Before the introduction of gravity-assisted valves, implantation of a programmable valve was a common procedure in the management of communicating hydrocephalus in children. Apart from other systems, the Medos Hakim programmable valve (Codman Co.), which is an adjustable ball-in-cone valve, has been widely used in the treatment of the aforementioned patients in the past 20 years. This valve allows a surgeon to change the opening pressure and to select a setting between 40 and 200 mm H₂O in a noninvasive way.¹¹ Both overdrainage and underdrainage can thus be managed. The literature reveals that pressure settings must be adjusted at least once after implantation in approximately 50% of the patients.¹⁷ Since the valves can be reprogrammed, the pressure setting can be adjusted without the need for surgery to replace the valve with another having a different pressure setting. For this reason, programmable valves help to reduce the number of revisions, decrease the duration of hospital stays, and improve the quality of life of affected patients.² These benefits appear to more than outweigh the higher acquisition cost of adjustable valves,¹⁸ which would seem to be less expensive than other valves in the long run.

However, it is not always possible to successfully change the pressure setting. In 1.5% of patients with Medos Hakim programmable valves, we were unable to change the pressure setting or to achieve the desired setting and therefore we had to remove the valves.⁷ Nevertheless, Medos Hakim programmable valves appear to be more reliable than other adjustable valves,⁵ although the possibility of damage caused by the magnetic field of a 3-T MR imaging system was discussed in the literature.¹,¹⁶ Inadvertent changes in opening pressure were reported in 27% of 583 patients.¹⁸

In recent years, we have noticed more Medos Hakim programmable valve defects at our institution. Malfunction was caused by dislodgement of the stator. All cases were reported to the German Institute for Drugs and Medicinal Products (Bundesinstitut fuer Arzneimittel und Medizinprodukte), and all valves were sent to the manufacturer for evaluation. The manufacturer informed the institute that the product had been improved in 2005 and that dislodgement of the stator from the base plate of the new product required a higher mean force. We conducted

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**More malfunctioning Medos Hakim programmable valves: cause for concern?**

**Clinical article**

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*Object.* In recent years, the authors have noticed a growing number of programmable valve defects at their institution. Therefore, they conducted this study to evaluate the increased incidence of malfunctioning valves.

*Methods.* They investigated all revisions that had been performed at their institution between 1994 and 2010 for dislodgement of the stator of a standard Medos Hakim programmable valve with a prechamber.

*Results.* Fifteen valves were removed because of dislodged stators. The valves had been implanted between May 16, 1993, and December 27, 2002, and were explanted between February 19, 2006, and January 22, 2010. Thus, the valves had been in place for a mean period of 11 years (median 11 years, range 7–14 years). The percentage of dislodged stators was almost 3% (15 of 546 valves). Particularly noteworthy is that all malfunctioning valves were found in children who had been younger than 1 year of age at the time of implantation.

*Conclusions.* Medos Hakim programmable valve malfunctions are rare events but should receive careful attention. When the pressure setting cannot be adjusted, a malfunction should always be suspected and radiographic imaging should be performed to assess the valve. Stator dislodgement is the most serious form of valve adjustment failure. (DOI: 10.3171/2011.5.JNS101396)

**Key Words** • hydrocephalus • Medos Hakim programmable valve • shunt • malfunction

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Abbreviation used in this paper: VPV = valve positioning verification.
the present study to evaluate the increased incidence of malfunctioning valves.

Methods

We assessed all revisions that had been performed at our institution between 1994 and 2010 for dislodgement of the stator of a standard Medos Hakim programmable valve with a prechamber. All patients with confirmed stator dislodgement underwent surgery during the study period. All valves had been implanted in the same department. When a valve had been implanted in our department and valve revision was performed at another hospital, we determined, if possible, whether the stator of the Medos Hakim programmable valve was dislodged. All valves were sent to the manufacturer for evaluation, and all cases were reported to the German Institute for Drugs and Medicinal Products.

Until the end of 2005, we used the Codman valve programmer, which was fitted with a more powerful magnet in 2000. In early 2006, the Codman valve positioning verification (VPV) system was introduced, and we have used this system ever since. The VPV system provides confirmation of valve adjustment without the need for radiographic imaging (Fig. 1).

Results

Between 1994 and 2010, 15 valves were removed because the stator had been dislodged from the base plate.

These 15 valves had been implanted between May 16, 1993, and December 27, 2002, and were removed between February 19, 2006, and January 22, 2010. The valves had thus been in place for a mean period of 11 years (median 11 years, range 7–14 years). Five hundred forty-six Medos Hakim programmable valves were implanted at our institution between 1994 and 2005, which was the year when the valve was improved and a considerably higher mean force was required to detach the stator from the base plate. The percentage of dislodged stators was thus almost 3% (15 of 546 valves).

Malfunctioning valves were seen only in children whose valve had been implanted when they were younger than 1 year of age. The mean age of the infants was 3 months at the time of implantation (median 1 month, range 1–11 months). This finding is particularly noteworthy since a greater number of valves were implanted in adult patients and older children during the same period of time.

Preoperative radiography always demonstrated dislodgement of the stator (Fig. 2). Surgery was never performed for unclear valve dysfunction, and in no case was the dislodgement detected only after valve removal. Five patients underwent prior MR imaging; before such imaging, only one of these patients had shown clear signs of overdrainage. One week before MR imaging, radiographs had been interpreted as normal. In retrospect, however, the dislodged condition of the stator was visible.

In 12 patients, radiographs were obtained on the basis of clinical grounds. In 10 of these patients, increased or decreased intracranial pressure was suspected. In 8 patients, there was clinical and imaging evidence of over-drainage. One of these patients had a chronic subdural hematoma with repeated bleeding. One child with headaches while upright presented to a small hospital where skull radiographs were obtained and interpreted as normal, although the stator was visibly dislodged. Two children showed dilation of the ventricular system and an increase in intracranial pressure. In both patients, surgery revealed a malfunctioning valve with a dislodged stator and ventricular catheter blockage. It is likely that initial overdrainage led to a collapse of the ventricular system and that the growth of tissue then blocked the ventricular catheter and caused an excessive accumulation of CSF. Two patients presented with nonspecific symptoms. One patient showed an increased incidence of seizures, and one child with a myelomeningocele that had been closed immediately after birth exhibited gait deterioration.

In the 3 remaining patients, radiographs were acquired only to verify the valve setting after routine MR imaging. In 2 of these cases, it was initially assumed that the valve setting was incorrect. After unsuccessful attempts to adjust the valve, a radiograph clearly demonstrated the dislodgement.

In 6 of the 15 explanted valves, previous radiographs had not demonstrated valve malfunction. The radiopaque marker on the base plate, however, was not visible (Fig. 2). The time interval between these radiographs and those
Malfunctioning Medos Hakim programmable valves

that demonstrated dislodgement of the stator was 1 month to 3 years.

Discussion

The number of revisions for malfunctioning valves does not appear to be considered a major problem in the literature. Although shunt revisions for valve dysfunction have been reported, only 3 papers describe the special problem of stator dislodgement from the base plate. Only 2 of the 15 valves with a dislodged stator were included in one of our earlier studies, which covered a period of 14 years. It is therefore particularly noteworthy that 2 valves with dislodged stators were found in 14 years and that as many as 13 valves were found in only 4 years. In all cases, the affected patients were children. There are no further reports investigating the frequency of this type of complication in large series of patients. The problem of dislodged stators appears to have been largely overlooked. The US FDA (www.fda.gov) had received a total of 1360 adverse event reports involving Medos Hakim programmable valves by December 31, 2010. Among these, 17 adverse events were associated with dislodgement of the stator or cam. One case of stator dislodgement was reported in each of the years 2000, 2001, and 2005. The other 14 cases, that is, the majority of these defects, were reported in the 5 years from 2006 to 2010. These data confirm our finding that the number of defects increases with the age of the valves. In this context, it should be noted that damage to the housing is also likely to occur in older patients after a sufficiently long period of implantation.

Sato et al. reported the case of a child with a crack in the rigid plastic housing and a deformed spring in the ball-spring mechanism of the valve. Radiography did not reveal these changes and in particular did not demonstrate dislodgement of the stator. As a result of the spring deformation, the opening pressure was 226 mm H2O instead of the selected level of 60 mm H2O. Reinprecht et al. analyzed a series of 78 children with Medos Hakim programmable valves and described an 8-year-old girl in whom drainage had developed because of a blockage of the operating pressure readjustment mechanism of the valve.

The literature does not suggest that MR imaging procedures or magnetic tools, such as the programmer or the VPV system, are believed to cause damage to the valve. Exposure to a magnetic field, however, can reveal the presence of a preexisting problem. Akbar et al. postulated that exposing a valve to high-field MR imaging might cause mechanical dysfunction. However, these authors used explanted valves in their study. In addition, they neither explained the reasons for removing the valves, nor did they provide details about the patients’ conditions, for example, CSF protein levels. Shellock et al. systematically assessed the effects of MR imaging at T on the function of Codman Hakim programmable valves. The highest temperature changes that they measured for the valves were 0.4°C and 0.8°C. In none of their in vitro experiments did they observe dislodgement of the stator or adverse effects on the function or programmability of the valve. Watanabe et al. explanted a malfunctioning Medos Hakim programmable valve. An examination of the valve showed a Y-shaped crack in the plastic housing and detachment of the white marker and cam from the base plate. A reduction in the force applied by the spring to the ball led to overdrainage resulting from a loss of support by the cam. Since the patient had not incurred a head injury and since radiography that had been performed 5 years earlier showed detachment of the white marker, an earlier impact to the head may have damaged the system. The authors concluded that this impact might have led to a decrease in the antimagnetic performance of the system and that the strong magnetic force of a 3-T MR imaging system might have caused detachment of the cam. We, too, detected malfunctions during pressure adjustments in an MR imaging environment. Regardless of the aforementioned studies on the safety of programmable valves during MR imaging, defective valves can still function until exposure to a magnetic field reveals the presence of a clinically relevant problem.

A further interesting aspect in our study is the absence of the small radiopaque marker on the radiographs, which was also reported by Watanabe et al. The detachment of this marker is likely to be the result of a deformed or damaged plastic housing and, in our opinion, can be regarded as a predictor of dislodgement.

Since no stator dislodgement was seen in valves that had been in place for < 7 years, it can be assumed that patient age and the time of implantation play a role in the development of valve malfunction or, in other words, that the valve mechanism ages or can be damaged by multiple

Fig. 2. Radiograph demonstrating dislodgement of the stator and the radiopaque marker (arrow).
minor traumas. This assumption is supported by the fact that all malfunctioning valves in our patient group and most malfunctioning valves referred to in the literature were implanted and explanted during childhood. Thus, valves appear to be subject to greater mechanical stress in children than in adults.

According to the manufacturer, the valve system was improved in 2005 and the detachment of stators of the new valves requires a higher mean force (see Appendix). It remains to be seen whether the aforementioned problems will cease to occur. We must wait up to 10 years for the answer to this question. It is important to report all malfunctioning valves to the responsible national authorities. Establishing a worldwide registry that collects data on explanted valves would be desirable and would help detect material-related problems at an early stage.

Conclusions

Medos Hakim programmable valve malfunctions are rare events but should receive careful attention. When the valve pressure setting cannot be adjusted, a malfunction should always be suspected and radiographic imaging should be performed to assess the condition of the valve. Compared with other causes of malfunctioning, stator dislodgement is the most serious form of valve adjustment failure since it leads to complete dysfunction of the valve. It should, of course, be noted that the percentage of valves with dislodged stators is nevertheless low. Especially in older children and adults, the valves appear to be highly stable despite their more complex mechanisms.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Mauer. Acquisition of data: Mauer. Analysis and interpretation of data: Mauer. Drafting the article: Mauer. Critically revising the article: Kunz. Administrative/technical/material support: Kunz. Study supervision: Mauer.

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Appendix

"An Increased number of malfunctioning Hakim Programmable valves: Cause for concern"

An invited editorial

Written by Dan McCusker M.S. & Matthew King

We appreciate the opportunity to respond to the comments made in this article. We hope our responses satisfy the author's needs.

**Design Changes implemented in 2005**

Design changes were undertaken in 2005 relative to the press fit between the stator and the baseplate as part of a tooling change for manufacturing component parts of the device. Because several reports concerning dislodgment of the stators from the base plates had been reported prior to 2005, Codman felt it was prudent to improve the fit between the stator and the baseplate as part of this tooling change.

The minimum acceptance criterion for push out force of the stator from the baseplate is 10N. Before 2005 the calculated minimum force to push out the stator was 10.2 N (max 102.1 N) based on extensive testing done at that time. From 2005, the minimum calculated force to push out the stator is 23.8 N (max 117.3 N).

The new design (tooling) exhibits an average push out force of 80N. Thus, the improvements made during this tooling change resulted in a much higher average force for displacing this component from the base plate. It is anticipated that this higher initial press fit will improve the long term integrity of the press fit.

**Reporting to appropriate health authorities**

All shunt failures reported to Codman, no matter the type of failure, are forwarded to the appropriate health authorities – e.g., in the U.S. in the form of an MDR and in the E.U. in the form of a Vigilance report.

It should be noted that Codman realizes that not all shunt failures are reported by Hospitals and/or Physicians. As a result, the numbers presented below could be considered lower than the true value.

**Current failure rates**

The rate for failures of this type reported to Codman is 0.024% through the end of 2008. Again, please note that it is likely that not all events are reported to Codman.
It is not clear as to why the author is seeing a failure rate 100 times the overall average or why the failures are only occurring in children. Perhaps additional studies are necessary to better understand these phenomena.

Note that no shunt failures of this type have been reported on product manufactured since the tooling change was implemented in 2005. Codman realizes that it has been only 5 years since the change, but is confident that the improvements implemented will reduce the number of failures of this type.

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