proGAV® Clinical Evidence
Aesculap-MIETHKE Adjustable Shunt
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Shunting has dramatically changed the outlook for patients with hydrocephalus. When left untreated, the mortality rate for hydrocephalic patients at ten years is over 50% with intellectual impairment in over 60%. Diversion of cerebrospinal fluid (CSF) with a shunt was used for the first time over half a century ago. The impact was significant. In shunted children the 10 year survival increased to nearly 95% with intellectual impairment in only 30%. Shunting has become the standard treatment for most hydrocephalus forms, with a long history of improvements made through biomedical, clinical and technical innovations. The result is that most patients with hydrocephalus have a normal life expectancy and many hydrocephalic children attain normal intelligence.

The use of shunts, however, has created many new and unique problems of shunt dependence with frequent shunt revisions being the rule for most patients. There are surgery-related complications such as shunt infections or malplacements of the catheters. And there are valve related complications like obstructions due to clogged lumen by cells or debris or mechanical failures related to improper function of the device. Shunt problems assume a major amount of many neurosurgeon's efforts, so one might say that hydrocephalus therapy is the management of complications.

Another specific problem in shunt-treated hydrocephalus patients is overdrainage of cerebrospinal fluid. The hydrostatic effect can result in draining too much fluid from the brain too quickly, causing hygromas or in worst case subdural haematomas. Overdrainage or correspondingly underdrainage can be caused by the wrong choice of the shunt valve or by the fact that the physiology of the patient has changed over time. This can happen during growth, pregnancy or change of weight which all can influence the hydrostatic effect.

The quest for the perfect shunt goes on. Gravitational valves were invented to compensate for the different hydrostatic pressures between the supine and the upright body position. Aschoff showed in a large series with gravitational shunts that the overdrainage rate can be reduced to zero. In order to emphasize this as a breakthrough he used a quote which symbolizes another medical landmark: “Gentlemen, it is no humbug”. These famous words are attributed to J.C. Warren, after he had performed the first surgical procedure with ether anesthesia.

Valves with a non-invasive adjustable opening pressure were introduced in the 1980’s. They allow the surgeon to change the opening pressure, without the need for revision surgery. These valves incorporate some kind of magnetically activated component which is potentially problematic since hydrocephalus patients frequently undergo MR imaging. In fact there are well known magnetic field-related hazards that involve adjustable valves. Exposure to powerful MR magnets could change the valve setting or permanently damage the device. They even may be accidentally readjusted by weak magnetic fields of 30-40 mT which could be produced by household devices or toys.

However, the adjustable shunts have become very popular in the management of hydrocephalus. It is believed that they may help in minimizing the number of surgical revisions. Furthermore they allow the patient to undergo a specialized or individualized treatment regime.

The Aesculap Miethke proGAV® valve combines the advantages of gravitational devices with the possibility of non-invasive adjustment. It consists of an adjustable ball-in-cone valve and a gravitational anti-siphon unit, all contained in solid, compact titanium housing. The adjustable unit has a coil spring which defines the opening pressure of the ball-in-cone valve. The tension of the spring can be adjusted by turning the rotor. The gravitational unit contains a tantalum ball, which defines the opening pressure of the valve and a sapphire ball, which ensures the precise closure of the valve. The opening pressure varies depending on the body position of the patient.

Rationale

In the horizontal position, the gravitational unit opens completely. Thus, there is no longer any resistance to the flow of the CSF and the gravitational unit has no effect at all when the patient is lying down. The opening pressure of the proGAV® is defined solely by the adjustable unit.

As soon as the patient moves into an upright position, the balls of the gravitational unit are moving down and gradually increase the resistance to CSF. The opening pressure of the gravitational unit increases steadily as the patient moves to the upright position. This provides effective protection against overdrainage.

The adjustment and the reading of the valve setting can be done with pensized instruments. The distance between the magnets integrated in the valve rotor is as large as possible to increase the reliability and safety of the readjustment. The adjustment range of the valve for the 21 steps between 0 and 20 cmH₂O is distributed over an angle of 300°. A possible inaccurate alignment of 15° is equal to only 1 cm of water, to ensure a precise and reliable adjustment.

Features of the proGAV® valve:
- Wide range of pressure levels for stepless adjustment between 0 and 20 cmH₂O
- Integrated gravitational unit for effective protection against overdrainage
- "Active-lock" mechanism to prevent inadvertent pressure level readjustments caused by external magnetic fields
- 3 T MR safe
- Instruments for easy and quick adjustment of the pressure level
- Titanium shell ensuring reliable operation independent of external or subcutaneous pressures

A major requirement for adjustable shunts is the resistance to unintended readjustment due to magnetic fields. Like all other adjustable valves the proGAV® valve is adjusted with a programming tool with magnets inside in a certain configuration. The proGAV® valve has an inbuilt mechanical brake ("Active-Lock"). This brake ensures pressure adjustment without the risk of unintended changes due to magnetic fields. Only if the brake is opened by an externally applied defined force on the device, can the adjustment of the valve be performed. This mechanism provides a resistance to external magnetic fields up to 3 Tesla.

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<td>IVP</td>
<td>Intraventricular pressure</td>
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<tr>
<td>Pₜₜₜ</td>
<td>Opening pressure in horizontal position (adjustable unit only)</td>
</tr>
<tr>
<td>Pₜₜₜ</td>
<td>Opening pressure in vertical position (adjustable + gravitational unit)</td>
</tr>
<tr>
<td>Pₚₚₚ</td>
<td>Pressure in the abdominal cavity</td>
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<tr>
<td>Pₚₚₚ</td>
<td>Hydrostatic pressure</td>
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horizontal: IVP = Pₜₜₜ + Pₚₚₚ
standing: IVP = Pₚₚₚ - Pₜₜₜ - Pₚₚₚ
Clinical Evidence

MRI Compatibility of proGAV®

The proGAV® valve was tested by the manufacturer according to ASTM (International Technical Standard) for MRI safety and compatibility. These standard tests evaluate if the presence of a medical device may cause injury to individuals during an MRI examination and in the MRI environment. Test parameters are torque, heat, and MRI artifacts. As a result of these tests the proGAV® valve was determined to be MRI-safe with relatively minor field interaction (data on file). Apart from these manufacturer’s in house tests two other laboratories performed and published their in vitro tests on the MRI stability of proGAV®.

Shellock et al.1 tested the MR safety of proGAV® in their Institute for Magnetic Resonance Safety. Magnetic field interactions (heating, functional alterations, torque) were assessed in a 3 T magnetom. In summary the valve showed only minor magnetic field interactions. The function was not altered by multiple exposure to the 3 T scanner and it is concluded that the product is safe for a patient undergoing MR imaging.

Lindner et al.2 investigated the hydrodynamic performance of proGAV® valve after exposure to 3 T. Their motivation was 1st their own experiences with another type of valve which was no longer adjustable after an MRI investigation and which subsequently had to be removed surgically and 2nd the observation that the number of 3 T magnetoms will increase in the next years and will probably replace the currently used 1.5 T machines. In a standardised protocol the hydrodynamic properties of the valve was tested in vitro before and after 3 T MRI exposure. The MRI protocol was performed analogous to clinical practice. The test results showed only minimal deviations of the hydrodynamics before and after MRI. One of the proGAV® was tested without a break to serve as a control. The results before and after MR of the control differ significantly, indicating a shift of the pressure adjustment without a functioning inbuilt brake. In conclusion the results give strong evidence that proGAV® valves maintain hydrodynamic function after MR scanning.

Allin et al.3 from the United Kingdom Shunt Evaluation Laboratory at Cambridge University evaluated the in vitro hydrodynamic properties of proGAV® according to their laboratory setting and protocol which has been published previously many times. An array of tests was performed before and after exposure to a 3 T MR scanner: pressure-flow curves, measurement of the operating pressure and setting of the valve, reliability of reprogramming, and reflux measurement. As a result the proGAV® valve was found to show good mechanical durability over the three month period of testing and good stability of hydrodynamic performance. Unlike some other adjustable valves, the proGAV® can not be accidentally readjusted by external magnetic fields such as a 3 T MR scanner.

Lavinio et al.4, also from the UK Shunt Evaluation Laboratory at Cambridge tested in an in vitro study all currently on the market adjustable valves on their interactions with magnetic fields. They found that all valves are safe to use for 3-T-MR-imaging. However, proGAV® and the Polaris® valves are the only ones which were immune to reprogramming by external magnets. All other valves are promptly reset by exposure to weak magnetic fields at a level which is easily reached by common household magnets. Additionally it was shown that proGAV® shows only minor T1-generated artefacts.

Certainly, all in vitro tests have their limitations when it comes to transferring the results into real patients where the performance of a shunt is very much dependant of the patient’s individual CSF dynamics, the anatomical situation, any concomitant diseases etc. All of which can be mimicked, but only in part within the laboratory setting. However, the laboratory allows for a controlled testing environment and also allows tests which would not be possible in humans. Favourable results from the laboratory are a prerequisite for their use in patients.

Regarding the MRI stability of proGAV® all in vitro measurements allow for the conclusion that proGAV® is a safe product. Furthermore it is one of few products which is not prone to unintentional readjustment, neither by household magnets nor by a 3-T-MR-imaging procedure.

Clinical experiences with proGAV® seem to confirm the in vitro results. So far there has been no clinical reports on a proGAV® valve that has been unintentionally readjusted by external magnetic fields. There is one publication by Toma et al.5 who compared MRI scans of two valve types in 8 patients. They found that the artefacts induced by the Strata® valve are significantly larger than that induced by proGAV®. All metallic implants produce artefacts in MR imaging to some extent. Since hydrocephalus patients undergo regular scannings, the safety and compatibility (artefact size) is a very important issue. Besides the basic safety of proGAV® shown in the laboratory investigations already described, this paper shows that proGAV® produces also minimal artefacts, thus improving imaging quality and diagnostics in hydrocephalus patients.
Clinical Evidence

Adjustment Procedure of proGAV®

Allin et al. measured the closing pressure in vitro and compared it to the valve setting as verified with the instruments. Regression analysis showed a significant linear relationship (R=0.97). They concluded "The programming tool was very straightforward and easy to use. Reliability was very high, the valve was correctly adjusted in >95 % cases. Verification of programming is quick and easy and does not require X-ray scan."

Meier et al. used proGAV® in 34 idiopathicNormal-Pressure Hydrocephalus patients. They did an X-ray control after each adjustment and found that in all cases the readings form the X-ray images and the measurements with the instruments were concordant with a deviation of +/- 1 cmH2O. In 6 patients (18 %) the readjustment of the valve was not possible due to postoperative swelling of the wound. After removal of sutures and after normal wound healing was achieved the adjustments were possible again. Similarly, Aschoff et al. report that postoperatively, when swelling is present, the proGAV® adjustment procedure can be difficult.

Rohde et al. used proGAV® in a series of 53 children with an age ranging from 0.1 to 17 years. They performed 26 opening pressure changes with proGAV® in 19 children and did not report of any complication related to the adjustment procedure. They pointed out an important technical note: skin incisions were made in a curved manner in order to position the valve in a subcutaneous pocket away from the incision site.

The prospective, multi-centre study by Sprung et al. documented 102 adjustment procedures. 90 % of them were controlled with an X-ray, without any report of a mismatch. In this study with overall 165 patients enrolled a total of 566 measurements of the valve setting were documented. In 98 % of cases the actual measurement matched with valve setting of the documented previous measurement. The adjustment could not be achieved in one patient with the subsequent decision to remove the valve surgically. The adjustment procedure is associated with some inconvenience to the patients. Patients were asked to rate it and 6 % said that it is not acceptable. Noteworthy, in all but 1 case readjustment was achieved still. 85 % said it is acceptable and 8 % did not give a rating. These findings from clinical use in 10 centres are very convincing for the accuracy of the measurement and for the precision and practicability of the adjustment procedure with the hand held instruments.
Clinical Outcome

Result of a large series of patients treated with proGAV® reported Aschoff et al. A total of 191 patients were documented in the period from 2002 to 2008. When using the standard proGAV® configuration together with the gravitational unit they found a very low rate of over-drainage (3.1 %). Special remarks were expressed concerning adjustment procedure and positioning of the gravitational unit. When wound swelling is present, obviously the adjustment procedure can be difficult and an improvement of instrument was suggested. Actually, the instruments were modified as a consequence of this and similar reports (communication from the manufacturer). Aschoff stresses the importance of a strictly vertical orientation of the gravitational valve and suggested to implant this part of the proGAV® valve on the thorax. The proGAV® valve does offer this option. Implantation on the thorax should particularly be considered when the patient is not active and spends a lot or all the time in bed and there in an elevated position of the head.

A prospective, multi-centre study was conducted in 10 neuro-surgical centres between 2004 and 2006 (Sprung et al.). 165 patients were enrolled and 144 were followed-up until an endpoint was reached up to 12 months postoperatively. Primary objective was to determine shunt survival and secondary objectives were to investigate the effectiveness of the handheld instruments for adjustment and reading of the valve setting (see previous chapter). The probability for a revision free interval at 1 year was 83 %. Some of the revisions were not valve-related. Thus the valve survival rate was 91 %. These rates compare very favourably with other published data. During the course of the study 102 readjustments of the valve in 65 patients were performed. Determination of pressure-level with the measuring instrument was safe and correspondent to X-ray-controls following adjustments. In conclusion the results of this study prove the reliability of the device and a good compliance for the new measurement and readjustment technique. A comparison of the literature with this multi-centre study is suggestive of fewer adjustments needed per proGAV®-patient and of higher survival rates.

Kaestner et al. described that in their patient population all patients who developed valve-related under-drainage were bedridden and had a gravitational valve implanted. They retrospectively analysed 34 patients, most of them treated with a proGAV® or GAV (which is a gravitational valve, too) and found out that out of 6 bedridden patients with a gravitational valve 4 developed a severe under-drainage. A possible explanation is that those patients are frequently lying in bed with their head elevated to about 20° or more. This leads to an activation of the gravitational unit and an increase of the opening pressure of the valve. The opening pressure could become disproportionally high compared to the lesser hydrostatic difference between the head and the abdomen and this could possibly lead to under-drainage. One could argue now generally not to use gravitational valves in bedridden patients. However, interestingly in the paper by Kaestner et al. they gave the perfect reason for gravitational valves. They had 5 bedridden patients with normal differential pressure valves. One patient developed a severe over-drainage with bilateral haemorrhage after resuming walking. The patient was finally treated with the implantation of a gravitational unit. Although far from being significant these observations indicate that bedridden hydrocephalic patients require special considerations. The treatment options are all mentioned in the paper:

- Patients who are, and most likely will stay, confined to bed are poor candidates for gravitational valves, however:
  - Implantation of a gravitational valve should be considered in order to prevent over-drainage problems for patients who might resume walking.
  - The gravitational unit can be implanted in the chest instead of the standard retroauricular position.
  - The adjustable valve can be lowered to 0 cmH₂O in case of under-drainage.
  - An adjustable gravitational unit (proSA) could be used.

An especially challenging patient group are children with hydrocephalus. Other than in adults, over-drainage in children leads to slit ventricles with repetitive ventricular obstructions, slit ventricle syndrome, and craniosynostosis. Previous studies suggested that adjustable differential pressure valves and gravitational valves could help to reduce complications related to over-drainage substantially. Rohde et al. reported for the first time their experience with the adjustable and gravitational valve proGAV® in children. They report the use of proGAV® in 53 children, mean age 7.3 years (range 0.1 to 17 years). The authors did not observe any valve-related complications and found an overall success rate of 88.7 %. In their view this justifies its further paediatric use.

Finally, Sprung and Schlosser addressed the question why the theoretical advantage of adjustable valves compared to valves with fixed opening pressures could not yet be proven in the majority of published shunt studies. There is still no high level clinical evidence in terms of a statistically significant result from
a randomized controlled trial. This seems contradictory to the “own experiences” of many physicians and to the increased use of adjustable valves evidenced by the high market share of adjustable shunts. Various difficulties arise when comparing results from shunt studies: no uniform inclusion criteria, variance in definition of the outcome criteria and of complications, and variance in the choice of pressure setting in conventional differential pressure valves. The authors suggest that additionally, too many patients are classified as “non-responders”. In their experience with 108 patients with the proGAV® shunt they had a closer look on the so called complications which actually could be treated with the adjustability of the valve. In 31 cases with the “complication” of under-drainage, they lowered the opening pressure with 29 patients improving thereafter. All 8 patients suffering from over-drainage “complication” could be treated successfully by increasing the pressure setting, thus avoiding a re-operation. They interpret their series that by adjustability many re-operations can be avoided and the number of non-responders can be diminished.
**Key Messages**

“The programming tool was very straightforward and easy to use. Reliability was very high… Verification of programming is quick and easy and does not require X-ray scan.”


“The proGAV® is resistant to inadvertent reprogramming even when exposed to 3T.”


“From the clinical point of view, the programmable gravity-assisted valve (proGAV® Aesculap) is an indispensable development in the valve manufactory technique, offering a new standard in the management of iNPH.”


“Gravitational valves have largely solved the problems of overdrainage… The current state-of-the-art of valve–treatment is the crossover of adjustable and gravitational valves.”

Abstracts

Programmable CSF shunt valve: in vitro assessment of MR imaging safety at 3 T.

Shellock FG, Habibi R, Knebel J.

AJNR American Journal of Neuroradiology 2006; 27(3):661-665

AIM: Assessment of MR imaging safety at 3 T of proGAV®.

METHODS: Standardized in-vitro test methods: translational attraction, MR-imaging related heating, effect on the function of the valve, imaging artifacts.

RESULTS: The product showed minor magnetic field interactions. The heating was not excessive (+0.8°C). The function of the programmable valve was not altered. Artifacts are relatively large.

CONCLUSION: The product is safe for a patient undergoing MR imaging at 3 T or less when specific safety guidelines are followed.

Effect of 3 T MRI on the function of shunt valves – Evaluation of PaediGAV, Dual Switch and proGAV®.

Lindner D, Preul C, Trantakis C, Moeller H, Meixensberger J.


AIM: To evaluate the function of different valves after exposure to a 3 T MRI.

METHODS: The hydrodynamic performance of three DUALSWITCH® valves, three paediGAV valves and three proGAV® valves were evaluated before and after exposure to 3 T. The valves were connected to a roller pump delivering a constant but adjustable flow and to computerized equipment for measuring the opening pressure in cmH2O. After completion of pre-scan tests, the valves underwent MRI-scan on 3 T human scale whole body scanner. Results from pre-scan and post-scan measurements were compared.

RESULTS: The average deviation of the valves after exposure to 3 T was 0.6 cmH2O.

CONCLUSION: There is strong evidence that the three tested valves maintain their function after exposure to 3 T.
In vitro hydrodynamic properties of the Miethke proGAV® hydrocephalus shunt.

Allin DM, Czosnyka ZH, Czosnyka M, Richards HK, Pickard JD.

BACKGROUND: Adjustable shunts are very popular in the management of hydrocephalus and are believed to help in minimizing the number of surgical revisions. The drawback with almost all constructions is that they may be accidentally readjusted in relatively weak magnetic fields (around 30 – 40 mT).

AIM: To evaluate the hydrodynamic properties of the proGAV® valve.

METHODS: The proGAV® Miethke shunt is composed of an adjustable ball-on-spring valve unit and an integrated over-drainage compensating gravitational device (known as the SHUNT ASSISTANT). A mechanical ‘brake’ is intended to prevent changes to the valve’s performance level in a strong magnetic field. The performance and hydrodynamic properties of a sample of three valves as evaluated in the UK Shunt Evaluation Laboratory.

RESULTS: All the shunts showed good mechanical durability over the three-month period of testing, and good stability of hydrodynamic performance over a one-month period. The pressure-flow performance curves, operating, opening, and closing pressures fell within the limits specified by the manufacturer and changed according to the programmed performance levels. The operating pressure increased when the shunt assistant was in the vertical position, as specified. The valve has a low hydrodynamic resistance (0.53 mm mmHg/ml-1/min). External programming proved to be easy and reliable. Strong magnetic fields from a 3 Tesla MR scanner were not able to change the programming of the valve.

CONCLUSION: The proGAV® shunt is an adjustable, low resistance valve that is able to limit posture related over-drainage. Unlike other adjustable valves, the proGAV® cannot be accidentally readjusted by external magnetic field such as a 3T MR scanner.

Magnetic field interactions in adjustable hydrocephalus shunts.


AIM: To determine the magnetic field safety and MRI compatibility of 5 adjustable models of hydrocephalus shunt valves.

METHODS: Five currently available adjustable hydrocephalus shunts, Codman Hakim (regular and with SiphonGuard), proGAV®, Medtronic Strata, Sophysa, and Polaris were tested in vitro, first in low-intensity magnetic fields, and then in a 3-T-MR unit for reprogramming, translational attraction, magnetic torque (MT), and volume of artifacts.

RESULTS: The proGAV® and Polaris® valves were not reprogrammed by magnetic fields up to 3-T. Other valves randomly changed settings, at intensities of field <50 mT. The Codman Hakim and the proGAV® valve showed negligible mechanical interactions and minor T1-generated artifacts.

CONCLUSION: All valves generated a distortion of the MR image, but can be considered safe for 3-T MR imaging. Only the Polaris and proGAV® models, are resistant to unintentional reprogramming even when exposed to a 3 T magnetic field.
Adjustable shunt valve induced MRI artifact: A comparative study.

AIM: To compare the artifact induced by implanted (in vivo) adjustable shunt valves.

METHODS: MRI scans of 8 patients with proGAV® and 6 patients with Strata valves were assessed for artifact area in different planes.

RESULTS: The Strata II valve induced significantly larger artifacts than the valve in spin echo MRI pulse sequence (29761 mm³ vs. 2450 mm³) and Diffusion weighted images (100138 mm³ vs. 38955 mm³).

CONCLUSION: Adjustable shunt induced artifacts can conceal brain pathology. This should influence the choice of valve type and the implantation site.

Clinical experience in the treatment of idiopathic normal-pressure hydrocephalus using the programmable gravity-assisted valve (proGAV® Aesculap).
Meier U, Lemcke J, Al-Zain F.

AIM: To evaluate if a programmable gravity-assisted valve can be used at a low-pressure level without a high rate of overdrainage.

METHODS: In a prospective follow-up study between June 2004 and July 2005, 34 iNPH patients underwent shunt surgery using the proGAV® valve. Patients were followed up after 6 months and, again, after 12 months.

RESULTS: The course of the symptoms of iNPH patients correlates with the opening pressure of the valve. The controlled adjustment of the programmable valve opening pressure in steps of 20 to 30 mmH₂O steps from an initial 100 to 70 and finally to 50 mmH₂O, allows an optimal adaptation of the cerebrum in the new pressure environment and reduces the overdrainage rate.

CONCLUSION: From the clinical point of view, the proGAV® valve is an indispensable development in the valve manufactory technique, offering a new standard in the management of iNPH.
First experiences with an adjustable gravitational valve in childhood hydrocephalus.

Rohde V, Haberl EJ, Ludwig H, Thomale UW.

AIM: To describe initial experience with proGAV® in treating childhood hydrocephalus.

METHODS: The proGAV® was implanted in 53 children (median age 7.3 years) with hydrocephalus of various origins. The mean follow-up period was 15.2 months (range 6 – 44 months).

RESULTS: No valve-related complications were observed. Four infections (7.5%) occurred, warranting the removal of the shunt. In 19 children, the opening pressure was changed at least once during the follow-up period, for underdrainage in 10, overdrainage in 8, and shunt weaning in 1, with substantial clinical improvement in 18 children. Overall, good clinical results were obtained in 47 (88.7%) of the 53 valve placements.

CONCLUSION: The first experiences with proGAV® in childhood hydrocephalus are promising and justify its further use in the pediatric population.

The adjustable proGAV®-shunt: a prospective safety and efficacy multicenter study.

Neurosurgery, 2010;66:465-474

AIM: To evaluate the efficacy and safety of the gravitation-assisted adjustable proGAV® shunt valve in everyday clinical practice.

METHODS: Patients of all ages with different types of hydrocephalus, first insertion procedure or surgical revisions, were followed-up prospectively for 12 months in 10 German centers. The protocol required re-examinations at 3, 6, and 12 months postoperatively. Study endpoints were valve explantation and shunt revision for any component of the shunt. Secondary objectives were to determine the effectiveness and compliance of the instruments for verifying and adjusting the pressure setting.

RESULTS: A total of 165 patients were enrolled onto the study, 20 (12%) of whom were children and adolescents. 9 deaths (5.5%) non-related to the shunt-operation or valve-function occurred. The probability for experiencing a revision-free interval at 1 year was 83%. The probability for a valve to "survive" was 91%. During the course of the study 102 readjustments of the valve in 65 patients were performed. In all but 1 case readjustment was achieved. Determination of pressure-level with the measuring-instrument was safe and correspondent to the required X-ray-controls following adjustments. No unintended readjustments had to be notified.

CONCLUSION: This prospective study demonstrated the effectiveness of the gravitational adjustable proGAV® valve in the treatment of hydrocephalus both in children and adults. The 1-year valve (91%) and shunt system (83%) survival rates compare favourably with other published data. Hand-held instrument allowed for a reliable adjustment and reading of pressure levels.
Experiences with 191 adjustable Miethke-proGAV® valves.

Aschoff A, Oracioglu B, Tilgner J, Unterberg A, Halatsch ME.


AIM: To report a large clinical series with the new valve.

METHODS: Prospective documentation of clinical outcome since 2002 with the proGAV® valve. 157 proGAV® valves were used in combination with the gravitational ShuntAssistant (SA) and 34 without (cases with high peritoneal pressure, meningo myelocele with risk of CSF fistula). Initially both valves were implanted in the retroauricular position. Soon technique was changed to a position of the proGAV® 2 - 3 cm from the burrhole and a thoracic implantation of the SA which better guarantees the obligatory vertical orientation.

RESULTS: Mortality 1.6 % (none valve-associated). Infection rate 6.7 %. One primary failure due to a torqued catheter. 4 showed blockage of adjustment and 4 were obstructed, probably due to debris. proGAV®s without SA developed 15 % subdurs, with the gravitational unit SA 3.1 %. The adjustment procedure can be difficult, especially postoperatively when swelling is present. There were no disadjustments due to MRT. Two cases were suspected but not confirmed of disadjustment (could also be an adjustment error).

CONCLUSION: proGAV® seems to be a MRI safe valve. Use of the gravitational unit SA, implanted on the thorax, is recommended. The adjustment tools need further improvement.

Gravitational shunt units may cause under-drainage in bedridden patients.

Kaestner S, Kruschat T, Nitzsche N, Deinsberger W.


AIM: To identify in which patients a gravitational valve is liable to lead to under-drainage.

METHODS: Retrospective survey of 34 patients over a 1 year period.

RESULTS: Four patients developed severe under-drainage. All of them had received a gravitational valve and all were bedridden. One patient with a differential pressure valve developed severe over-drainage after regaining mobility.

CONCLUSION: If a patient is bedridden and lies in a head elevated position, this leads to activation of the gravitational unit which may cause under-drainage.
Adjustability of valves for shunting hydrocephalus is luxury, progress or necessity? Our personal experience to stimulate debate.

Sprung C, Schlosser HG.


AIM: To elucidate the discrepancy between missing statistical evidence and obvious theoretical advantage of adjustable shunts and their increased use in clinical practice.

METHODS: Evaluation of the clinical experience with 108 patients with the adjustable shunt proGAV® from 2/2004 until 4/2007 concentrating on the radiological and clinical results including the possibilities for improvement of clinical outcome by valve re-adjustment.

RESULTS: In 65 patients there was no indication to change the initial shunt setting with 54 patients showing a satisfying clinical outcome. In 31 cases with the “complication” of functional underdrainage the opening pressure was lowered with 29 responders. All 8 patients suffering overdrainage-related “complications” could be treated successfully by elevating the pressure-setting avoiding re-operations. 9 patients demonstrated signs of under – as well as overdrainage during follow-up.

CONCLUSION: The difficulties to prove superiority of adjustability stem not only from different inclusion criteria, variance in definition of complications or the variability in the choice of pressure setting in conventional D-P-valves, but are also due to the fact that too many patients were classified as belonging to the non-responders. Only those patients should be subsumed under the category of “non-responders”, who do not improve clinically despite reduction of ventricles, change of valve or following adequate alteration of pressure setting in programmable devices. The results of the proGAV® –series support our opinion that by adjustability many re-operations can be avoided and the amount of non-responders can be diminished.
Reference List


# Abbreviations

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<th>Definition</th>
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<tr>
<td>ASTM</td>
<td>ASTM International is an international standards organization (ASTM), (originally known as the American Society for Testing and Materials)</td>
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<td>CSF</td>
<td>cerebro spinal fluid</td>
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<td>MRI</td>
<td>magnetic resonance imaging</td>
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<td>T</td>
<td>Tesla = unit of magnetic flux density</td>
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<td>mT</td>
<td>Millitesla</td>
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<td>iNPH</td>
<td>idiopathic normal pressure hydrocephalus</td>
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<tr>
<td>SA</td>
<td>ShuntAssistant (Miethke gravitational valve)</td>
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<td>CNS</td>
<td>Congress of Neurological Surgeons</td>
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