opening pressure of about 11 mmHg [57, 116] (fig. 3). The „Joseph Implant“ has a slit mechanism as well [47]. The „OptiMed Shunt“ uses 180 to 200 parallel tubes with 0.06 mm internal diameter to produce a resistance with a threshold opening pressure [65, 96]. In the „Ahmed Glaucoma Valve“ the silicon tube leads to a trapezoid chamber with two elastic silicon membranes which are stretched against each other (Fig. 4,5). The narrow side of the trapeze leads to the fibrous chamber around the plate. The membranes open at a pressure of about 8 mmHg and also prevent a backflow of aqueous humour after any rubbing of the eye. In an experiment the Ahmed valve was

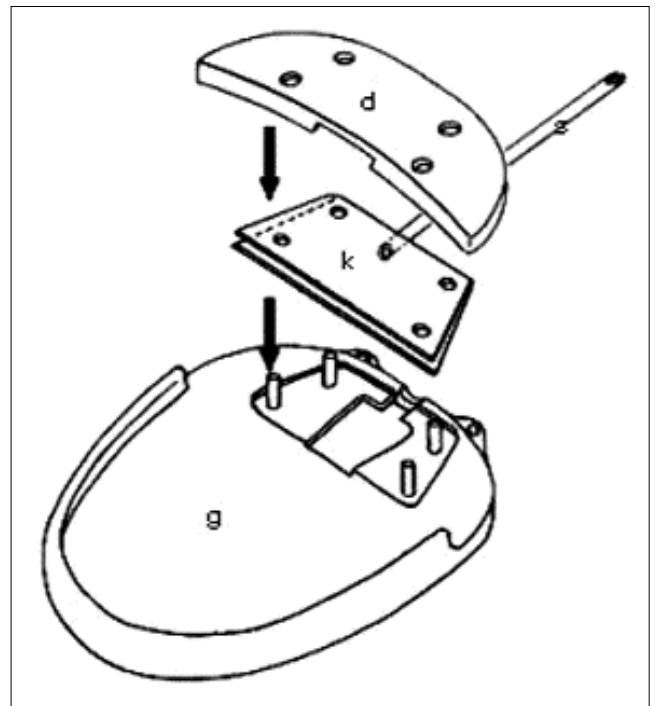


Fig. 4. Ahmed glaucoma valve systematic structure: ground plate (g) and cover plate (d) made of polypropylene, valve mechanism made of two silicon membranes (k), silicon tube (s).

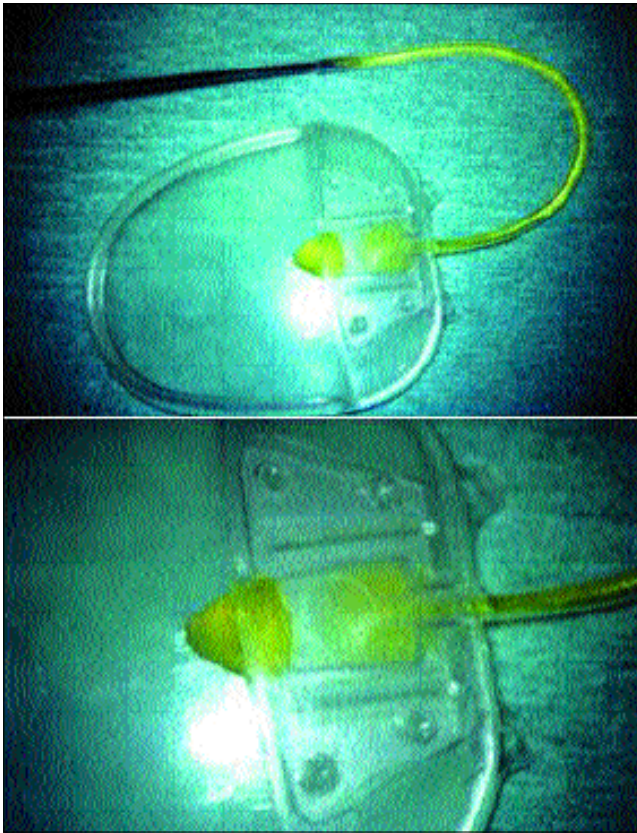


Fig. 5. Ahmed glaucoma valve; above: total view; below: the valve mechanism of the two silicon membranes is demonstrated by fluorescein.

shown to open at a pressure of 11-14 mmHg and close at a pressure of 6 mmHg, with only a small rise of the IOP in the anterior chamber at increased drainage [30, 34]. The trapezoid form of the chamber should lead to a slight flow resistance at filtration according to the Venturi principle, but it is doubtful whether the Bernoulli equation applies at these small flows and differences of cross-section [63]. The effect limiting IOP is based more likely on a valvar function of the silicon membrane. The „White Glaucoma Pump Shunt ®” consists of a pump reservoir between two valves, which help to „milk” the eye through lid movements or manually [19, 122, 123].

Examination of implant device performance in vitro has shown that only the Ahmed device functions consistently as a valve. There was no outflow in the case of IOP below the opening pressure of 11-14 mmHg. The flow volume increased quickly when IOP was between 14 and 20 mmHg [30, 34]. All other devices behaved like a pure resistance element and showed a characteristic of outflow proportional to IOP. However in the Ahmed valve the outflow resistance is higher than in the Krupin valve, the OptiMed implant, the Joseph implant, or, as to be expected, the Baerveldt implant without valve or resistance mechanism.

Most drainage plates are made of silicon, only in the Molteno implant and the Ahmed glaucoma valve polypropylene is used. Polypropylene is said to cause more inflammatory reaction in tissue [5]. In clinical outcomes, however, no essential differences concerning the IOP regulation are noticed. The material of the plate seems to play a minor role where the filtration bleb forms, because the plate is surrounded with aqueous humour and has little contact with the vagina bulbi tissue itself.

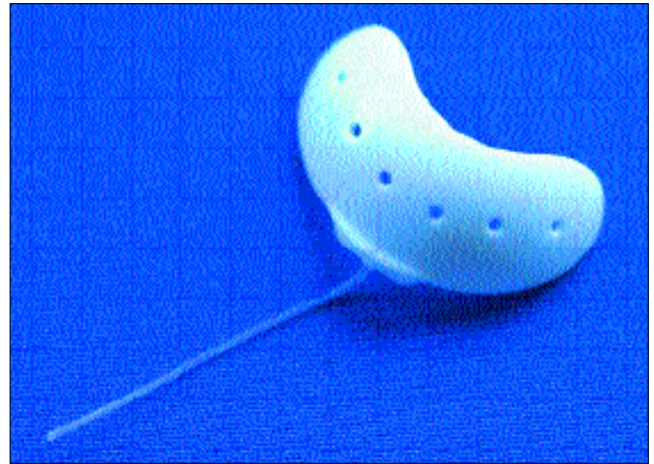


Fig. 6. Baerveldt drainage system (425mm<sup>2</sup>).

Molteno and Baerveldt implants are also available (fig. 6) with a special form of the explant to limit the aqueous humour outflow in the first weeks after implantation. The silicon tube in the „pressure ridge Molteno device” [35] and the 'Baerveldt implant with bioseal' [9] leads into a small „chamber”, which is formed by prominent edges of the plate and the overlying sclera or conjunctiva. The idea is, that a certain IOP is required before the aqueous humour will lift the plate from the conjunctiva or sclera. In addition, the plate can be fixed to the conjunctiva or sclera with absorbable sutures. Later the fibrous capsule develops around the whole plate and an adequately sized filtration bleb forms [65]. Nevertheless, the dosage and the prediction of the initial aqueous humour outflow is poor with these devices [39].

To our knowledge there are seven different AS commercially available in the moment, most of them are offered in various sizes. The Molteno implant, the Baerveldt glaucoma implant, von Denffer silicon drainage device, the Krupin eye valve with disc, the Ahmed glaucoma valve, the OptiMed IOP-regulator and the White glaucoma pump shunt. The first three have no IOP- or flow-restricting valves. Members of the American Glaucoma Society mostly use Molteno Implants, Baerveldt Implants, the Ahmed valve, or the Krupin valve with disc [18].

## Complications

### Early complications

The most feared complication after AS implantation is excessive hypotonia in the early postoperative phase. It is induced by overdrainage of aqueous humour and can lead to anterior chamber flattening with possible contact between endothelium and the silicon tube, choroidal effusion with choroid detachment, hypotonic maculopathy, or suprachoroidal haemorrhage. The various valve mechanisms described were developed to minimise overdrainage in the early postoperative period.

### Choroidal Effusion Syndrome

A choroid detachment occurs in 10% to 20% cases using AS of classic design [1, 29, 56, 59, 119]. There are two possibilities using AS without built-in outflow restriction: either implantation of the AS in a first step without implantation of the tube into the eye then, in a second step, after allowing development of a capsule of connective tissue around the „explant”, about 6 to 8 weeks [85], insertion of

the tube into the anterior chamber; or complete implantation but temporarily closing the tube by a ligature either of a non absorbable suture, which has to be removed [97], or by an absorbable suture, which means automatic removal of the restriction after some time [79, 84]. Some authors recommend inserting a nylon thread into the tube to close it. The other end of the thread is placed under the conjunctiva far from the implant [28, 109], allowing easy removal of the blockage as required. In the first postoperative phase no filtration will take place in such a procedure, therefore slits in the silicon tube must be made to achieve some immediate filtration [107, 119]. In the case of drainage device implantation via the pars plana, temporary occlusion of the silicon tube can be achieved by a vitreous gas tamponade to avoid a hypotensive phase [73].

All these procedures, however, can not reduce the risk of an early hypotonic phase completely [51, 66].

#### **Choroidal haemorrhage**

The incidence of suprachoroidal haemorrhage after AS implantation varies from 0 % to 6 % [82, 90, 92, 117, 119, 124]. Implants with an IOP-regulation mechanism or a drainage tube ligature have a better prognosis. Predisposing factors are considered to be reduced IOP, angle closure glaucoma, and a large number of previous surgical events [92]. A choroid haemorrhage represents the greatest risk of a reduced vision postoperatively [61, 120].

#### **Endothelium and Lens**

Another consequence of the early postoperative hypotonia is a flattening of the anterior chamber, with a risk of endothelium- and lens injury by the silicon tube in the anterior chamber or even tube obstruction by the iris.

#### **Motility disorders**

Large implants and a large filtration bleb can affect the motility of the adjacent eye muscles, so that diplopia is possible. In a prospective study motility disturbances were noticed among 24 patients in 46% after the implantation of double-plate Molteno implants [25]. Restricted function of the muscle rectus superior, Pseudo-Brown syndrome and paralysis of the muscle obliquus superior were observed, but the diplopia usually regressed during one year. An incidence of motility disorders of 7 to 27% was reported for the 350-mm<sup>2</sup> and the 500-mm<sup>2</sup> Baerveldt implants, the incidence tending to be higher for the larger size [66, 109]. In small implants, like the Ahmed valve, only implanted into one quadrant, the incidence is lower (2-3%) [48, 117]. The addition of fenestration to the Baerveldt plate and a flat design may limit the size of the bleb, which could reduce the incidence of motility disturbances. Adhesions between capsule and muscle probably play a role too. Krishna *et al* and Tribble *et al* noticed motility disorders in only 3% and 2% patients having the 350-mm<sup>2</sup> Baerveldt plate [56, 119].

#### **Transient Hypertension**

An hypertensive phase appears in the first three months in up to 80% of the patients [8, 46]. The reason for this is the increasing inflammatory response and fibrovascular scarring of the connective tissue surrounding the drainage plate [67, 83]. Histologically an increased cell infiltration of the cyst wall in a non-functional filtration bleb was reported, compared to eyes with a regulated IOP [70]. In this phase IOP control is important not only to minimize glaucoma damage, but also for the long-term reduction of IOP. According to Molteno a higher post-surgery IOP leads to a large primary filtration area, greater scarring, and a lower permeability of

the wall of the filtration bleb [83]. Therefore he recommended, besides an anti-inflammatory treatment, a reduction of the IOP by drugs in the first postoperative phase. Stents or ligatures of the drainage tube have to be removed of course. The development of the filtration reservoir can be checked by ultrasound (fig. 7). A tube closure or valve occlusion can be recognized or rather excluded in this way. Needling of the filtration reservoir [8, 17, 60] as well as subconjunctival 5-FU injection [8] are recommended too. In most cases IOP will decrease spontaneously after some months [8], which is caused by reduced cellular elements as well as collagen fibre dispersion in the capsule [67], which decreases the tissue resistance. Especially in cases with Ahmed glaucoma valves a consistent massaging of the bulb will lower a spontaneously increased IOP to a normal level again [46].

In the case of inadequately controlled IOP additional medication can be used such as  $\beta$ -blockers, adrenergic substances, or carboanhydrase inhibitors. Pilocarpin should be avoided because of induction of conjunctiva fibrosis. A second AS implanted in another quadrant frequently leads to success [15]. AS implantation can be combined with mitomycin C to achieve a greater drop in IOP where severe scarring is present [114]. Some authors describe a significant improvement of filtration [55, 95], but increased risk of post surgical hypotonia [94], however others did not see this effect [16, 62, 119], so that the value of mitomycin C in AS is still uncertain. Additionally, the implantation of the explant in Tenon's capsule, not directly on the sclera, may cause less scarring and thus lead to a better long-term outcome.

#### **Late complications**

##### **Endothelium/Cataract**

Especially in patients with lens and in those with flat anterior segments the risk of contact of the endothelium with the drainage tube exists and this can lead to chronic endothelial cell loss [75] with consecutive endothelial decompensation. Therefore, some authors recommend implanting the tube through pars plana into the vitreous body in patients after keratoplasty, iridial angle anomalies, and in phacic patients with anterior chamber flattening [43, 50, 72, 105]. However, to prevent vitreous incarceration of the drainage tube a complete vitrectomy must be performed. The pars plana implantation is also recommended in neovascular glaucoma to avoid irritations and haemorrhage from pathological vessels in the iridial angle [72, 105]. Disadvantages of this method are the risk of retinal complications, the impossibility of visual examination of the tube in case of an apparent obstruction, as well as a higher risk of hypotonia, and as a consequence an increase of rubeosis iridis [104]. Here the drainage tube does not enter tangentially through the sclera and therefore leakage of aqueous humor is more likely. However, endothelial decompensations have been described after pars plana implantation too [53], which is not surprising as a lot of patients already have a limited endothelial function preoperatively through the course of their disease. According to Molteno endothelial cell loss after a correct tube implantation in the anterior chamber is similar to that after trabeculectomy [82] (fig. 8).

Induction or progression of cataract are reported in 8% to 34% of phacic patients [1, 48, 65, 66, 79, 109]. However, the same incidence of cataract development is also described for classical glaucoma surgery.

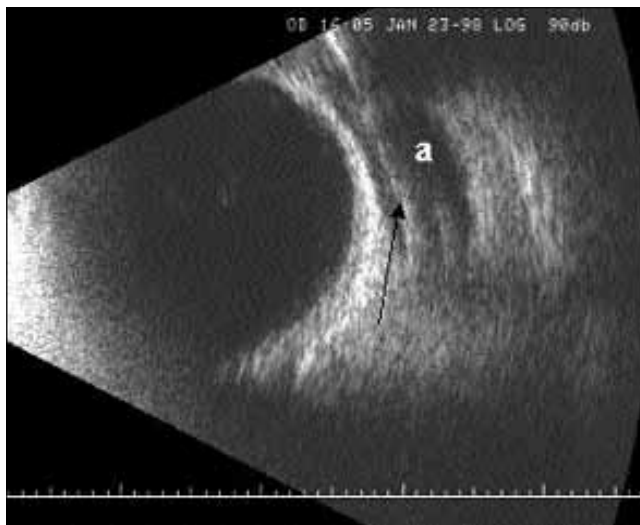


Fig. 7. Filtration area viewed ultrasonically to check its functioning: filtration bleb (a), reflection at implant (arrow).

#### Erosion of the conjunctiva

Due to the superficial position of the drainage tube it is possible that it penetrates the conjunctiva. Therefore, it is generally recommended to cover the tube at the scleral entrance and in its anterior part with a graft of pericardium, dura, fascia lata, or sclera. Alternatively, the tube may be inserted through a sclera tunnel [46, 91]. In examinations with a large number of patients the risk of conjunctiva erosion with exposure of the tube or plate is reported to be between 1% and 3% [56, 61, 86, 90, 116].

This complication is the cause of endophthalmitis developing after AS implantation [38]. We noticed one case with tube extrusion and onset of endophthalmitis in 30 patients with an Ahmed valve. Beside a systemic antibiotic therapy the AS has to be removed [8, 79].

#### Dislocation of the tube

Some authors reported insufficient filtration after a displacement of the tube in 2% to 3% of the implants [77, 79], or after a blockage by the iris or scarring tissue in up to 6% [1, 8, 79] 11% [48, 56, 66]. This complication however, occurs usually as a result of incorrect implantation and is avoidable. The tube should be diagonally cut during the implantation into the anterior chamber, with the opening towards the endothelium to avoid a tube blockage by the iris.

#### Indications and results

AS are used when other filtration operations with additional antifibrotic therapy have failed because of excessive postsurgical scarring. Primary surgical indications for AS implantation can be where the conjunctival conditions don't allow the formation of a filtration bleb, progressive scarring of the conjunctiva exists or is to be expected, for example after previous operations and penetrating eye injuries with anterior iridial angle synechia, ocular pemphigus, Fuchs-Stevens-Johnson Syndrome and secondary glaucoma due to active or recurrent uveitis. In addition they could be used with success in cases of anatomical anomalies such as the Irido-Corneal-Endothelial syndrome (ICE) and in aniridia. In USA they are used as primary therapy to treat neovascular glaucoma after unsuccessful panphotocoagulation and in patients who want to wear contact lens [18, 29, 110].

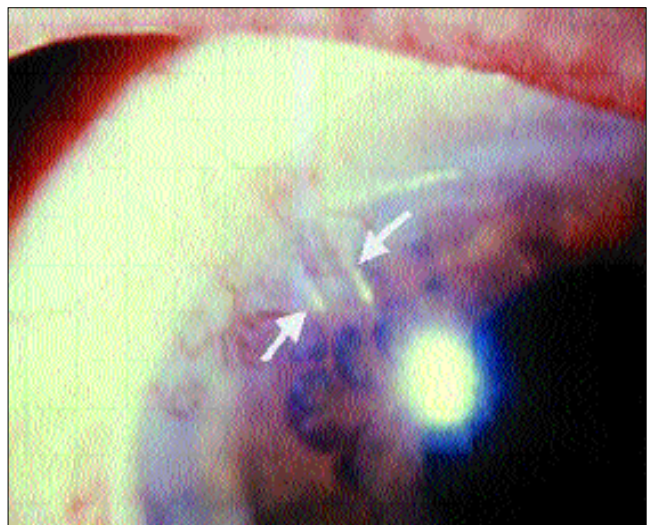


Fig. 8. Regular position of the silicon tube of glaucoma drainage systems in the anterior chamber (arrow).

#### After failed filtration operation

After several unsuccessful glaucoma operations the success rate of AS implantation was between 24% and 90% at a mean follow up between 12 and 48 months [69, 77, 79].

#### After previous operations with conjunctival opening

Also after other previous operations with conjunctival opening a classical filtration operation fails frequently because of conjunctival scarring. In these situations some authors recommend implanting AS and report a successful regulation of the IOP in 46% to 83% [42, 69, 79]. In a randomized study the 350 mm<sup>2</sup> Baerveldt implant was implanted in 107 aphacic, pseudophacic patients, or after failed classical filtration operation, and IOP regulation was achieved in 98% in the short term and in 79% for at least 5 years [13]. The implants with a plate size of 500 mm<sup>2</sup> showed lower success in IOP regulation.

Among 16 patients with glaucoma who had undergone an encircling band operation and who additionally received a Baerveldt implant, the IOP was regulated without medication in 56% and with additional local medication in all the remaining patients [106]. Furthermore, AS were implanted after vitreoretinal operations with a success rate of 60% to 80% as regards IOP regulation after 1 to 2 years [37, 68, 72]. AS must not be implanted before silicon oil is removed from the eye, otherwise a flow of oil in the space below the conjunctiva is to be expected [49, 87]. After injuries of the bulb AS are frequently implanted due to conjunctival scarring. In an examination of 38 eyes the success rate was 76% [36].

#### Uveitis

The secondary open angle glaucoma in uveitis represents an indication for primary AS implantation [18]. Da Mata et al [22] implanted an Ahmed valve in 21 consecutive patients and the IOP was controlled in all patients at a mean follow up of 24.5 months. However, the implant had to be replaced in one patient after one year. The authors emphasize the importance of immune modulating therapy to control the uveitis, which had probably contributed to this success-rate. Other authors also report on IOP regulation in 100% after 18 months [33] and 90% after 52 months [121].

#### Neovascular glaucoma

The most important therapeutic strategy in neovascular glaucoma (NVG) is the treatment of the primary disease and the

inhibition of vessel proliferation through the reduction of retinal ischemia by means of panretinal photocoagulation or cryocoagulation. If the rubeosis iridis has already caused synechias in the iridial angle, these procedures and additional medical therapy will not be sufficient to decrease the IOP. In principle, cyclodestructive and filtration surgery are the options. In an interview among members of the American Glaucoma Society about neovascular glaucoma, 29% of them preferred AS implantation to other sorts of filtration surgery [18]. In the literature the success rate for AS implantation in this indication is between 22 and 97% [110]. Irritations of the neovascularizations by the tube may cause bleeding into the anterior chamber. As vitrectomy is frequently necessary in these patients anyhow transscleral implantation of the drainage tube into the vitreous body is recommended to avoid haemorrhages [72, 105].

In a retrospective study Eid et al (1997) compared 24 patients after AS implantation with 24 patients after Nd-YAG cyclophotocoagulation and found that on a long-term basis the IOP was better controlled and a hypotonia or blindness occurred more rarely after AS implantation. After three years the success rate was 28.8% in the cyclophotocoagulation group (i. e. IOP regulation without serious complications) but still 56.7% in the AS-implantation group. Nevertheless, AS implantation at this indication involves a considerable risk, because the post-surgical hypotonia may trigger vascular proliferations [104]. Due to the establishment of the diode laser with improved dosage control the complication rate for cyclophotocoagulation is lower now [23, 110], and therefore we would prefer cyclophotocoagulation by diode laser to a filtering surgery.

#### **Keratoplasty**

Many patients with significant corneal disease requiring penetrating keratoplasty have concurrent glaucoma. Both corneal opacity and glaucoma can be prominent features of such ocular conditions as aniridia, aphacic or pseudophacic bullous keratopathy, ICE, chemical burns, trauma, congenital glaucoma, posterior polymorphous corneal dystrophy, and herpetic keratitis. In addition glaucoma is one of the most serious complications after penetrating keratoplasty. Glaucoma after penetrating keratoplasty is multifactorial and probably related to distortion of the angle with collapse of the trabecular meshwork during and after the operation [4]. If it does not respond to medication it has to be treated surgically, which is problematic but essential for graft prognosis. In this situation filtration operations with mitomycinC application, cyclodestructive procedures, or AS implantation could be used. Randomized, prospective studies are needed to determine which of the currently available treatment options show the best results. In a retrospective analysis Ayyala et al [6] examined patients with pre-existing or secondary glaucoma after penetrating keratoplasty. The patients received a trabeculectomy with mitomycin C (17), AS implantation (10), or Nd: YAG laser cyclophotocoagulation (11). There were no significant differences between these small groups in IOP control or graft clarity. The main problem was the frequent graft failure as a result of the glaucoma operation. Graft failure was noticed in two patients after trabeculectomy and in one patient after cyclophotocoagulation, which corresponds to the reported incidence in the literature of 4-34% and 11-65% respectively. None of the patients with AS implantation had a graft failure, which is surprising, because other authors reported an incidence between 10 and 51% [4]. The etiology is probably multifactorial. Chronic inflammation due

to the immunological reaction to the foreign body, blood-aqueous-humour-barrier disturbance, or mechanical irritations of the endothelium during and after the operation may contribute to IOP elevation. Uncontrolled higher IOP over a long time deteriorates the graft prognosis. MitomycinC trabeculectomy appears to be the safest operation in term of graft survival and should be the first surgical option to be considered in post keratoplasty glaucoma [4]. Implantation of a glaucoma drainage device appears to be preferable to other surgical options for patients with extensive limbal conjunctival scarring, anterior chamber flattening, extensive peripheral anterior synechias, or failed filtration surgery. The incidence of graft failure after implantation of a glaucoma drainage device in the vitreous cavity or sulcus [102] seems to be considerably lower than after implantation in the anterior chamber (2% vs 17% [2]). However, this remains controversial because another retrospective examination showed only 41% clear grafts 24 months after pars plana insertion [108]. Whether glaucoma surgery and penetrating keratoplasty should be sequential or concurrent to maximize both IOP control and corneal graft clarity remains to be evaluated [2, 20, 58]. Limited data from previous studies have suggested a higher rate of graft survival if glaucoma drainage devices are implanted before penetrating keratoplasty [10, 99]. Generally, after keratoplasty the success rate regarding IOP regulation through AS implantation lies between 71% and 96% [2, 4, 20, 108].

#### **Keratoprosthesis**

Glaucoma represents a special challenge in patients with a keratoprosthesis (KPro). Approximately 40% of the patients suffer from glaucoma before KPro surgery because of the severe anterior segment changes and often multiple previous operations. Another 30% developed it after keratoprosthesis implantation [74, 88]. Due to the deterioration in the corneal and conjunctival situation absorption of topical antiglaucoma medications is no longer sufficient and classical IOP-lowering operations are doomed to failure. In addition, IOP measurement above the cornea is not practicable and therefore problematic. Therefore, glaucoma associated with keratoprosthesis is treated effectively with AS, which can control the IOP in most patients. Netland et al [88] implanted glaucoma drainage devices in 36 eyes (35 Ahmed valves, 1 Krupin valve). They checked the IOP in 81% and observed a progression of glaucoma in only 5 patients. We implanted the Ahmed valve in 14 osteo-odonto-keratoprosthesis patients (6x primary and 2x secondary) and we noticed no glaucoma progression in a follow up of 3 years on average [45].

#### **Congenital glaucoma**

The management of most childhood glaucoma usually involves surgery as a primary intervention. Congenital glaucoma is generally best managed initially with trabeculotomy. The increased tendency to postoperative scarring and episcleral fibrosis in children relative to adults contributes to the lower success rate of trabeculectomy in the pediatric population. Especially in American references, in such a situation the implantation of AS are preferred to cyclodestructive procedures, because the latter are difficult to dose and treatments often have to be repeated to achieve the desired degree of IOP reduction [93, 115]. AS achieve a success rate between 60 and 80% in infants and children [24, 32, 89, 93]. Cunliffe et al [21] reported a long-term follow up (mean 11.2 years) of 34 eyes where Molteno drains were used in the treatment of glaucoma presenting in childhood. IOP control was achieved in 85% of eyes and the vision



was maintained in 57%. However 32% of these cases required further surgical intervention such as tube shortening, tube repositioning, including insertion in the posterior chamber, AS replacement or additional insertion of AS. For two eyes, patch grafts to prevent erosion of the tube were required. However, the variety of aetiologies and the small numbers preclude any definite conclusions from these series. Normalization of the IOP postoperatively may cause the elastic young eye to shrink, shifting the tube and possibly causing it to touch the cornea, which has frequently been noticed in buphthalmic eyes [32, 89]. Two-stage insertion of an aqueous shunt is particularly beneficial in children who have Sturge-Weber syndrome (SWS), to reduce their significant risk for massive intraoperative or postoperative choroidal effusion and haemorrhage [14, 115]. However, Hamush et al (1999) noticed in a similar number of 11 eyes with SWS no suprachoroidal haemorrhage or retinal detachment after one-stage insertion of an Ahmed valve. The use of additional postoperative antiglaucoma medication to control IOP is even more common after shunt surgery in young children than in adults.

The glaucoma in Irido-Corneal-Endothelial syndrome is presumed to be caused by a membrane covering the trabecular meshwork. It is estimated that filtering surgery fails secondary to the continued growth of the endothelial membrane over the filtration site. The long-term success of AS implants appears to be better than that of trabeculectomy with an antifibrotic agent [26].

#### Comparison between various AS:

Prospective randomized studies to compare the various AS are rare. In such a study Smith et al [112] compared the Molteno two-plate implant with the ACTSEB method and found no differences in vision and IOP control. However, more complications occurred among the 21 patients in the ACTSEB group, including three suprachoroidal haemorrhages. In a retrospective examination to compare the two-plate Molteno implant with the Ahmed valve, it was noticed that although both AS were equally successful in lowering the IOP to below 22 mmHg the IOP achieved with the Molteno implant was lower on average [7] and the hypertensive phase was less pronounced. This was attributed to the greater plate surface area, which was 270 mm<sup>2</sup> for the Molteno implant in contrast to 185 mm<sup>2</sup> for the Ahmed valve, and to the higher flow resistance of the Ahmed valve. Complications due to postoperative hypotonia did not occur significantly more frequently in the Molteno group, because the tube was closed by a 4-0 nylon stent initially. When hypertension developed, it was treated successfully by removing the stent or by needling the filtration bleb with 5-FU. In another study, retrospective analysis of 350-mm<sup>2</sup> Baerveldt implants and two-plate Molteno implants showed no significant differences in the results [111].

#### Comparison of trabeculectomy and AS-Implantation

To the best of our knowledge there has been only one prospective study to compare AS implantation with other surgical methods to treat uncomplicated glaucoma. Wilson et al [124] compared the implantation of the Ahmed glaucoma valve with trabeculectomy in a randomised clinical study. 117 consecutive patients were randomized. Trabeculectomy with or without mitomycinC or implantation of the Ahmed valve were carried out. After a short follow up (9.7 months on average) they found no significant differences concerning IOP lowering

or the number of complications. In 83.6% of trabeculectomy cases and in 88.1% of AS implantations the IOP was lower than 21 mmHg and at least 15% lower than preoperatively. However, more patients with an Ahmed valve needed additional topical medication. Anterior chamber flattening and choroidal effusion occurred in both groups equally frequently. Other serious complications were not described. Similar outcomes were reported by Molteno [83] in a retrospective study of 180 patients with primary open angle glaucoma, additional risk factors undergoing Molteno implant surgery and 238 patients with primary open angle glaucoma without additional risk factors undergoing trabeculectomy. In another study of a small series the „White Pump Shunt“ showed no significantly better IOP lowering compared with trabeculectomy but a significantly higher complication rate [19].

This shows that AS implantation, as a large and expensive operation, is surely not indicated in uncomplicated glaucoma. Even if two of these studies showed no increased rate of complications for AS implantation, Tuli et al showed [120] in a retrospective analysis of 2285 filtration glaucoma operations that after AS implantation more suprachoroidal haemorrhages occurred than after trabeculectomy without implantation [9 out of 615 (1.5%) ], 30 out of 1248 (2.4%) with an antimetabolite, 2 out of 72 (2.8%) after AS with IOP-limiting valve and 25 out of 359 (7.1%) AS without valve. However the patients in this study were selected and not randomized.

#### Drainage implant when? – a Conclusion

By implanting a glaucoma drainage device an adequate reduction of IOP can be achieved in about 75% patients. For patients with complicated glaucoma there are scarcely differences between the various implants in their ability to lower IOP. Where devices with an integrated outflow-restriction device are implanted, IOP does not seem to fall quite as much. However, such an outflow restriction is extremely important in the first postoperative period to avoid grave complications. Thus, summing up, implants to lower IOP should be regarded as ultimate ratio for complicated glaucoma patients when other filtration operations are deemed to fail. In other cases they are less suitable because they cause more complications, and higher costs, than other treatment options.

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