



A new minimally invasive cervical pedicle screw (CPS) fixation system using intra-operative computed tomography-guided navigation

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Background: Since its introduction, placement of cervical pedicle screws (CPS) has been considered a procedure with a very high-risk profile. Minimally invasive CPS placement was not even considered at all. However, as surgical techniques and image guided intra-operative navigation have been refined over the last decade, navigated CPS placement has become a standard procedure in well-established spine centers. Currently, the first off-the-shelf percutaneous CPS placement platforms are becoming available. The aim of this study is to assess feasibility and accuracy of an minimally invasive surgery (MIS) CPS fixation system in a pilot series.

Methods: Between January and July 2023, we treated a cohort of ten patients using a new cervical MIS platform. Forty pedicle screws were inserted percutaneously in the c-spine using intra-operative computed tomography (CT) guided navigation and retrospectively analysed for accuracy using a modified Gertzbein & Robbins (G&R) classification. Adverse events and other patient-related data were also documented.

Results: Ninety percent of all screws were placed accurately (80% on perfect trajectory, 10% showed minor perforations). Another 10% (four screws) caused pedicle wall breaches between 2 and 4 mm, but were not revised, since misplacement was not associated with neurological deficit or inferior biomechanics. One patient experienced neurological deterioration, but not associated with screw misplacement. The transverse foramen was breached twice, however not endangering the vertebral arteries.

Conclusions: In this pilot series MIS CPS placement yielded accurate placement rates comparable to open surgical approaches reported in the literature. Hence, MIS CPS placement appears to be a feasible and safe procedure in selected cases.

Keywords: Cervical pedicle screws (CPS); minimally invasive surgery (MIS); navigation; instrumented fusion; computer-assisted surgery (CAS)

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Introduction

The ongoing demographic transition is associated with a strong upward-trend in cases of degenerative spine disease. This translates into spine surgeries, especially instrumented fusion (1,2). The resulting need to evolve operative techniques has led to rapid progress in the fields of navigation and computer-assisted surgery (CAS) (3) besides other promising methodological advances, like e.g., three-dimensional (3D) printed tubular templates/guides for screw insertion (4). In this context, computed tomography (CT)-assisted spinal navigation has been shown to have a decisively positive effect on accuracy of implant placement compared to freehand and fluoroscopy-assisted techniques (5-7). High rates of accuracy can be achieved in instrumented fusion throughout the thoracolumbar and cervical spine even in cases of revision surgery, as demonstrated by our previous studies (8,9).

Instrumented surgery of the cervical spine demands exceptional precision and care. The small size of targeted structures, especially pedicles, raises the probability of implant misplacement. Furthermore, the close proximity of nerve roots, spinal cord and the vertebral arteries poses a potential risk of causing relevant harm to the patient in case of screw misplacement.

Nowadays, cervical instrumentation techniques mainly rely on two types of screw-rod systems. Lateral mass screw (LMS)-based systems, as introduced by Roy-Camille in the 1960s, are a solid tool in the hands of an experienced spine surgeon and associated with a low risk of harming vital structures. Cervical pedicle screw (CPS) technique, as proposed by Abumi *et al.* in 1994 (10), on the other hand has a significant potential of harming the vertebral artery, or

any of the above-mentioned anatomical structures, but the biomechanics are considered superior (11). CPS placement yields up to four-fold the pull-out strength compared to LMS (12).

The introduction of intra-operative CT (iCT) navigated screw placement has facilitated the implementation of CPS placement as clinical standard. In our spine centre, we observed an increase in CPS placement rates (CPS/LMS) from 10% (mostly C7, followed by C2) to 66%, due to the availability of iCT navigation (9).

However, the exposure of CPS insertion points at the far lateral aspect of the lateral mass is associated with severe soft tissue morbidity, potentiated by the need to perform a substantial angulation manoeuvre to attain an adequate trajectory. This is particularly unfortunate in cases, where dorsal decompression is not indicated.

Recently the Aesculap® Ennovate® cervical platform (B. Braun, Melsungen, Germany) was extended by a market ready minimally invasive surgery (MIS) implant system. We report on workflow, feasibility, and a pilot series of our first ten cases using an exclusively MIS approach for CPS implantation. We present this article in accordance with the STROBE reporting checklist (available at <https://jss.amegroups.com/article/view/10.21037/jss-24-45/rc>).

Methods

We retrospectively analysed the accuracy of MIS pedicle screw placement in 10 patients that underwent dorsal MIS instrumentation of the cervical spine between January and July 2023. All cases were treated in accordance with clinical standard at our department of neurosurgery at RWTH Aachen University Hospital. All patients gave written informed consent to the surgical procedure after being briefed by a physician. These cases featured patients with degenerative spine disease after ventral decompression and primary dorsal instrumentation after cervical trauma. Patient related data, such as age, body mass index (BMI), sex, American Society of Anaesthesiologist (ASA) score and surgery related data (scan-to-scan time, blood-loss, levels of fusion, hospitalisation) were documented. All surgeries were conducted by the first author (C.B.).

The accuracy was determined using a modified Gertzbein & Robbins (G&R) classification. Screws on perfect trajectory (grade A) and minor perforations ≤ 2 mm (grade B) were deemed acceptable. Pedicle or foramen transversarium perforations > 2 mm (grade C and

Highlight box

Key findings

- The first report on a market ready percutaneous/minimally invasive surgery (MIS) system for cervical pedicle screw fixation.

What is known and what is new?

- So far cervical pedicle screws insertion is considered a high-risk technique that requires navigation and open surgery.
- We report on feasibility and our results of the first ten patients treated with percutaneous cervical pedicle screw fixation.

What is the implication, and what should change now?

- MIS cervical pedicle screw insertion should be considered for selected patients.

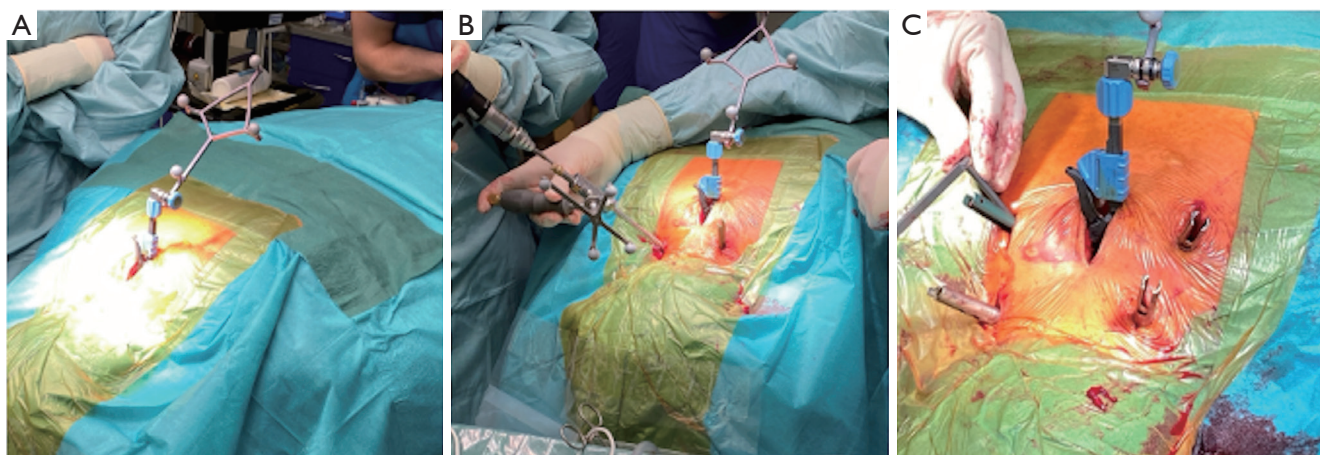


Figure 1 Intraoperative handling. (A) The reference array is attached to a spinous process (C7 in this case) via small median skin incision. (B) Navigated pediculation using a navigated drill-guide and a power-tool followed by K-wire insertion. Each skin incision is planned in direct trajectory of the planned cervical pedicle screws. (C) Rod insertion in standard percutaneous fashion.

above) were considered major breaches/misplacements. The assessment was performed by two independent observers.

Surgical workflow

To facilitate a better understanding of the surgical workflow, different intra-operative situations are displayed in *Figure 1*, while the operating room setup is displayed in *Figure 2*. After induction of general anaesthesia patients are flipped over into prone position on a carbon fibre table. The head is fixed in a radiolucent Mayfield-clamp (DORO® LUCENT, Pro Med Instruments GmbH, Freiburg, Germany). The spinous process of the lowest vertebra to be fused is identified under fluoroscopy. A small mid-line incision of approximately 3 cm is marked above the spinous process, followed by disinfection, and draping in standard fashion. It is vital to disinfect the skin up to the far lateral, almost ventral aspects of the neck since the entry points of the screws will be about 5 cm away from the mid-line.

After incision of the skin and paramedian fascia subperiosteal dissection of the neck muscles is performed to expose the targeted spinous process. A reference array is firmly attached to the spinous process (*Figure 1A*) and the surgical site is covered with sterile draping material.

The patient is rotated into the iCTs gantry (*Figure 2*) (AIRO®, Stryker Corporation, Kalamazoo, MI, USA) followed by the acquisition of the 3D dataset by the fully-fledged 32-slice helical CT-scanner. The data is transferred

to the CAS Planning station (Brainlab Curve®, Brainlab, Feldkirchen, Germany) and the surgery table is rotated out of the gantry, back into surgery-position.

After verification of adequate precision of the navigation dataset, skin incision points are determined in perfect trajectory of the screw using a navigated stylus. A 2-cm skin incision is performed and the cervical superficial fascia opened sharply. The muscles are dissected bluntly to gain access to the facet joints. Now the navigated drill-guide (Aesculap® Ennovate® MIS, B. Braun) is inserted and navigated pediculation is performed using a high speed drill (Colibri II, Synthes GmbH, Zuchwil, Switzerland) and a 2.6-mm drill-bit (Aesculap® Ennovate® MIS, B. Braun) (*Figure 1B*). K-wires are inserted. We usually start at the vertebrae most distant from the reference array since manipulation can cause inaccuracies of the navigation dataset. K-wires are implanted in all desired pedicles before screw insertion, also minimising manipulation.

The MIS system offers different dilators to insert the screw with minimal manipulation. Self-tapping cannulated extended tab pedicle screws (3.6–4.5 mm) are inserted, guided by the K-wires. The system is equipped with extra sheaths to stabilise the polyaxial screw heads (*Figure 1C*) until rod implantation to minimise the force necessary to release the screw since the extended tap is quite thin. Rods in diameter 3.6 or 4.0 mm can be implanted in standard MIS fashion (*Figure 1C*). Before final implantation of the rods a second intraoperative CT scan is performed to assess screw trajectories and perform corrections if necessary.

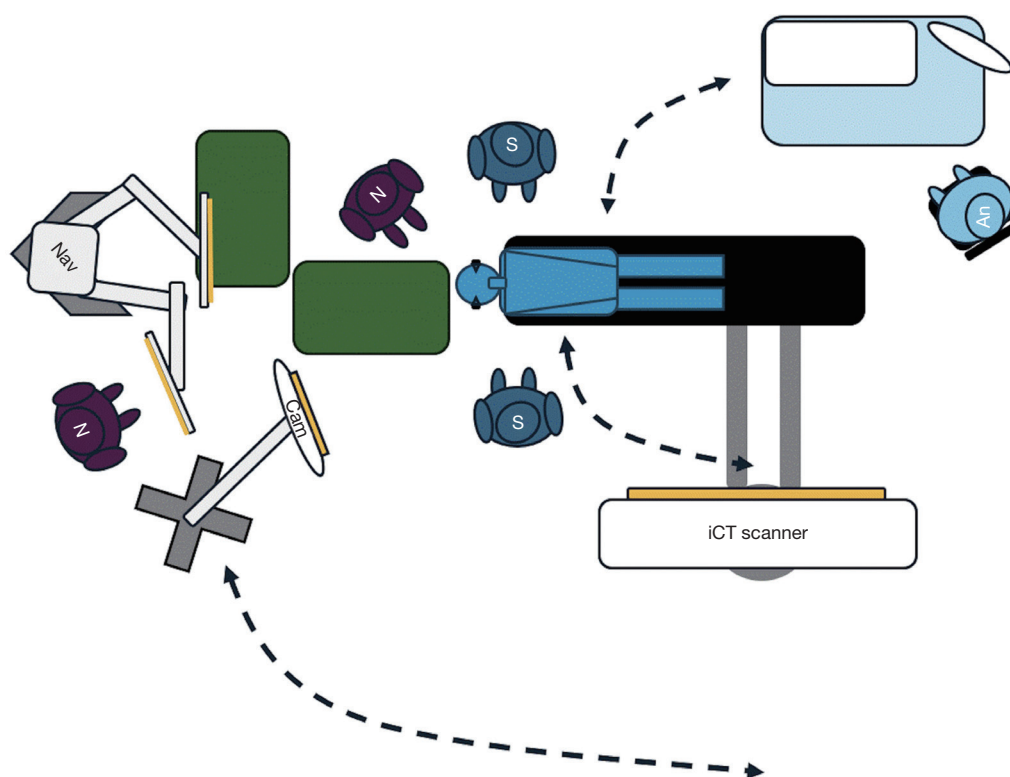


Figure 2 Display of the intraoperative setup. Dotted lines represent the change in setup during CT scans. As the carbon OR-table is rotated, anesthesiologic equipment and Cam are also moved. All personnel leaves the OR during CT scan. Patient can be monitored from outside via telemetrics and camera. S, surgeon; N, OR-nurse; An, anaesthesiologist; Nav, navigation; Cam, infrared camera; iCT, intraoperative computed tomography; OR, operating room; CT, computed tomography.

(Figure 3A).

Follow up is performed by clinical assessment and biplanar X-ray as depicted in Figure 3B,3C.

Statistical analysis

Descriptive statistics are depicted as mean \pm standard deviation (SD), absolutes or percentages respectively.

Institutional board approval

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of RWTH Aachen faculty of medicine for the department of neurosurgery at RWTH Aachen University Hospital (No. EK 23-230). An informed consent regarding this retrospective analysis was not deemed necessary by the ethics committee as all procedures were indicated following clinical standard.

Results

Description of the study group

This study, conducted from January to July 2023, included 10 patients who underwent minimally invasive cervical dorsal instrumentation. Among the patients, there were 5 males and 5 females, with a mean age of 62.4 ± 19.2 years. For additional details on the baseline group characteristics, see Table 1.

Descriptive analysis of the surgical procedures

All patients underwent dorsal fixation across two vertebrae (from 1 up to 4 segments) and were each fitted with 4 MIS transpedicular screws. The cervical disorders comprised 2 pathological, 4 degenerative and 4 trauma cases (see Table 2). Of the total 40 screws, 32 (80%) were placed with excellent accuracy, classified as Gertzbein & Robbins (G&R) Grade A. Additionally, 4 screws (10%) were acceptably positioned,

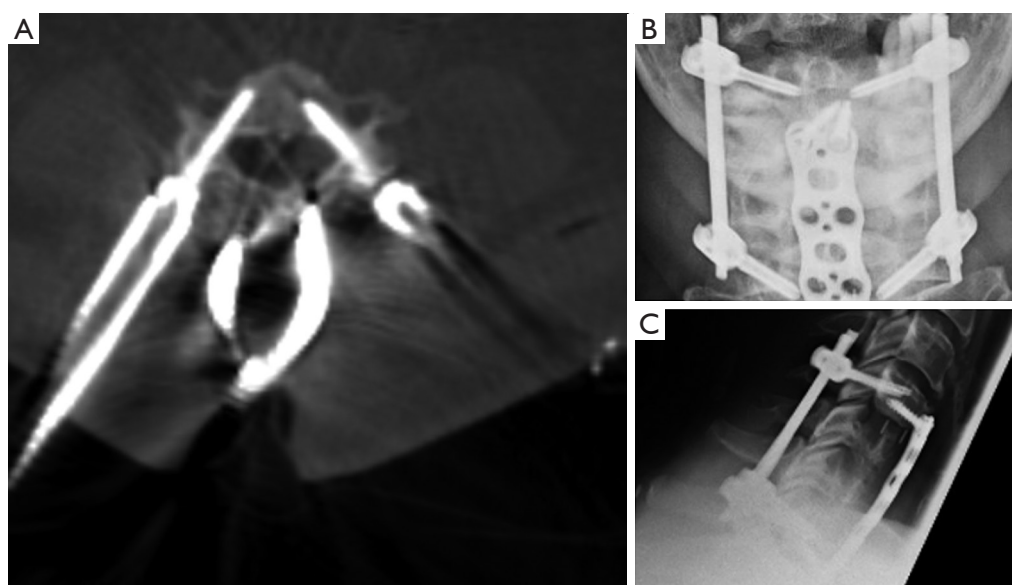


Figure 3 Examples of intra and postoperative radiographical assessment. (A) Accuracy of screw placement is usually assessed intraoperatively before rods are implanted. In this case at level C4. The reference was also attached to the spinous process of C4. (B,C) Are examples of postoperative radiograms of a patient that received percutaneous dorsal fixation due to minor bone quality following ventral 2-level corporectomy in a case of degenerative cervical myelopathy.

Table 1 Baseline characteristics showing demographics and major comorbidities of our ten patients

Characteristic	Values
Age (years)	62.4±19.2
BMI (kg/m ²)	27.6±3.9
ASA score	2.7±0.48
Diabetes	1 [10]
High blood pressure	5 [50]
Nicotine abuse	2 [20]
Malignancy	3 [30]

Data are presented as mean ± SD or n [%]. BMI, body mass index; ASA, American Society of Anaesthesiologist; SD, standard deviation.

aligning with G&R Grade B, while 4 screws (10%) were categorised as G&R Grade C (see *Table 3* and *Figure 4*). There was no mechanical need for revision of any screws since the other screws were either optimally or acceptably placed.

Adverse events

In a singular instance (patient number 9) a patient showed

postoperative deterioration of motor function, however it was not related to a screw misplacement. MRI diagnostics indicated the absence of bleeding or new spinal cord injury, implying that it was most probably a decompression-related occurrence or associated with positioning of the patient. In two cases (patient number 2 and 8), the bony boundary of the transverse foramen was affected. However, there was no damage to the vertebral artery or cerebral perfusion. Additionally, the affected patients showed no signs of neurological deficits, obviating the need for revision surgery.

Discussion

This study aimed to assess accuracy and feasibility of a new dorsal percutaneous instrumentation system for the cervical spine.

We achieved an optimal accuracy for 80% of iCT navigated CPS placement using a true MIS approach and an acceptable accuracy rate of 90% in total. For open surgical, iCT navigated insertion of CPS, accuracy rates of around 93% can be found in the literature (9). In this small cohort of patients, no major complication was observed. Due to the proximity of vital vascular, as well as neuronal

Table 2 Surgical disease and demographic characteristics for each patient

Patient No.	Disease	Previous anterior treatment	Age (years)	Gender	ASA score	BMI (kg/m ²)	Time of surgery (min)	Length of stay (days)
1	Pathological fracture	None	69	Male	3	32	106	3
2	Pathological fracture	Corpectomy C6, vertebral body replacement, anterior plate C5–7	64	Female	3	35	75	5
3	Degenerative	Corpectomy C5+6, vertebral body replacement, anterior plate C4–7	63	Male	3	28	103	5
4	Traumatic	Corpectomy C6, vertebral body replacement, anterior plate C5–7	43	Female	3	25	89	5
5	Traumatic	ACDF C6/7, anterior plate C6–7	77	Male	3	29	88	9
6	Degenerative	Corpectomy C4+5, vertebral body replacement, anterior plate C3-6	61	Female	3	22	75	10
7	Traumatic	Corpectomy C6, vertebral body replacement, anterior plate C5–7	17	Male	2	23	91	14
8	Degenerative	ACDF C3/4, anterior plate C3–4	79	Female	2	27	55	6
9	Degenerative	Corpectomy C5+6, vertebral body replacement, anterior plate C4–7	76	Female	3	27	70	14
10	Traumatic	ACDF C6/7, anterior plate C6–7	75	Male	2	28	109	4

ASA, American Society of Anaesthesiologist; BMI, body mass index; ACDF, anterior cervical discectomy and fusion.

Table 3 Screw diameter (in mm) and Gertzbein & Robbins grade (in brackets) (A: perfect trajectory; B: perforation ≤ 2 mm; C: >2 mm, ≤ 4 mm) for each patient

Patient No.	Screw diameter in mm (Gertzbein & Robbins grade)											
	C3		C4		C5		C6		C7		T1	
	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	left
1	–	–	–	–	–	–	4 (A)	4 (A)	–	–	4.5 (A)	4.5 (A)
2	–	–	–	–	4 (A)	4 (C)	–	–	4.5 (A)	4.5 (A)	–	–
3	–	–	3.6 (A)	3.6 (A)	–	–	–	–	4.5 (A)	4.5 (A)	–	–
4	–	–	–	–	3.6 (A)	3.6 (B)	–	–	4.5 (A)	4.5 (A)	–	–
5	–	–	–	–	–	–	4 (A)	4 (A)	4 (A)	4 (A)	–	–
6	3.6 (A)	3.6 (C)	–	–	–	–	–	–	3.6 (A)	3.6 (A)	–	–
7	–	–	–	–	3.6 (A)	3.6 (B)	–	–	3.6 (A)	3.6 (A)	–	–
8	3.6 (A)	3.6 (B)	3.6 (A)	3.6 (C)	–	–	–	–	–	–	–	–
9	–	–	3.6 (A)	3.6 (C)	–	–	–	–	4 (A)	4 (A)	–	–
10	–	–	–	–	–	–	4 (A)	4 (B)	4 (A)	4 (A)	–	–

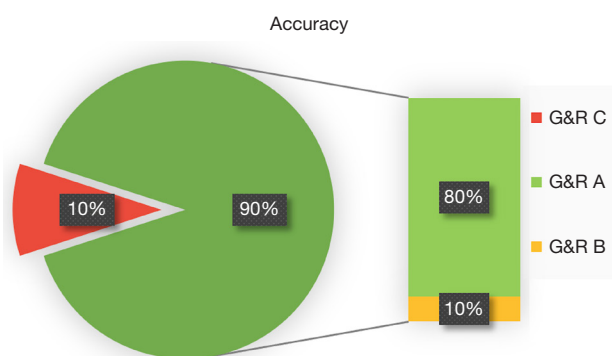


Figure 4 Accuracy of minimally invasive cervical pedicle screw placement according to G&R grade (A: perfect; B: perforation ≤ 2 mm; C: > 2 mm, ≤ 4 mm). The red color illustrates the percentage of screws considered misplacements (grade $\geq C$). The percentage of acceptably placed screws is illustrated in dark green (G&R A+B). G&R, Gertzbein & Robbins.

structures CPS implantation can be associated with fatal complications. Despite the fact that the technique itself reaches back to the early 1990s, a first regular clinical implementation came only after the introduction of intra-operative image-guided navigation. Percutaneous pedicle screw placement of the cervical spine is still not clinical standard and data on attempts to use regular C-spine instrumentation systems in a MIS fashion is rare (13,14). However, percutaneous instrumentation techniques of the thoracolumbar spine have yielded favourable results regarding general surgical complication rates, infection rates and blood loss, especially in oncological patients and are associated with shorter hospital stay compared with open surgery (15). To our knowledge, the above-mentioned MIS platform is the only off-the shelf, full-MIS system for dorsal fixation system of the C-spine applicable for all navigation platforms.

The surgical workflow is intuitive and easily adoptable by surgeons who are familiar with percutaneous instrumentations of the spine. However, a certain level of experience in navigated CPS placement is strongly advised before considering percutaneous CPS placement even if aided by intra-operative CT guidance. The haptic feedback is very limited compared with thoracolumbar instrumentations, since any force applied to the lateral aspect of the facet-joints might cause a rotation of the vertebra and have lateralisation of the screw trajectory towards the transverse foramen. In our case series most patients received ventral fusion prior to dorsal MIS

instrumentation. Consequently, local mobility of the spine might have been reduced, aiding a safe implantation of the pedicle screws.

Our case series is limited in size, therefore we cannot draw conclusions regarding any clinical profit for the patients that undergo dorsal MIS fixations of the cervical spine using our technique. The aim of this study was to showcase this new technique and its feasibility, however larger comparative series are needed to evaluate advantages in relation to risk.

Conclusions

In the hands of an experienced spine surgeon the MIS platform offers a great toolkit for percutaneous dorsal fixation of the C-spine. Our early case-series demonstrates acceptable accuracy rates and an intuitive workflow. Percutaneous CPS placement is a feasible and safe surgical procedure in a well selected collective of patients. However, larger series are needed to evaluate advantages and risk ratios.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://jss.amegroups.com/article/view/10.21037/jss-24-45/rc>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of RWTH Aachen faculty of medicine for the department of neurosurgery at RWTH Aachen University Hospital (No. EK 23-230). An informed consent regarding this retrospective analysis was not deemed necessary by the ethics committee as all procedures were indicated following clinical standard.

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