Disruption of silicone valve housing in a Codman Hakim Precision valve with integrated Siphonguard

Report of 2 cases

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Authors of this report describe 2 patients who had undergone shunt insertion for hydrocephalus and who, at 6 weeks or 9 months after their last revision, presented with symptoms of shunt dysfunction and CSF collections at the valve site. At the ensuing shunt revision in both patients, the silicone housing was fractured and the Siphonguard was disconnected from the Codman Hakim Precision flat-bottom valve. The cause of these failures was not clear since manipulation, bending, and twisting of the valves were not thought to have occurred during implantation.

A review of the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database revealed 58 cases of silicone housing failure in the Codman Hakim Precision valve with integrated Siphonguard since the year 2000. A single report was found in the databases administered by the Canadian Medical Devices Sentinel Network (CMDSNet).

The Codman Hakim Precision valves with integrated Siphonguard are delicate devices that do not withstand the intraoperative handling tolerated by other valves. When these valves are implanted, gentle handling and wide exposures are needed to minimize the risk of valve damage. Valves should be handled according to the manufacturer’s instructions.

However, in light of this particular pattern of failure, it is recommended that the manufacturer redesign this valve to provide handling tolerance that is characteristic of other valves on the market. The featured cases illustrate the importance of the surgeon’s role in postmarket surveillance of medical devices and reporting device failures to the responsible agencies and manufacturers.

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Key Words • hydrocephalus • Codman Hakim Precision valve • Siphonguard

MECHANICAL failure of shunt systems occurs most frequently because of catheter or valve obstruction, although the failure of shunt components is also well known. Catheters break or separate at stress points; calcification renders tubing brittle and adherent to subcutaneous tissues, predisposing to fracture; and valves migrate with calvarial growth. Ventricular catheters can separate from connectors if the catheter tip is adherent to ependyma, choroid plexus, or arachnoid. Distal catheters can pull off distal valve connectors. Adjustable valves have the additional problem of magnetic interference resulting in valve obstruction or failure of the valve setting.1-3 Changes in valve performance over time are likely to occur but are not well understood.

Disruption of the silicone shunt valve housing has not been frequently documented in the literature. In this report we describe 2 patients who required shunt revision because the valve’s silicone housing was fractured and the Siphonguard (SG) was disconnected from its flat-bottom Codman Hakim Precision valve (CHPV). We also review the reports of similar valve failures in US and Canadian postmarket surveillance databases.

Case Reports

Case 1

Communicating hydrocephalus was diagnosed in this patient in infancy. A ventriculoperitoneal (VP) shunt was placed using an occipital entry point with frontal horn tip placement. Catheters were barium impregnated, the distal
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catheter was open-ended, and the valve was a PS Medical differential pressure, medium pressure silicone valve (Medtronic).

The first revision was performed for ventricular catheter blockage when the child was 2 years of age. Five further revisions were needed over the next 7 years. These included, in chronological order, removal and replacement with the insertion of a Cordis Orbis-Sigma Valve (OSV) I for infection. Two further revisions were required because the distal and then the proximal catheters pulled off the OSV I connectors. Prior to the index operation, one further revision was needed to exchange a blocked OSV I with an OSV II.

Three years later, when the patient was 12 years old, the OSV II became blocked and was replaced with a flat-bottom CHPV (medium low pressure) with integrated SG. The new valve was slipped into the existing subcutaneous pocket without recognized torsion or flexing of the components and was secured to the pericranial cicatrix at the cranial valve connector. Six weeks later the patient presented with symptoms of shunt obstruction. Computed tomography scanning showed an increase in her normally slit ventricles, a known retained ventricle catheter, and a broken valve at the level of the SG (Fig. 1). The valve was replaced. The explanted valve showed fracture of the silicone housing with separation of the SG from the valve.

Case 2

This patient had presented with posthemorrhagic nonobstructive hydrocephalus in infancy. An endoscopic third ventriculostomy did not control her hydrocephalus, and thus a VP shunt was placed using an occipital entry point with frontal horn tip placement. Catheters were barium impregnated, the distal catheter was open-ended, and the valve was a PS Medical differential pressure, medium pressure silicone valve.

Thirteen years later the patient returned with symptoms of shunt obstruction. Imaging suggested a ventricular catheter fracture above the catheter-to-valve connection, which was confirmed when the ventricular catheter was replaced and the valve was upgraded to an OSV I.

One year later, the patient presented again with shunt dysfunction and showed distal subcutaneous displacement of the OSV I. The ventricular catheter was replaced and a new OSV I was repositioned so that its distal connector was not at a point of stress. A short segment of tubing and straight connector allowed the old distal catheter to be used.

One month later she again returned with separation at the straight connector. At this time the distal catheter was replaced.

Nine months later, when she was 15 years old, symptoms recurred. On exploration, the shunt was found to be intact and functional. A valve change was elected, the OSV I was removed, and a CHPV with integrated SG was implanted. The new valve was placed in the old pocket without recognized stress or torsion.

Nine months later, the patient returned with headaches and vomiting. A standard shunt series was not helpful in defining the cause of obstruction; however, a tangential view of the valve suggested misalignment of the components. At the time of shunt revision, the valve and SG were disconnected and the silicone housing for the SG was fractured (Fig. 2).

Postmarketing Database Review

Methods

Manufacturer and User Facility Device Experience (MAUDE). This database of the US FDA (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) was queried using the MAUDE search engine and the following terms: Product Class: shunt, central nervous system, and components; Brand Name: Siphonguard; and Manufacturer: Codman. All records that met these criteria were individually reviewed to determine the nature of the valve failure, and those reports describing silicone housing fractures, tears, or disruption were analyzed.

Canadian Medical Devices Sentinel Network (CMDS Net). A request was made to Health Canada’s CMDSNet for the number and nature of reports made for Codman SG products. The same search terms were provided.

Results

MAUDE. For the period from January 1, 2000, to
August 2013, the MAUDE database returned 295 reports of presumed adverse events involving the Codman Hawkim SG. No events involving the SG were reported to the database prior to 2000. These reports described 1) the failure of CSF or irrigation to flow through the device either at insertion or when the device was explanted due to shunt obstruction, 2) overdrainage resulting in subdural hematoma formation, 3) infection, and 4) fractures of the device’s silicone housing.

Fifty-eight cases of punctures, cuts, and tears of the silicone housing for the SG-integrated Precision valves have been reported. Many of the reports describe separation of the SG from its housing, resulting in CSF collections at the valve site. Others describe the leakage of CSF through the silicone housing through tears, holes, or fractures. Commonly, the valve was not made available to the manufacturer for analysis.

When the manufacturer did evaluate the device, slits in the silicone housing were described in the follow-up reports and were ascribed to operator-inflicted cuts, handling during implantation, or explantation or trauma to the valve by the patient. Unfortunately, many follow-up reports have not been completed.

CMDSNet. The CMDSNet provided an aggregated report. The search strategy and individual reports were not made available to us. From 2002 to 2013, there were 10 reports of CHPV failure. These included programming failures, microvalve failures due to debris, and one report of silicone housing separation.

Discussion

In both of our cases, a CHPV with integrated SG replaced a malfunctioning occipital valve (OSV) and was inserted into the existing subcutaneous pocket. Both revisions used two incisions: one proximal to the ventricular catheter valve connection and one at the distal catheter valve connector to expose the existing OSV and to provide access to the subcutaneous pocket for placement of the new CHPV. In both cases the valve was slid into the pocket without bending or torsion from the short incision at the level of the bur hole so that the distal connection was made through the lower incision at the distal connector. The valve and tubing were handled with rubber-shod forceps, and the connectors were handled with a connector holder. Both ventricular and distal catheters were Codman Bactiseal catheters.

It is highly unlikely that the valves we describe left the fabrication facility without meeting the manufacturer’s specifications; however, the use of the device in vivo appears to expose it to new and unexpected stresses resulting in failures such as those described here.

The manufacturer offers the following instructions to surgeons using any of the Precision valves: 1) Use extreme care when handling silicone products, as silicone has a low tear resistance and electrostatic properties. 2) Do not use sharp instruments when handling the silicone valve or catheter; use shod forceps. Cuts or abrasions from sharp instruments can rupture or tear the silicone components. 3) Do not fold or bend the valve during insertion. Incorrect insertion can rupture the silicone housing.

Postmarket surveillance in the US is provided through a voluntary reporting system run by the FDA. The MAUDE database contains reports of adverse events involving medical devices. The data comprises voluntary reports submitted by the user facility, distributors, and manufacturers since 1996. In Canada, postmarket surveillance of medical devices, including shunts, is the responsibility of Health Canada through the CMDSNet.

It is apparent from the MAUDE and CMDSNet data that this pattern of valve failure has been known since the integrated SG was introduced. The addition of the SG to the Precision valve appears to have created a construct that can fail when the valve is used according to standard and recommended procedures. In our cases, no recognized stress was placed on the valve. Perhaps when replacing other valves with the CHPV and integrated SG, the subcutaneous location for the valve must be complete-
Fractured silicone housing

ly exposed and the valve should not be slid into an existing “pocket.” Beyond these recommendations, it is not clear how the operator could prevent this type of failure from (re)occurring. We recommend that the manufacturer redesigns the silicone housing or reinforces the base of the valve to mitigate the stresses on the silicone housing that occur during routine clinical use.

Conclusions

Based on our review of postmarket surveillance reports and our own experience with the integrated antisiphoning device, the CHPV with integrated SG seems to be less robust than other valves on the market. Particular care during implantation may not prevent this type of failure.

Disclosure

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

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