Complication rates for preexisting baclofen pumps and ventricular shunts following scoliosis correction: a preliminary study

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OBJECTIVE Many patients undergoing spinal fusion for neuromuscular scoliosis have preexisting neurosurgical implants, including ventricular shunts (VSs) for hydrocephalus and baclofen pumps (BPs) for spastic cerebral palsy. Recent studies have discussed a possible increase in implant complication rates following spinal fusion, but published data are inconclusive. The authors therefore, sought to investigate: 1) the rate of implant complications following fusion, 2) possible causes of these complications, and 3) factors that place patients at higher risk for implant-related complications.

METHODS Cases involving pediatric patients with a preexisting VS or BP who underwent spinal fusion for scoliosis correction between 2005 and 2016 at a single tertiary children's hospital were retrospectively analyzed. Patient demographics, implant characteristics, spinal fusion details, neurosurgical follow-up, and implant complications in the 180 days following fusion were recorded and analyzed.

RESULTS Overall, 75 patients who underwent scoliosis correction had preexisting implants: 39 had BPs, 31 VSs, and 5 both. The patients' mean age at fusion was 13.49 ± 2.78 years (range 3.62–18.81 years), and the mean time from the most recent previous implant surgery to fusion was 5.70 ± 4.65 years (range 0.10–17.3 years). The mean preoperative and postoperative Cobb angles were $62.4^\circ \pm 18.9^\circ$ degrees (range 20.9° – 109.0°) and $23.5^\circ \pm 13.3^\circ$ degrees (range 2.00° – 67.3°), respectively. No VS complications were identified. Two patients with BPs were found to have complications (unintentional cutting of their BP catheter during posterior spinal fusion) within 180 days postfusion. There were no recorded neurosurgical implant infections, failures, fractures, or dislodgements. Although 10 patients required at least 1 surgical procedure for irrigation and debridement of the spine wound following fusion, there were no abdominal or cranial implant wound infections requiring revision, and no implants required removal.

CONCLUSIONS The results of this study suggest that spinal fusion for scoliosis correction does not increase the rates of complications involving previously placed neurosurgical implants. A large-scale, prospective, multicenter study is needed to fully explore and confirm this finding.

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KEYWORDS hydrocephalus; cerebral palsy; scoliosis; ventriculoperitoneal shunt; baclofen pump; spinal fusion; spine

BOTH hydrocephalus and cerebral palsy are often associated with a number of comorbid conditions, such as spina bifida and spinal deformity.^{15,17} The most notable of these deformities is scoliosis, a condition that is characterized by a $> 10^\circ$ lateral curvature of the spine.¹³ There are a number of treatments for scoliosis; in more severe cases, it may be treated with a spinal fusion.

In these cases, a spinal construct is formed to maintain the spine in a more linear fashion.^{3,5}

Because patients may have hydrocephalus and/or cerebral palsy in addition to scoliosis, a number of patients undergo ventricular shunt (VS) and/or intrathecal baclofen pump (BP) placement and subsequent spinal fusion. Recent studies and case reports have shown a possible relation-

ABBREVIATIONS BP = baclofen pump; I&D = irrigation and debridement; IV = intravenous; OR = operating room; VS = ventricular shunt; VUMC = Vanderbilt University Medical Center.

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ship between spinal fusion and increased implant failure in patients with preexisting implants.^{1,4,6,7,9–12,15,18} Common causes of implant failures include infection, malfunction, obstruction, and catheter fracture.^{2,16} A number of hypotheses have been proposed to explain a relationship with spinal fusion; for example, causes of shunt failure have been hypothesized to include newly introduced mechanical stress, growth-related stress, and surgical technique.¹⁵

Previous publications in this area have primarily been case reports, hypothesizing the potentially increased risk of neurosurgical implant complications after spinal fusion surgery. Few large studies have quantitatively analyzed the association between scoliosis fusion and failure of preexisting neurosurgical implants. Therefore, we sought to use retrospective analysis to 1) investigate the rate of implant complications related to scoliosis fusion, 2) analyze causes of implant complications, and 3) find factors that place patients at higher risk for implant-related complications.

Methods

A total of 75 pediatric patients with neuromuscular scoliosis who underwent fusions between August 2005 and August 2016 at Monroe Carell Jr. Children's Hospital were retrospectively selected from available billing information and chart review. Inclusion criteria selected for patients who 1) received surgical treatment (posterior arthrodesis/posterior segmental instrumentation) for scoliosis at Vanderbilt University Medical Center (VUMC), 2) had a minimum of 6 months of follow-up care at VUMC, and 3) had received an implant prior to their scoliosis fusion.

Data collected for each patient included patient demographics, implant history (prior to scoliosis fusion), spinal fusion information, and postoperative follow-up. Patient demographics included date of birth, sex, race, ethnicity, and insurance status. Implant history encompassed the type and side of the implant(s), the date of the most recent implant procedure, and the type of operation. Information regarding the spinal fusion included the date of the surgery, vertebral levels fused, side of the major Cobb angle, pre- and postoperative Cobb angle measurements, and postoperative complications (including details of postoperative spine wound complications/infections). All Cobb angles were measured using upright spinal radiographs at the most recent date prior to fusion (preoperative) and the earliest date following fusion (postoperative). Finally, follow-up information included any returns to the operating room (OR) within 180 days, the indication for the return to the OR, and information about the patient's next neurosurgical operation (if applicable).

Results

Overall, 793 posterior spinal fusions were performed at Monroe Carell Junior Children's Hospital from August 2005 to August 2016. Of these, 75 (9.5%) were performed on patients with preexisting baclofen pumps and/or ventricular shunts. Demographics for this cohort are shown in Table 1.

Of the 75 included patients, 31 had solely a ventricular shunt (VS), 39 had solely an intrathecal baclofen pump (BP), and 5 had both. In total, 69/75 (92.0%) had their

TABLE 1. Patient demographics

Characteristic	No. of Pts (%)
Sex	
Male	32 (42.7%)
Female	43 (57.3%)
Ethnicity	
Hispanic or Latino	1 (1.3%)
Not Hispanic or Latino	71 (94.7%)
Unknown/unreported	3 (4.0%)
Race	
American Indian or Alaska native	1 (1.3%)
Asian	1 (1.3%)
Black or African American	8 (10.7%)
Native Hawaiian or other Pacific Islander	0 (0.0%)
White	65 (86.7%)
Unknown/unreported	0 (0.0%)
Other	0 (0.0%)
Insurance	
Public	59 (78.7%)
Private	16 (21.3%)

Pts = patients.

most recent implant surgery prior to scoliosis correction performed at our institution. Table 2 reports information regarding the implant characteristics for both VSs and BPs. In all, there were 36 VSs, almost all of which were ventriculoperitoneal shunts (97.2%), and there were 44 BPs. For both VSs and BPs, a majority of implants were

TABLE 2. Implant characteristics

Characteristic	No. of Cases (%)
Shunt	36 (48.0%)
Type	
Ventriculoperitoneal	35 (97.2%)
Ventriculoatrial	1 (2.8%)
Side	
Right	22 (61.1%)
Left	12 (33.3%)
Both	2 (5.6%)
Concavity	
Concave	19 (52.8%)
Convex	15 (41.7%)
Both	2 (5.6%)
Pump	44 (58.7%)
Side	
Right	38 (86.4%)
Left	6 (13.6%)
Concavity	
Concave	19 (43.2%)
Convex	25 (56.8%)

TABLE 3. Implant indications

Implant & Indication	No. of Cases (%)
Shunt	
Spina bifida	14 (38.9%)
Congenital hydrocephalus	7 (19.4%)
IVH	5 (13.9%)
Trauma	3 (8.3%)
Infection	2 (5.6%)
Lissencephaly	1 (2.8%)
Achondroplasia	1 (2.8%)
Pfeiffer syndrome	1 (2.8%)
Idiopathic intracranial HTN	1 (2.8%)
Unknown	1 (2.8%)
Pump	
Cerebral palsy, nontraumatic	40 (90.9%)
Cerebral palsy, traumatic	4 (9.1%)

HTN = hypertension; IVH = intraventricular hemorrhage.

placed on the patient's right side. There were more VSs placed on the concave side of the patient's scoliosis curvature, whereas BPs were more commonly placed on the convex side.

The indications for implant placement are shown in Table 3. For VS placement, the most common indications were spina bifida, congenital hydrocephalus, intraventricular hemorrhage, trauma, and infection. A large majority (90.9%) of the BPs were placed due to nontraumatic cerebral palsy.

Information about each patient's most recent implant operation (prior to spinal fusion) is provided in Table 4. For a majority of VSs, there was a revision following initial placement of the shunt. On the other hand, a majority of BPs did not require revision. Patients were followed routinely by neurosurgery for VS and BP care. No additional implant-related follow-up was provided prior to or after the spine fusion.

A summary of characteristics related to the spinal fusion procedures is provided in Table 5. The patients' mean age at spinal fusion was 13.49 ± 2.78 years (range 3.62–18.81 years), and the fusion procedure was performed an average of 5.70 years (SD 4.65 years, range 0.10–17.3 years) after their most recent implant operation. The mean preoperative and postoperative Cobb angles were $62.4^\circ \pm 18.9^\circ$ (range 20.9° – 109.0°) and $23.5^\circ \pm 13.3^\circ$ (range 2.00° – 67.3°), respectively, resulting in an average Cobb angle change of 38.92° . The average number of vertebral levels fused was 14.20. In all cases, patients had both thoracic and lumbar vertebrae fused. Ten patients (13.3%) required postoperative irrigation and debridement (I&D) of their spinal wound; however, no implants needed to be removed, and no I&D of cranial or abdominal wounds was required. Of note, spine fusion cases follow a standard surgical-site infection reduction protocol at our institution, and these cases are tracked.

A list of patients requiring I&D following posterior spinal fusion is provided in Table 6. Of these, 7 patients had VSs and 3 had BPs, and half of the cases included subfas-

TABLE 4. Implant operation information

Variable	Value
Most recent procedure type	
New shunt insertion	12 (16.0%)
Shunt revision	17 (22.7%)
Shunt insertion following infection	3 (4.0%)
New baclofen pump	29 (38.7%)
Pump revision	14 (18.7%)
Age at most recent implant surgery, yrs	
Mean (SD)	7.79 (5.23)
Median (IQR)	8.88 (2.55–11.41)

IQR = interquartile range.

cial involvement. Of note, in 2 cases, the BP catheter was seen during the I&D; however, neither patient required revision, removal, or replacement of the pump. In one of these 2 cases, cultures were positive for coagulase-negative *Staphylococcus*, and in the other they demonstrated methicillin-resistant *S. aureus*. The patient in the first of these 2 cases was treated with 2 I&D procedures, 8 weeks of intravenous (IV) vancomycin and rifampin, followed by 6 months of oral trimethoprim/sulfamethoxazole and rifampin. The second patient required 3 I&D procedures, 8

TABLE 5. Scoliosis surgery characteristics

Characteristic	Value
Age at scoliosis surgery, yrs	
Mean (SD)	13.49 (2.78)
Median (IQR)	13.32 (11.78–15.40)
Time btwn last implant & spine surgery, yrs	
Mean (SD)	5.70 (4.65)
Median (IQR)	4.41 (2.11–8.00)
Preop major Cobb angle	
Mean (SD)	62.39° (18.93°)
Median (IQR)	59.50° (50.80°–72.75°)
Side of major curve	
Right	34 (45.3%)
Left	41 (54.7%)
Spinal areas fused	
Cervical	0 (0%)
Thoracic	75 (100%)
Lumbar	75 (100%)
No. of levels fused	
Mean (SD)	14.20 (2.20)
Median (IQR)	15.00 (14.00–15.00)
Postop major Cobb angle	
Mean (SD)	23.47° (13.29°)
Median (IQR)	20.80° (12.65°–33.90°)
Change in Cobb angle	
Mean (SD)	38.92° (14.10°)
Median (IQR)	37.40° (27.45°–50.15°)

TABLE 6. I&Ds following posterior spinal fusion

Case No.	Implant Type	Subfascial Involvement	Implant Involvement	Implant Replaced or Removed
1	Shunt	Yes	No	No
2	Shunt	No	No	No
3	Shunt	No	No	No
4	Shunt	Yes	No	No
5	Shunt	No	No	No
6	Shunt	Yes	No	No
7	Shunt	No	No	No
8	Pump	No	No	No
9	Pump	Yes	Yes	No
10	Pump	Yes	Yes	No

weeks of IV vancomycin, and 8 months of oral levofloxacin and rifampin. All 7 patients were initially treated with a course of IV antibiotics and then transitioned to longer-term oral antibiotics. After discharge, they were followed in both spine and infectious disease outpatient clinics.

Table 7 shows all follow-up implant operations that were performed within 180 days of spinal fusion. No patient had VS complications and 2 patients had BP complications related to spinal fusion (unintended BP catheter cutting during posterior spinal fusion, which required intraoperative repair, in both cases). In each of these cases, the BP catheter was violated during exposure of the spine. When the complication was identified, a new catheter was inserted into the intrathecal space and connected to the end of the previous catheter leading to the generator. The fusion operation was then continued to completion. Four other pump operations were planned (catheter repositioning or pump replacement for end of generator life) and are not considered complications of the spinal fusion. There were no cases of baclofen withdrawal, baclofen overdose, CSF leak, or cranial or abdominal wound revisions.

Discussion

Patients who receive neurosurgical implants, including VSs and BPs, often have a number of comorbid conditions. One of the most common of these conditions is scoliosis, which may occur due to a variety of factors in many patients with spina bifida or cerebral palsy.^{1,15} In turn, such patients often are treated with spinal fusion to aid in scoliosis correction.

Prior studies have presented evidence of an increase in neurosurgical implant failure rates following neuromuscular scoliosis correction. For example, Caird et al. provided evidence that spinal fusion increases the rate of BP failure, and Lai et al. provided a series of cases pertaining to shunt failure.^{7,15} More recently, Hatano et al. reported a 21% shunt complication rate following spinal fusion.¹¹ A number of hypotheses have been proposed for this relationship; these include mechanical stress, aged or brittle implants, and surgical technique.¹⁵ However, prior evidence has not been consistent; both Borowski et al. and Yaszay et al. found that posterior spinal fusion did not increase complication rates in baclofen pumps.^{6,18}

TABLE 7. Shunt or pump operations within 180 days following scoliosis correction

Operation	Within 90 Days	Within 180 Days
Shunt		
Reoperations	0	0
Pump		
Catheter repair due to unintentional cutting*	2	2
Catheter repositioning (planned)	1	1
Replacement (battery end of life)	0	3

Values represent numbers of operations.

* Marked as complication of scoliosis fusion. Repair of catheter completed during scoliosis correction operation.

In the present study, 6 of the 75 included patients required some form of implant revision within 180 days of their spinal fusion. Only 2 of these revisions were considered to be potential spinal fusion complications, as 3 patients needed baclofen pump revisions due to battery end-of-life, and 1 patient had an intraoperative revision that was planned prior to scoliosis correction. Our study indicates that implant failure rates are not significantly higher following spinal fusion. However, increased care, especially during the exposure portion of the procedure, must be undertaken. Due to the low failure rate in our study, potential underlying causes of implant failure (such as time between surgeries, age at fusion, number of levels fused, and Cobb angle change) could not be analyzed.

There are a number of reasons why the failure rate following spinal fusion may not be higher than the general implant failure rate. It could be that changes to the integrity of the implant or newly placed mechanical stress are simply not notable enough to cause functional failure of the device. Additionally, it may be that the surgical technique regarding implant placement is accommodating of future spinal fusion, such as through the placement of excess shunt tubing. It is important to note that although the overall rate of VS failure is decreasing compared to historical controls, there remains a baseline rate of failure in the natural history of VS in the overall population.¹⁴ Although we did not observe VS failure in the 36 patients with VSs, it is likely this is due to the small size of our overall cohort.

One important statistic to note is that the patients in this study had a large number of wound complications following spinal fusion. Specifically, 10 patients (13.3%) required at least 1 I&D procedure, which is consistent with the range of 5%–20% reported for infection rates in neuromuscular scoliosis fusions in the literature.⁸ In our 10 cases, half of the infections were suprafascial only. In two of the cases in which I&D was required, BP pump catheters were seen in the field. The catheters were left in place, and fortunately, no subsequent removal or revision was required. All patients who required I&D received an initial course of IV antibiotics, and transitioned to longer-term oral antibiotics.

It is also important to note that many surgeons intentionally cut the BP catheter in the initial stages of the

scoliosis correction operation and reconnect it at the end of the case. However, this is not the standard practice at our institution, due to concern over baclofen withdrawal or lack of baclofen relief in the initial postoperative period due to interruption of baclofen infusion during the surgery. We suggest that the pump tubing be left intact during the spine surgery if possible.

This study is not without limitations, the most notable of which being the sample size. In this study, there were only 2 patients who were deemed to have an unexpected implant failure within 180 days of spinal fusion. Given that 2 cases were identified in our study cohort of 75 patients, assuming a case-control study design and power of 0.80, we would need over 3500 controls to properly assess the impact of spinal fusion on implant failure. It is difficult to find a large number of similar patients at any one institution; accordingly, a large, multicenter study including high-volume institutions, would be needed to convincingly determine the impact of spinal fusion on implant failure.

Conclusions

In conclusion, our study suggests that patients with previously placed neurosurgical implants are not at increased risk for implant failure following spinal fusion for scoliosis correction. While additional surgical caution must be used to avoid damage to the implant structure and functional integrity, spinal fusions can still be performed safely in this group of patients. Further large-scale, multicenter studies should be performed to validate this finding.

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Disclosures

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

Conception and design: Bonfield. Acquisition of data: Dallas, Sborov, Chotai. Analysis and interpretation of data: Bonfield, Dallas. Drafting the article: Dallas, Sborov. Critically revising the article: Bonfield, Dallas, Guidry. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Bonfield. Administrative/technical/material support: Guidry. Study supervision: Bonfield.

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