Hydrocephalus Treatment

The Need for Action

AESCULAP

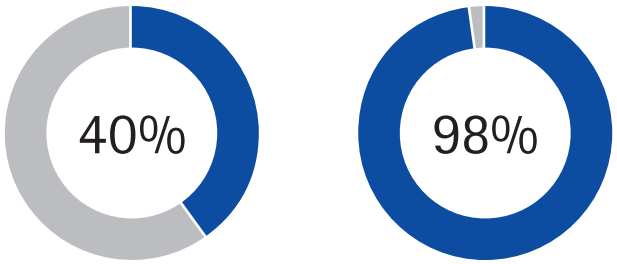
TAKE THE HEADACHE OUT OF TREATING HYDROCEPHALUS

Shunts are life-saving devices, but despite long-term experience with shunt implantation and the continuing development of shunt technology, they are known for their high failure rates[1]. Furthermore, conventional shunts fail to address the posture-dependent gravitational effects that influence shunt performance. Overdrainage-related complications can necessitate a variety of revisions which are burdensome for patients as well as their healthcare teams, and are accompanied by unavoidable perioperative risks[2]. In addition, a healthcare system's responsibility not only includes better patient outcomes, but also an expectation to focus on sustainability from a business and operations perspective.

FAILURE RATES AND COMPLICATIONS

High failure rates continue to overshadow the effectiveness of shunts[3]. It is generally estimated that 40% of shunts fail within two years and 98% within 10 years[1], with no difference between conventional valves[4] and programmable valves[5].

HIGH FAILURE RATES[1]



Proportion of shunts failing within **2 years**

Proportion of shunts failing within **10 years**

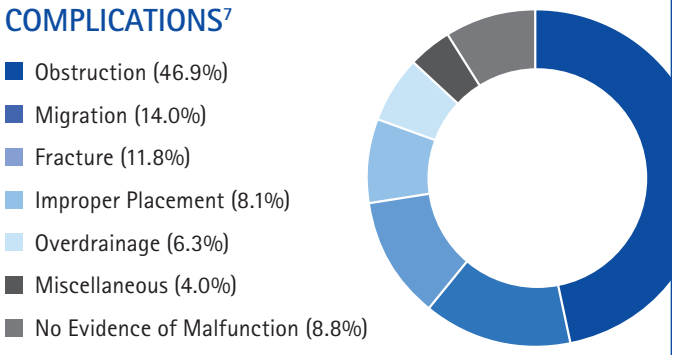
High failure rates overshadow the effectiveness of shunts[1].

Nearly every fourth shunted patient is affected by complications, and there has been little improvement in reducing these complications[6]. The most common cause for complications is obstruction within the catheters or valve[7]. A relatively high frequency of non-traumatic subdural hematoma, a potential complication of overdrainage, has also been reported[6].

MECHANICAL FAILURE

Mechanical failure is the most common cause of multiple shunt revisions[8], with catheter or valve obstruction being the predominant reason[7]. Failure of individual shunt components may also occur, e.g., at stress points or due to poor design[9].

COMPLICATIONS[7]

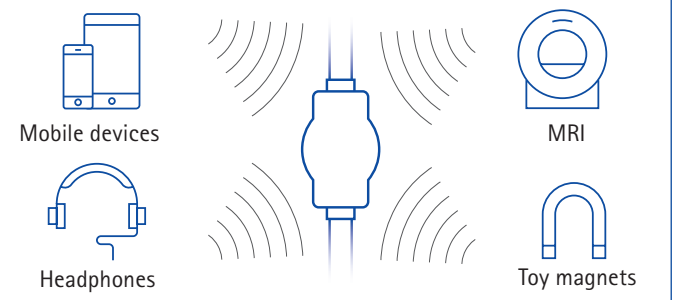


About one in four patients experiences at least one complication[6].

ACCIDENTAL REPROGRAMMING

Pressure settings of adjustable valves can be unintentionally reprogrammed by low-intensity magnetic fields, which are ubiquitous in today's environment. Smartphones[10], headphones[11], hearing devices[32, 33], tablet devices[12], nurse badges[34] and even toy magnets[13, 14] have been shown to change the pressure settings

ACCIDENTAL REPROGRAMMING[10-14]



External magnetic fields can change the pressure settings of adjustable shunt valves.

of adjustable shunt valves. The optimal pressure setting of the adjustable valves is of great importance to the patient. Therefore, it comes as no surprise that the possibility of accidental valve adjustments in everyday life is a cause of concern and leads to great uncertainty among patients and doctors alike.

IMPLICATIONS FOR HEALTHCARE SYSTEMS

Numerous follow up examinations and revisions could have large implications for hospitals. With the focus on improving patient safety, lowering costs and better patient-physician interactions, healthcare systems must work toward producing better patient outcomes, streamline patient experiences and improve health system efficiencies. In addition, healthcare systems also have a responsibility towards physician wellness.

EACH PATIENT IS UNIQUE

When choosing valves it is important to select a valve for each patient individually according to the type of hydrocephalus and underlying condition(s), physical attributes as well as the anticipated postoperative management needs[15]. Each patient with hydrocephalus is unique and requires customized setting of the valve opening pressure.

Are patients getting optimal individualized treatment?

Patients differ with respect to the effective hydrostatic pressure difference between the ventricular system and the abdominal cavity, the major driving force of overdrainage. Selection of the optimal opening pressure of the valve is complex, hence the potential for patient-valve mismatches.

Necessary corrections of patient-valve mismatches, overdrainage-related complications, and high rates of shunt revision require time-consuming follow-up examinations and reoperations, which are burdensome for patients and are inevitably associated with perioperative risks. They also put an additional strain on the already limited time of physicians and surgeons, who are already under stress because of an ever-increasing workload[16] and limited consultation time[17].

Are conventional adjustable valves the best available therapy?

Treatment with conventional adjustable valves always means finding a compromise:

- Lowering the valve opening pressure in order to achieve a better patient outcome bears the risk of overdrainage while sitting or standing.
- The effect of gravity in the upright position is often the cause of typical overdrainage complications such as hygroma and subdural bleeding, which may lead to severe headaches and nausea[18, 31].
- Adjusting the valve opening pressure towards higher pressures to compensate for overdrainage symptoms can lead to underdrainage in the supine position.

The opening pressure often needs to be adjusted multiple times until an adequate compromise for fluid drainage between upright and supine position for the individual patient is found. Other treatment strategies have been suggested, including lying supine intermittently throughout the day[35] and drug therapy to address the chronic headaches. However, patients with conventional adjustable valves almost never benefit from optimal opening valve pressures in both the supine and upright positions.

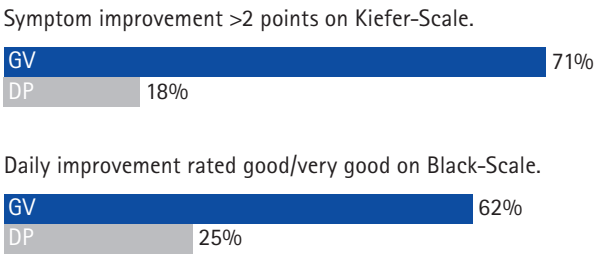
There is a better way.

Despite the many individual patient factors, there is one thing that is 100% certain: all active patients are exposed to the effects of gravity on cerebrospinal fluid drainage when standing, and not only for a few hours a day, but up to 16 hours – every day. Overcoming this posture-dependent gravitational effect may help to prevent overdrainage and could address other factors that can lead to complications, such as shunt obstruction[18]. This leads to improvement of patient outcomes.

YOUR SOLUTIONS

Gravitational shunts provide neurosurgeons with a tool to address the posture-dependent effects of gravity, one that has demonstrated good patient outcomes and a significant reduction of overdrainage events[18, 31]. In addition, the economic benefit of using gravitational shunt systems is significant based on the reduction in revision surgeries, which can lead to reducing healthcare costs, improving quality of life for the patients, but more importantly, allowing hospitals to focus their resources in service areas that are sustainable from a business and operations perspective[36].

Gravitational valves (GV) improve patient outcomes compared to differential pressure valves (DP)[31].



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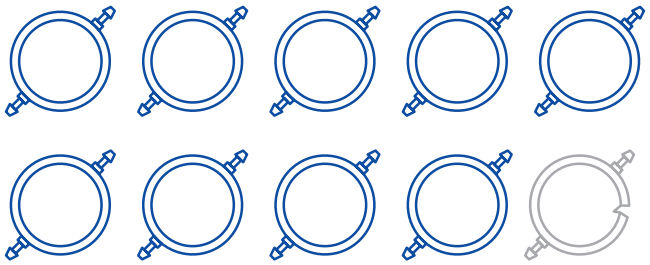
BETTER OUTCOMES

Clinical studies have shown that Miethke gravitational shunts reduce the risk of revisions. They exhibit a high rate of shunt survival across all age groups, with valve survival rates as high as 90% at 12 months[19] and above 80% after 2 years[20]. For infants, a group known to have a higher rate of complications than adult patients, an 84% survival rate was observed[20]. In patients with gravitational valves, the risk of overdrainage was reduced by 36% compared to conventional valves, i.e., one additional overdrainage complication in every third patient undergoing shunting can be prevented by using a gravitational valve[21]. A recent study demonstrated that implanting a secondary gravitational valve in patients with <10 lifetime shunt revisions resulted in a 67.3% decrease in catheter obstruction at one year, and 43.3% at five years. In patients with 10 or more lifetime shunt revisions, obstruction rate decreased by 75.8% and 65.6% at one and five years, respectively[18].

AVOID REVISIONS[19]



Valve survival rates up to 90% at 12 months

AVOID COMPLICATIONS[21]

overdrainage rate with **conventional** valves

overdrainage rate with **gravitational** valves

Implanting a gravitational valve avoids one additional overdrainage complication in about every third patient.

BETTER DESIGN

All Miethke valves are manufactured with high precision from titanium. The strength of titanium allows for a low profile while maintaining optimized flow paths. The rigid housing makes the titanium shunt valves unsusceptible to subcutaneous pressure. Titanium is considered an excellent choice for biomedical applications with high biocompatibility[22]. In addition, titanium is MR conditional[23].

MIETHKE GRAVITATIONAL VALVES

Made from Titanium

for high MRI- and biocompatibility

Rigid housing

unsusceptible to subcutaneous pressure

BETTER PROTECTION

Current evidence suggests that a delay in treatment is harmful for the patient[24], even when the delay is as short as three months[25]. Especially infants with hydrocephalus, whose brains are still developing, the primary treatment choice and possible complications have a significant impact on the long-term success[26]. For example, infants who received a gravitational shunt as part of a shunt revision had a lower rate of shunt survival than those with a primary implantation of a gravitational shunt[26], stressing the importance of optimal primary treatment choice.

BENEFIT FROM PRIMARY IMPLANTATION[26]

22%

higher survival of gravitational valves after **primary** vs secondary implantation

Patients with hydrocephalus benefit from early treatment with gravitational valves.

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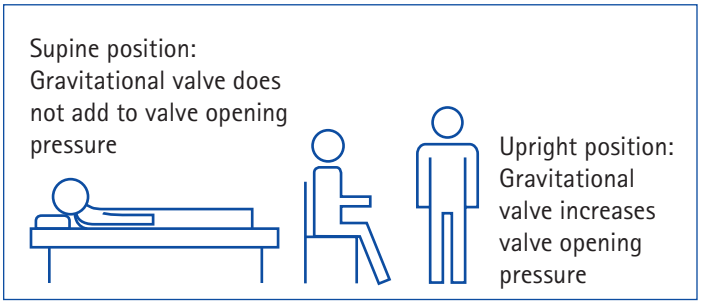
OPTIMIZE – DON'T COMPROMISE

The critical issue in shunt technology is to simulate the posture-dependent hydrostatic pressure change[18, 27]. Gravitational shunts, which compensate for posture-dependent hydrostatic pressure changes, can mitigate overdrainage[18, 31]. In the horizontal position, the gravitational valve opens completely and does not contribute to the overall flow resistance, while in the vertical position, the flow resistance is determined by both the gravitational valve and the differential pressure valve.



Clinical practice has shown that using programmable valves with Miethke gravitational shunts can lower the number of shunt revisions due to over and underdrainage[18, 28] and improve symptoms and the overall daily function[27]. Furthermore, gravitational shunts have been shown to be effective in treating hydrocephalus in infants[29]. Miethke gravitational shunts can compensate for overdrainage without compromising the setting for the supine position. The optimal opening pressure for each patient when standing and when lying can be set independently–without needing to compromise.

DON'T LET MAGNETIC FIELDS BOTHER YOU

The unintentional reprogramming of valves by low-intensity magnetic fields is of great concern for patients, their families and physicians alike. How can one be sure that a valve will not be reprogrammed accidentally? The key question is whether the programmable valve itself is protected from reprogramming by the strong fields generated during MRI. If the magnetic fields of an MRI system cannot reset the setting, then low-intensity magnetic fields should also have no influence. Programmable Miethke valves have an 'Active-Lock mechanism' which protects them from reprogramming by magnetic fields of up to 3 Tesla.

Protected against reprogramming
up to 3 Tesla

M.blue™ Valve – THE NEXT SHUNT GENERATION

Born out of 26 years of shunt excellence, the M.blue Valve was created. When developing a hydrocephalus valve which offers an optimal individual treatment, it is crucial to focus on the customization of the opening pressure during the active time of the day, i.e., the upright body position. After fixed pressure gravitational valves and adjustable gravitational valves, the M.blue Valve provides neurosurgeons and patients with the next generation of hydrocephalus valves operating in a position-dependent manner and addresses the preference towards a SIMPLE, UNITIZED, ALL in ONE version.

TAKE THE HEADACHE OUT OF TREATING HYDROCEPHALUS

The Miethke proSA® Valve was the first gravitational valve which could be programmed for variable degrees of overdrainage control. It demonstrated good clinical outcomes in adolescent and adult hydrocephalus patients[30, 31], which was attributed to the valve gravitational technology[31]. The number of revisions and complications were also lower compared to other valves[30]. The postoperative adjustability of the opening pressure level is regarded as a key advantage of this gravitational valve[31]. The overall verdict is that the proSA Valve is reliable, helpful and safe[31].

The M.blue Valve takes the proSA Valve to the next level, by combining the adjustable gravitational unit with a fixed differential pressure unit. Together, these two units automatically adjust the opening pressure depending on the patient's body position. For particularly challenging forms of hydrocephalus, requiring an even greater flexibility in treatment, the M.blue plus® Valve is available. Partnering the adjustable gravitational unit with an adjustable differential pressure unit enables customizable pressures based on the patient's body position.

BETTER CONTROL.
BETTER TECHNOLOGY.
BETTER PROTECTION.
BETTER OUTCOMES.

References

1. Lutz BR, Venkataraman P, Browd SR. New and improved ways to treat hydrocephalus: Pursuit of a smart shunt. Surg Neurol Int 2013;4(Suppl 1):S38-50.
2. Freimann FB, Sprung C. Shunting with gravitational valves--can adjustments end the era of revisions for overdrainage-related events?: clinical article. J Neurosurg 2012;117(6):1197-204.
3. Gutierrez-Murgas Y, Snowden JN. Ventricular shunt infections: immunopathogenesis and clinical management. J Neuroimmunol 2014;276(1-2):1-8.
4. Drake JM, Kestle JR, Milner R, et al. Randomized trial of cerebrospinal fluid shunt valve design inpediatric hydrocephalus. Neurosurgery 1998;43(2):294-303; discussion -5.
5. Pollack IF, Albright AL, Adelson PD. A randomized, controlled study of a programmable shunt valve versus a conventional valve for patients with hydrocephalus. Hakim-Medos Investigator Group. Neurosurgery 1999;45(6):1399-408; discussion 408-11.
6. Merkler AE, Ch'ang J, Parker WE, et al. The Rate of Complications after Ventriculoperitoneal Shunt Surgery. World Neurosurg 2017;98:654-8.
7. Beuriat PA, Puget S, Cinalli G, et al. Hydrocephalus treatment in children: long-term outcome in 975 consecutive patients. J Neurosurg Pediatr 2017;20(1):10-8.
8. Chiriac A, Poeata I, Iliescu B. Mechanical failures of ventriculo-peritoneal shunts. Romanian Neurosurgery 2012;XIX(3):226-9.
9. Woerdeman PA, Cochrane DD. Disruption of silicone valve housing in a Codman Hakim Precision valve with integrated Siphonguard. J Neurosurg Pediatr 2014;13(5):532-5.
10. Ozturk S, Cakin H, Kurtuldu H, et al. Smartphones and Programmable Shunts: Are These Indispensable Phones Safe and Smart? World Neurosurg 2017;102:518-25.
11. Spader HS, Ratanaprasatporn L, Morrison JF, et al. Programmable shunts and headphones: Are they safe together? J Neurosurg Pediatr 2015;16(4):402-5.
12. Strahle J, Selzer BJ, Muraszko KM, et al. Programmable shunt valve affected by exposure to a tablet computer. J Neurosurg Pediatr 2012;10(2):118-20.
13. Anderson RC, Walker ML, Viner JM, et al. Adjustment and malfunction of a programmable valve after exposure to toy magnets. Case report. J Neurosurg 2004;101(2 Suppl):222-5.
14. Zuzak TJ, Balmer B, Schmidig D, et al. Magnetic toys: forbidden for pediatric patients with certain programmable shunt valves? Childs Nerv Syst 2009;25(2):161-4.
15. Miyake H. Shunt Devices for the Treatment of Adult Hydrocephalus: Recent Progress and Characteristics. Neurol Med Chir (Tokyo) 2016;56(5):274-83.
16. Powell A, Savin S, Savva N. Physician Workload and Hospital Reimbursement: Overworked Physicians Generate Less Revenue per Patient. Manufacturing & Service Operations Management 2012;14(4):512-28.
17. Irving G, Neves AL, Dambha-Miller H, et al. International variations in primary care physician consultation time: a systematic review of 67 countries. BMJ Open 2017;7(10):e017902.
18. Koueik J, Kraemer M, Hsu D, et al. A 12-year single-center retrospective analysis of antisiphon devices to prevent proximal ventricular shunt obstruction for hydrocephalus. J Neurosurg Pediatr 2019:24:642-651.
19. Sprung C, Schlosser HG, Lemcke J, et al. The adjustable proGAV shunt: a prospective safety and reliability multicenter study. Neurosurgery 2010;66(3):465-74.
20. Thomale UW, Gebert AF, Haberl H, et al. Shunt survival rates by using the adjustable differential pressure valve combined with a gravitational unit (proGAV) in pediatric neurosurgery. Childs Nerv Syst 2013;29(3):425-31.
21. Lemcke J, Meier U, Muller C, et al. Safety and efficacy of gravitational shunt valves in patients with idiopathic normal pressure hydrocephalus: a pragmatic, randomised, open label, multicentre trial (SVASONA). J Neurol Neurosurg Psychiatry 2013;84(8):850-7.
22. Sidambe AT. Biocompatibility of Advanced Manufactured Titanium Implants-A Review. Materials (Basel, Switzerland) 2014;7(12):8168-88.
23. Saini M, Singh Y, Arora P, et al. Implant biomaterials: A comprehensive review. World journal of clinical cases 2015;3(1):52-7.

24. Toma AK, Watkins LD. Surgical management of idiopathic normal pressure hydrocephalus: a trial of a trial. Br J Neurosurg2016;30(6):605.

25. Toma AK, Stapleton S, Papadopoulos MC, et al. Natural history of idiopathic normal-pressure hydrocephalus. Neurosurg Rev2011;34(4):433-9.

26. Gebert AF, Schulz M, Schwarz K, et al. Long-term survival rates of gravity-assisted, adjustable differential pressure valves in infantswith hydrocephalus. J Neurosurg Pediatr 2016;17(5):544-51.

27. Suchorska B, Kunz M, Schniepp R, et al. Optimized surgical treatment for normal pressure hydrocephalus: comparison betweengravitational and differential pressure valves. Acta Neurochir (Wien) 2015;157(4):703-9.

28. Golz L, Lemcke J, Meier U. Indications for valve-pressure adjustments of gravitational assisted valves in patients with idiopathic normal pressure hydrocephalus. Surg Neurol Int 2013;4:140.

29. Xinxing L, Hongyu D, Yunhui L. Using individualized opening pressure to determine the optimal setting of an adjustable proGAV shunt in treatment of hydrocephalus in infants. Childs Nerv Syst 2015;31(8):1267-71.

30. Kehler U, Kiefer M, Eymann R, et al. PROSAIKA: a prospective multicenter registry with the first programmable gravitational device for hydrocephalus shunting. Clin Neurol Neurosurg 2015;137:132-6.

31. Tschan CA, Antes S, Huthmann A, et al. Overcoming CSF overdrainage with the adjustable gravitational valve proSA. Acta Neurochir (Wien) 2014;156(4):767-76; discussion 76.

32. Pierson MJ, Wehrmann D, Albers JA, et al. Programmable shunt valve interactions with osseointegrated hearing devices. J Neurosurg Pediatr 2017;19(4): 384-390.

33. Chadwick K, Moore J, Tye G, et al. Management of patients with cochlear implants and ventriculopertioneal shunts. Cochlear Implants International 2014;15:4, 185-190

34. Fujimara R, Lober R, Kamian K, et al. Maladjustment of programmable ventricular shunt valves by inadevertent exposure to a common hospital device. Surg Neurol Int 2018;9:51

35. Walker ML, Fried A, Petronio J: Diagnosis and treatment of the slit ventricle syndrome. Neurosurg Clin N Am 1993;4:707-714.

36. Aesculap Neurosurgery: Hydrocephalus Value Brief Clinical and Economic Value of Gravitational Valves for the Treatment of Hydrocephalus. DOC1289 2016;2.

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