

ORIGINAL ARTICLE

MRI safety of a programmable shunt assistant at 3 and 7 Tesla*

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Abstract

Objective. Several new shunt technologies have been developed to optimize hydrocephalus treatment within the past few years. Overdrainage, however, still remains an unresolved problem. One new technology which may reduce the frequency of this complication is the use of a programmable shunt assistant (proSA). Inactive in a horizontal position, it impedes CSF flow in a vertical position according to a prescribed pressure level ranging from 0 to 40 cm H₂O. **Methods.** We exposed the proSA valve in an *ex vivo* protocol to MR systems operating at 3 and 7 Tesla to investigate its MRI safety. **Results.** Following 3 Tesla exposure, no changes in valve settings were noted. Adjustment to any pressure level was possible thereafter. The mean deflection angle was 23 ± 3°. After exposure to 7 Tesla, however, there were unintended pressure changes, and the mechanism for further adjustment of the valves even disintegrated. **Conclusion.** According to the results of this study, proSA is safe with heteropolar vertical magnet alignment at 3 Tesla. Following 7 Tesla exposure, the valves lost their functional capability.

Keywords: anti-siphon device; hydrocephalus; shunt; valve.

Introduction

Although several new developments have been applied in shunt technology within the past few years, the treatment of hydrocephalus is still burdened by several side effects.^{1–4} Programmable valves allow to regulate the opening pressure of the valves percutaneously, but they may not completely prevent from overdrainage due to the siphoning effect.^{1,4–9} One technique to overcome this problem is the in-line use of both a programmable valve and an anti-siphon device.^{5–7,9}

A more recent development is the programmable shunt assistant (proSA). This is an adjustable anti-siphon device which can be used as alone or in addition to any other valve. Since its first implantation in Germany in 2009, it is now in use more and more. According to the specifications of the manufacturer, the proSA should be implanted in combination with a differential pressure unit, since, theoretically, reflux might occur without a valve in-line.

ProSA is built of a titanium casing with a ball-cone valve at its proximal part. A coil spring secures the opening pressure of the ball-in-cone valve, and the sapphire ball warrants the closure of the valve. The weight is connected to the spring and keeps the sapphire ball in its position. The tension of the spring resulting in opening pressure is adjustable by turning the rotor. The position of the rotor can be changed transcutaneously with the aid of the magnets which are embedded at its two ends (Fig. 1).

Theoretically, overdrainage should be avoidable with this technique which regulates cerebrospinal fluid (CSF) drainage from the intraventricular space depending on the body position. Inactive in a horizontal position, it regulates CSF flow in a vertical position according to a prescribed pressure level ranging from 0 cmH₂O to 40 cmH₂O. This is the advantage of this new valve in comparison with well-known valves including anti-siphon devices with 'fixed' pressure level.

Since magnetic resonance imaging (MRI) is used routinely during management of patients with hydrocephalus, any adjustable valve should be safe in the MRI environment and unintended changes of valve settings should be avoided.^{10–18} The aim of this *in vitro* study was to investigate whether the proSA is safe during 3 and 7 Tesla MRI examinations.

*Presentation of this study prior to publication.

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**Contribution of each author:

MJM: idea, conception, design and coduction of the study, data collection, interpretation and writing the paper. PMK: conduction of the study, data collection and interpretation, important intellectual impact. MS: conduction of the study, important intellectual impact. FG: interpretation, writing the paper. JK: conduction of the study, interpretation, writing the paper.

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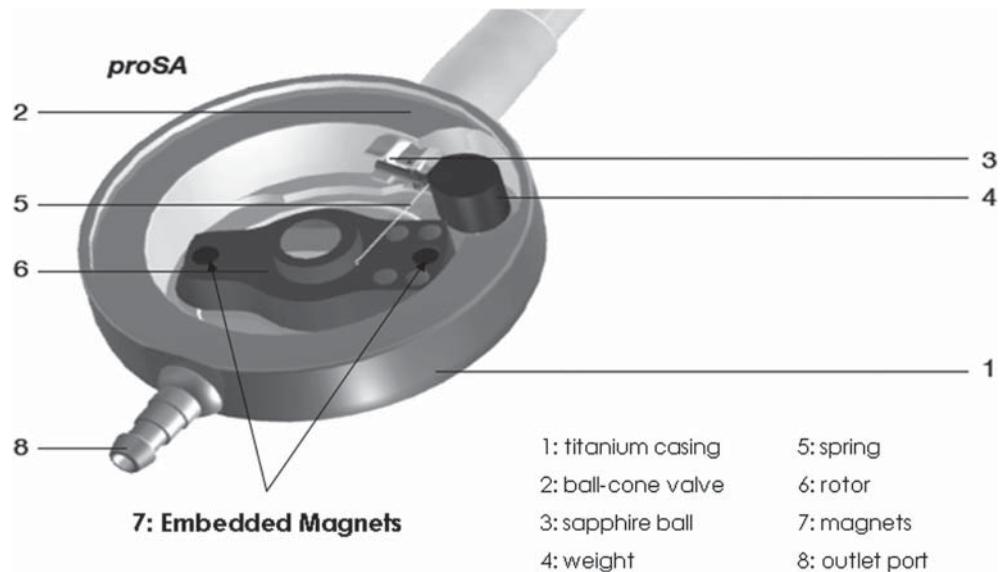


Fig. 1. Graphic of the proSA showing the components inside the valve.

Material and methods

Twenty proSA valves adjusted at a pressure level of 16 cm H₂O with different brake powers (five valves respectively with 200 g, 400 g, 600 g and 800 g) were exposed to the magnetic field of a 3 Tesla MRI system (Allegra, Siemens, Erlangen, Germany). Another 20 valves were exposed to the magnetic field of a 7 Tesla MRI system in a small animal MRI unit at the Medical School Hannover (Pharmascan 70/16; Bruker Biospin MRI GmbH, 76256 Ettlingen, Germany).

The alignment of the magnets in the valves which were exposed to 3 Tesla MRI differed from those which underwent 7 Tesla MRI exposure. The former had vertical and heteropolar magnets within the valves, and the latter had horizontal and homopolar magnets. With a heteropolar and vertical alignment of the magnets inside the valve bigger magnets are necessary in comparison to a homopolar and horizontal alignment to provide the same reliability of transcutaneous adjustment capability. Therefore, re-alignment of the magnets was performed before exposure to the magnetic field of the 7 Tesla MRI. If this smaller magnets could resist the stronger magnetic field of 7 Tesla, bigger magnets with same alignment (vertical and heteropolar) could also be investigated.

The valves were bonded on a plastic frame, and they were positioned perpendicular to the magnetic field so that they would be exposed to the maximal magnetic field (Fig. 2). The exposure time in the magnetic field was 5 minutes. The magnetic field was static and homogenous. T1-weighted spin echo sequences (TR 500 ms, TE 20 ms, Matrix size 256 × 256 mm, field of view 30 cm, slice thickness 3 mm, SAR 2.0 W/kg) were carried out. Following the MRI studies functional testing of the valves was obtained by evaluation of the performance of the readjustment procedure.

In general, the probability of intracorporal displacement under external magnetic field is estimated by the deflection angle.

For measurement of the deflection angle the valves were hung up from a cord (with a weight less than 0.01% of the valve weight) that was attached at the 0° vertical position at

the bore of the MRI system (Fig. 3). The valve hanging on the cord was held on the vertical position and then released. The deflection angle was determined as the angle between the plumb line and the displacement of the valve toward the MRI port. The deflection angle toward the MRI was measured three times and then averaged.

Results

3 Tesla MRI

There was no unpredicted event during the 3 Tesla examinations. During the MRI exposure, sufficient brake power avoided relevant changes of the pressure level in any valve due to the static homogenous field of the 3 Tesla MRI. Following the 3 Tesla studies functional testing of the valves did not reveal abnormal function. That means, all valves could be adjusted to any pressure level, and the brake mechanism was intact to assure the new adjusted pressure level.

After verification of the MRI safety with heteropolar vertical magnets, the mean deflection angle of these valves was $23 \pm 3^\circ$ (Fig. 3).



Fig. 2. The valves are bonded on a plastic frame for MRI investigation.



Fig. 3. Measurement of the deflection angle at 3 Tesla.

7 Tesla MRI

The valves were not safe at the magnetic field of 7 Tesla MRI. There were unintended pressure changes of unpredictable extent during the exposure. The valves with homopolar horizontal magnets even lost their functional capability. Adjustment to various pressure levels was not possible after exposure to the 7 Tesla MRI. It became clear that valves with such an alignment of the magnets would not be appropriate for further use. The deflection angle was not measured.

Discussion

The study was performed to investigate the safety and reliability of the new proSA during and following 3 and 7 Tesla MRI.

To minimize shunt-related morbidity resulting from underdrainage or overdraining, programmable valves are now considered an alternative to differential pressure valves which provide a fixed CSF flow rate.^{4-9,19} Such programmable valves permit non-invasive changes of the CSF flow rate and make repeat surgery avoidable.^{12,17,18,20} One major problem, nevertheless is that nowadays MRI is the diagnostic method of choice during follow-up of hydrocephalic patients.^{9-14,20-23} It is well known that exposure to the magnetic field can move shunt valves, alter the programmed settings or even permanently damage the valve.^{11,12,17,20,24-26} Therefore, safety and reliability of a valve during and after MRI scanning is crucial.

Our investigations confirm the safety and the reliability of the new proSA when exposed to a magnetic field of a 3 Tesla MRI. Unintended changes of valve settings did not occur, and the valves could be adjusted following the MRI procedure to any level while the brake mechanism remained intact.

The brake is provided by the power which clamps the rotor inside the valve body to avoid unintended readjustments due to exposure to external magnetic fields.

This construction principle has been realized in the adjustable unit of the programmable gravitational adjustable valve (proGAV).²⁷ Most likely, 3 Tesla MRI will more and more replace the contemporary 1.5 Tesla units.^{11,14,22} Clinical

examinations by 7 Tesla MRI are performed rarely. However, we included such an *ex vivo* investigation in advance. At 7 Tesla, even the smaller magnets lost their functional capability. This might imply that current technology of magnetic CSF shunt valves would not be suitable for higher magnetic fields. So far, 7 Tesla MRI is routinely used for experimental investigations and may remain for decades in the paraclinical field. Once, higher Tesla MRI is in clinical use routinely, reliable shunt technology might have to be non-magnetic.

The mean deflection rate of $23 \pm 3^\circ$ was acceptable even though it was higher than the 9° for the proGAV valve as confirmed earlier.¹³ Recently, the American Society for Testing and Materials (ASTM) issued a guideline for the evaluation of the deflection angle on a passive implant in the MR environment.²⁸ This guideline determined that 'if the implant deflects less than 45° , then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight).'²⁸ Deflection of less than 45° would indicate no serious displacement of the valve inside the body of the patients making it suitable for implantation.²⁹

The major focus of the present *in vitro* study was to investigate the impact of high magnetic fields on the functionality of the mechanisms to maintain valve settings and to allow subsequent readjustment. Limitations of this study are that we did not investigate whether there were temperature effects, and translational or torque forces were not quantified. Furthermore, hydrodynamic tests might ultimately demonstrate not only the functional capacity of the valve but also whether it would influence its pressure-flow performance. At present, clinical studies on the efficacy of this new valve in the management of hydrocephalic patients are being conducted. Lacking clinical data, clinicians should still monitor their patients closely after MRI imaging, at least approving the valve setting before sending them to an unmonitored environment.

Conclusion

The proSA which has been introduced recently with heteropolar and vertical magnet alignment is safe and reliable for 3 Tesla MRI examinations in the *in vitro* environment. Unintended changes of pressure settings and serious displacement within the body should not occur. Exposure to 7 Tesla affects the valve settings and the functional capability of the valves with homopolar and horizontal magnets.

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Disclosure

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

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We have no personal or institutional financial interest in the investigated valve.

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