Medtronic
Engineering the extraordinary

O-arm™ intraoperative imaging and StealthStation™ surgical navigation

Value Summary

Table of content

Executive summary

Instrumented spine surgery: burden and unmet needs

Instrumented spine surgery uses a variety of implantable hardware such as pedicle screws, wires, plates, cages and/or interbody devices to stabilize the spine. It is indicated in conditions such as degenerative diseases, spinal deformities, traumatic injuries, and tumors.[1-8]

Accurate placement of surgical hardware is a major challenge in instrumented spine surgery due to the proximity of the spinal cord, vertebral artery, and nerves to the pedicle of each vertebra.[9, 10] Advancements in image-guided techniques, together with optics and video equipment, have made accurate placement of pedicle screws and other implantable hardware more easily achievable both in conventional open surgery and in minimally invasive approaches.[7, 8, 11]

Intraoperative 2D fluoroscopy without navigation is the most common image guidance technique;[5, 12] however, screw placement accuracy is limited by the absence of 3D information and the lack of real-time tracking of instrumentation relative to patient anatomy.[7,13] Techniques without navigation can lead to screw placement inaccuracy and the need for revision surgery (0.8–5.2 % of patients undergoing instrumented spine surgery), increasing the humanistic and economic burden of spinal surgery.[5, 12-15] Screw misplacement can lead to serious complications such as nerve root injury and spinal cord infarction, which can potentially result in paralysis, hemorrhage, pseudoaneurysm, pain, hematoma, infection, and perforations of internal organs (i.e. lung, ureter, gut, or the esophagus).[16-22] In addition, fluoroscopy is associated with concerns about surgical site infections and radiation exposure to both surgical staff and patients.[8, 23]

There is an unmet need for an intraoperative surgical system that improves accuracy of screw placement, minimizing the need for revision surgery and the clinical and economic burden associated with spine surgery complications, and reduces radiation exposure to patients and staff during procedures.

Advancements in surgical imaging and navigation: Medtronic O-arm™ surgical imaging and StealthStation™ navigation systems

O-arm™ surgical imaging and StealthStation™ navigation systems provide an easy-to-use and complete solution for instrumented spine surgery. The O-arm™ system is a multidimensional, intraoperative surgical imaging system that produces real-time 3D and multiplane 2D images to facilitate clinical decision-making. The StealthStation™ system is an advanced navigation system integrating real time intra-procedural images and displaying them on a screen to facilitate instrument navigation.

The O-arm™ surgical imaging and StealthStation™ navigation systems offer a streamlined workflow for the entire surgery. Automatic registration and data transfer, memory position of the robotic gantry, and full integration of Medtronic instruments and powered tools simplify the navigation process in order to increase screw placement accuracy and safety,[3, 7, 12, 24, 25] even in more complex cases.[2, 24] In addition, O-arm™ surgical imaging and StealthStation™ navigation systems eliminate the need for fluoroscopy and reduce radiation exposure for surgeons and surgical staff.[26-29]

Clinical value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

The O-arm™ surgical imaging and StealthStation™ navigation systems significantly improve screw placement accuracy in instrumented spine surgery compared with other current practice options.[8, 11, 14, 25, 28, 30-34] The O-arm™ intraoperative imaging and StealthStation™ navigation systems are associated with higher rates of safe (defined as pedicle violation <2 mm) screw placement (95.5–99.7%) compared with other current practice options (78.5–96.3%).[11, 14, 25, 28, 31, 32]

Misplaced screws can be corrected intraoperatively during the index procedure with the O-arm™ surgical imaging and StealthStation™ navigation systems, avoiding the need for additional revision surgery.[2, 8, 24, 35, 36]

The O-arm™ surgical imaging and StealthStation™ navigation systems reduce radiation exposure for surgeons, staff,[27, 28, 37, 38] and patients[8, 39] by eliminating the need for fluoroscopy and minimizing the cumulative radiation dose.

Humanistic value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

The use of O-arm™ surgical imaging and StealthStation™ navigation systems significantly improves post-operative patient reported outcomes for disability (Oswestry Disability Index [ODI]) and leg and back pain (Visual Analogue Scale [VAS]) compared with fluoroscopy.[7, 31, 40]

Economic value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

The O-arm™ surgical imaging and StealthStation™ navigation systems may provide a cost-saving investment for hospitals and healthcare systems by improving screw placement accuracy and minimizing the need for revision surgeries,[12, 41, 42] decreasing radiological expenditure,[30] and reducing procedure times.[14, 39, 43-45]

Clinical picture – Spine surgery

Instrumented spine surgery is performed to stabilize the spine using a variety of implantable hardware such as pedicle screws, wires, plates, cages or interbody devices. Instrumented spine surgery is indicated in children or adults with conditions such as degenerative diseases, trauma, spinal deformities, and tumors.[1-8]

Accurate placement of surgical hardware is a major challenge in instrumented spine surgery due to the proximity of the spinal cord, vertebral artery, and nerves to the pedicle of each vertebra.[9, 10] Advancements in image-guided techniques, together with optics and video equipment, have made accurate placement of pedicle screws and other implantable hardware more easily achievable, both in conventional open surgery and in minimally invasive approaches.[7, 8, 11, 37]

The incidence of spine surgery has increased in Europe, US, and Asia over the last three decades; the increased prevalence of osteoporosis and degenerative spine diseases among aging populations is partly responsible for this trend.[46-50]

Instrumented spine surgery

Instrumented spine surgery is a means of stabilizing the spine or correcting spinal alignment using implantable hardware.[2, 5] Spine fixation surgery is indicated when conservative therapy (i.e. analgesic treatment and physical therapy) fails, for the management of a range of conditions in both children and adults, including degenerative diseases, traumatic injuries, tumors, and spinal deformities (**Table 1**).[1-8, 28]

Table 1.

Indications for instrumented spine surgery

Spinal deformities	Degenerative diseases	Trauma	Tumor
• Scoliosis • Kyphosis • Kyphoscoliosis • Lordosis • Spondylolisthesis	• Slipped or herniated disc • Stenosis • Osteoarthritis • Spondylosis • Spondylolisthesis	• Spinal fracture and dislocation • Osteoporosis	• Primary spinal tumors • Metastases

References: [3, 5, 6, 9, 31]

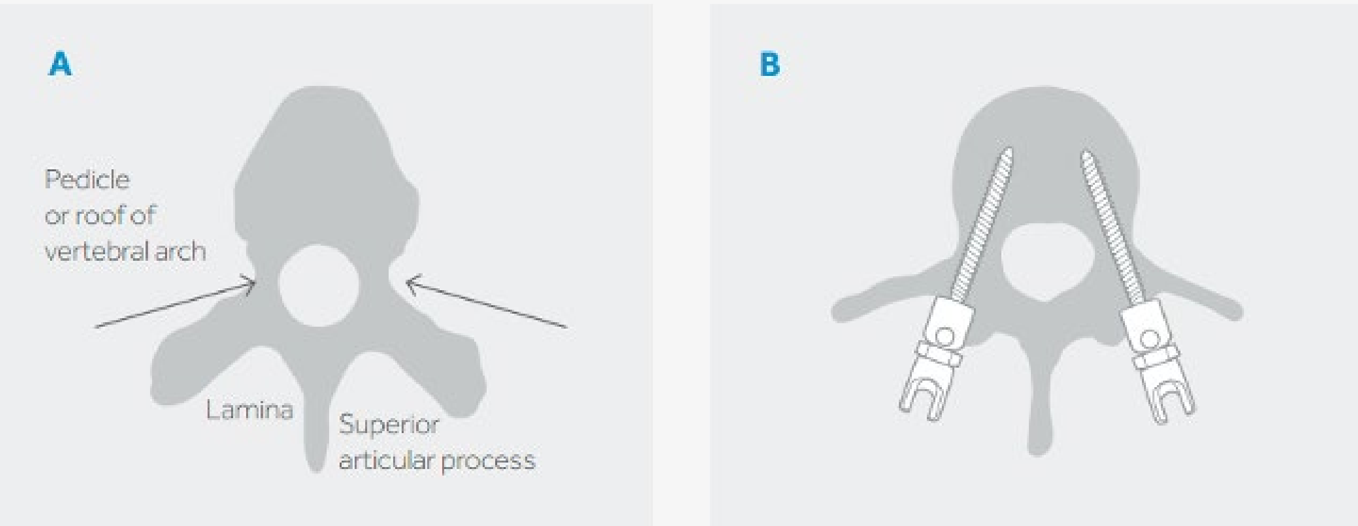
Surgical instrumentation used in spine fixation procedures includes screws, wires, cages, hooks, and interbody devices.[5] Depending on the spinal region, additional hardware can be used, including lateral mass screws and transarticular screws for the atlantoaxial joint in the cervical region, and sacroiliac screws for the pelvic region.[9, 10, 29]

Among implantable hardware, pedicle screws are the mainstay of instrumented spine surgery (**Figure 1**).[8] Anatomically, pedicles are the short appendages that project from each side of a vertebra, with spinal nerves exiting the cord under each pedicle (**Figure 1**). Due to the proximity of the spinal cord, vertebral artery, and spine roots to pedicles, accurate screw placement is a major challenge in instrumented surgery.[9,10]
The use of conventional open surgery for spine procedures is associated with severe complications such as muscle dissection and blood loss.[7,8,11] Minimally invasive surgery (MIS) has been developed to achieve the same clinical outcomes as open surgery, while minimizing the muscle dissection required to expose and visualize anatomical landmarks,[7] therefore preserving midline ligamentous structures and reducing blood loss, post-operative pain, and length of hospital stay.[8]

To enable visualization of unexposed spinal structures, minimally invasive approaches build on advances in optics and video equipment, together with image guidance techniques.[8] Many instrumented open spinal procedures can be performed using a minimally invasive approach.[37] Vertebroplasty and kyphoplasty procedures can also be performed as MIS, using image guidance for accurate pedicle needle insertion.[37,51]

Figure 1.

Illustration of the pedicle of a vertebra (A) and pedicle screw insertion (B)



Epidemiology

Evidence from the US, Europe, and Japan shows that the incidence of spine surgery has increased over the last three decades in part due to the increased prevalence of osteoporosis and degenerative spine diseases (e.g. stenosis, osteoarthritis, and disc degeneration) among aging populations.[46-50]

A retrospective study in the US reported an 88% increase in spinal fusion procedures between 1998 (74 per 100,000 persons) and 2014 (139 per 100,000 persons).[49] This upward trend was maintained in patients >65 years of age.[49] The rate of surgical correction of deformity in the US was forecast to increase by 87.9% by 2030 and 143.0% by 2040, compared with 2014 rates.[48] Among primary surgeries for lumbar spinal stenosis, single spinal fusions increased from 35.3% to 47.2% from 2010 to 2014 and complex fusions from 5.7% to 7.1%, while decompressions decreased from 47.5% to 34.6%, based on an analysis of administrative data.[52] A shift in the healthcare setting of spinal surgeries was also reported in the literature, with the incidence of outpatient procedures increasing almost 10% from 2013 (13.6 per 100,000 persons) to 2014 (14.8 per 100,000 persons).[53]

In Europe, a retrospective study in the UK reported a significant two-fold increase in surgeries for degenerative lumbar spine disease between 1999 and 2013 (from 24.5 to 48.8 cases per 100,000 persons), with procedures in patients aged ≥60 years increasing 2.8-fold.[50] The number of spinal implant procedures in Europe is predicted to expand with a compound annual growth rate (CAGR) of 3.5% between 2019 and 2030,[47] although the COVID-19 pandemic may have affected estimations of market fluctuations (Table 2).[47]
In Japan, a retrospective study found a 2.4-fold increase in spinal surgeries between 2003 and 2017, with instrumented surgeries increasing 2.3-fold.[46]

Table 2.

Forecast market growth for spinal implant procedures in Europe

	CAGR (2019-2030), %					
	France	Germany	Italy	Spain	UK	Overall
Total spinal implant procedure	3.8	3.6	3.5	2.3	2.8	3.5
Thoracolumbar procedures	4.3	3.1	3.8	2.1	2.4	3.4
Cervical procedures	3.0	4.7	2.7	3.0	3.8	3.7

Abbreviation: CAGR, compound annual growth rate.
Source: Clarivate, Spinal implants. Market insights. 2022.[47]

Burden – Complications of spine surgery

Clinical burden

Screw misplacement can lead to serious complications, such as nerve root injury and spinal cord infarction, which can potentially result in paralysis, hemorrhage, pseudoaneurysm, pain, hematoma, infection, and perforations of internal organs (i.e. lung, ureter, gut, or the esophagus).[16-22]

Revision surgery to correct screw misplacement is associated with high morbidity.[35, 54, 55] Compared with the index procedure, revision surgery is associated with an increased risk of central nervous system complications, infection, and hematoma in patients with spinal deformities.[54, 56]

Economic burden

[ex-US] Spinal surgery is associated with a high economic burden, largely driven by the costs of managing complications, including revision surgery.[57, 58] Revision procedures are associated with additional healthcare resource utilization and costs from the payer perspective, with a cost analysis in Belgium reporting a mean cost increase of 87.6% for revision surgeries compared with the index procedure.[59]

[US] Spine surgery has a high impact on health insurance budgets in the US, primarily driven by the cost and consequences of complications, including revision surgery.[60] Among Medicare patients undergoing cervical spinal fusion, 6.1% experienced at least one complication, with infection and revision procedures leading to increased costs (+$15,998) and length of hospital stay (+4.8 days).[60]

Clinical burden

Misplacement of pedicle screws and other instrumentation can occur during instrumented spinal surgery (**Figure 2**), often due to a lack of intraoperative visual access, which not only impairs localization and visualization of anatomical structures but also confirmation of screw placement at the end of the procedure.7 Fluoroscopy based image guidance was associated with screw misplacement rates of up to 13.1% in surgeries performed between 2014 and 2020.[61]

While screw misplacement is infrequent and mostly asymptomatic[35] it can lead to severe damage to the surrounding nerves and tissues and serious, burdensome complications requiring revision surgery.[9, 35, 51] Complications from screw misplacement may be acute or delayed, temporary or permanent depending on whether damage occurs to vasculature,[7, 35, 62] the spinal cord, or nerves in proximity to the vertebral structures targeted in spine fixation surgery.[9, 10, 35] A rupture of the aorta can result in potentially lethal hemorrhage or pseudoaneurysm.[16-19] Neurological complications include nerve root injury and spinal cord infarction, potentially resulting in paralysis.[20-22] Other complications of screw misplacement include pain, hematoma, infection, and perforations of internal organs (i.e. lung, ureter, gut, or the esophagus).[17, 22] Screw misplacement can lead to considerable clinical and humanistic burden on patients.[58] Rates of intraoperative and post-operative complications from screw misplacement are presented in **Table 3**. If screw placement accuracy is not verified intraoperatively, revision surgery may be required.[35, 54, 55] The incidence of misplaced screws with conventional fluoroscopy that required revision surgery ranged from 0.8% to 5.2%, in three studies on lumbar spine fusion performed between 2014 and 2020.[61] Revision surgery is associated with high morbidity,[54] and in patients with spinal deformities, has been associated with an increased risk of central nervous system (CNS) complications, infection, and hematoma compared with the index procedure.[54, 56]

Table 3.

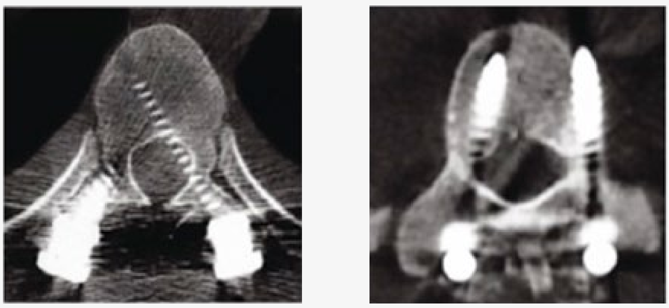
Rates of complications due to screw misplacement

Complication	Rate	Surgery indication	Study period	Reference
Intraoperative				
Neurological injury	9–16%	PLIF	2014-2016	Wang et al 2019[14]
Transient neuropraxia	2%	Transpedicle instumentation fixation	1990-1999	Wang et al 2005[63]
Dural tear	5.4–10%	PLIF	2014-2016	Wang et al 2019[14]
CSF leak	4%	Transpedicle instrumentation fixation	1990–1999	Wang et al 2005[63]
Spinal cord infarction	0.75%	Anterior exposure of thoracolumbar spine	1985-2002	Orchowski et al 2005[21]
Post-operative				
Instrumentation failure	3–12%	Transpedicle instrumentation fixation	1990–1999	Wang et al 2005[63]
Permanent root injury	2%	Transpedicle instrumentation fixation	1990–1999	Wang et al 2005[63]
Deep tissue infection	1.5%	Posterior instrumented spinal fusion	Systematic review (studies from 1995–2021)	Freire-Archer et al 2023[62]

Abbreviations : CSF, cerebrospinal fluid; PLIF, posterior lumbar interbody fusion.

Figure 2.

Examples of pedicle screw misplacement resulting in perforation of the median wall (A) and both median and lateral walls (B)



A. Perforation of canal

A. Perforation of lateral pedicle

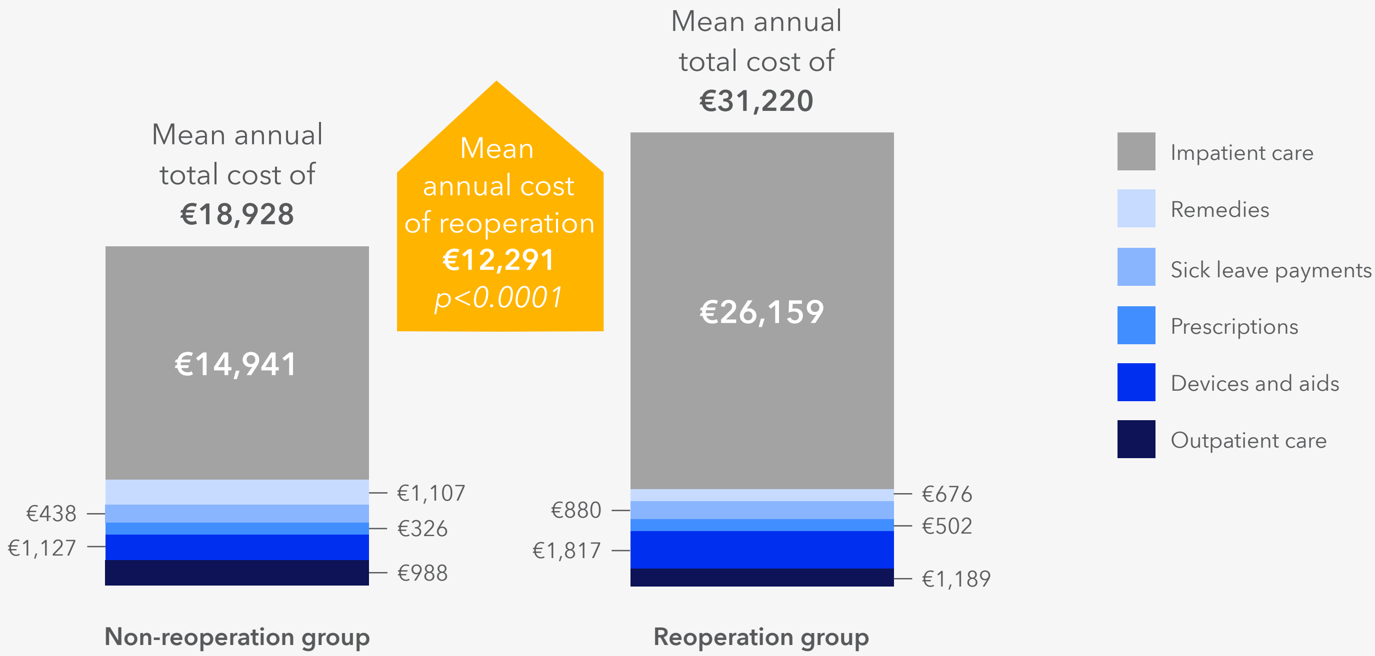
Economic burden (ex-US)

Spinal surgery is associated with a high economic burden, largely due to the costs of managing complications, including revision surgery.[57, 58] A retrospective study of patients undergoing posterior instrumented spine surgery in Canada highlighted the association between complications and increased healthcare resources utilization (HCRU). Patients with longer hospital stays were significantly more likely to have experienced complications and less likely to have undergone MIS than those with shorter hospital stays ($p<0.001$ each).[57]

Revision surgery is associated with additional resource utilization and costs from the payer perspective.[58, 59, 64] Among adult patients with spinal deformity in Belgium, reoperations were associated with a mean cost increase of 87.6% compared with the index procedure (€44,907±23,429 vs €23,944±7,302).[59] The mean annual cost of reoperation following instrumented spine surgery in Germany was estimated at €12,291 (2010 prices), highlighting the impact of revision surgery on health insurance budgets.[58] The mean combined cost of index and revision surgery in patients who underwent reoperation was €31,220 over the 12 months following primary surgery, compared with a mean annual cost of €18,928 in patients who did not undergo reoperation ($p<0.0001$) (**Figure 3**).[58] This significant cost increase was primarily due to inpatient HCRU and the requirement for additional devices and aids (**Figure 3**).[58] Direct medical costs for reoperation in the 12 months after the first surgery were 18.4%, 18.9%, and 21.2% higher than for the index procedure for instrumented dorsolumbar fixation, scoliosis, and cervical surgery, respectively, in a cost analysis performed in Spain.[64]

Figure 3.

Mean direct and indirect costs in the 12 months following instrumented spine surgery with and without reoperation (Germany, 2010 prices).



Adapted from Jacob et al 2016.[58]

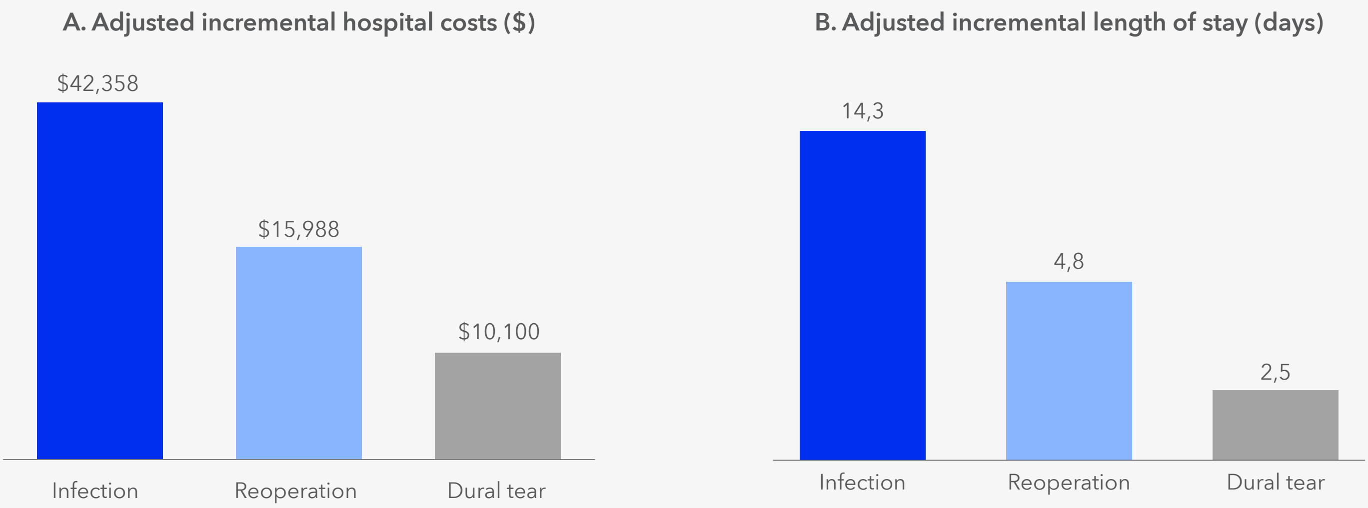
Economic burden (US)

Spine surgery has a high impact on health insurance budgets in the US.[60] In the Medicare program, which provides medical insurance to individuals >65 years old or with a disability, spinal fusion surgery was among the highest admission expenditures in 2013, with reimbursement to hospitals exceeding $3.6 billion.[60]

The economic burden associated with current practice in spinal surgery is primarily driven by the cost and consequences of complications, including reoperation.[60] A retrospective analysis showed that among Medicare patients undergoing cervical spinal fusion, 6.1% experienced at least one complication, including infection, dural tear, and/or revision surgery.[60] Patients with complications following surgery experienced significantly longer hospital stays (+9.1 days, p<0.001) and higher costs (incremental cost of $28,638 [2014 prices], p<0.001) compared with those without complications (**Figure 4**).[60]

Figure 4.

Adjusted incremental hospital costs (A) and length of stay (B) estimates in patients experiencing complications following spine surgery in the US



Multivariate regression model (controlled for demographic characteristics, comorbidities, surgical approach, and complications) estimates of incremental costs and length of stay in Medicare patients with complications vs patients without complications. All estimated incremental values are statistically significant (p<0.001). Costs are based on 2014 prices.
Adapted from Culler et al 2017.[60]

Limitations of current practice and unmet needs

Intraoperative 2D fluoroscopy without navigation is the most common image guidance technique;[5, 12] **however, screw placement accuracy is limited** by the absence of 3D information and the lack of real-time tracking of instrumentation relative to patient anatomy.[7, 13] There are also concerns about the risk of surgical site infections and radiation exposure to surgical staff.[8, 23]

Non-navigated surgical imaging techniques can lead to screw placement inaccuracy and the need for revision surgery, increasing the humanistic and economic burden of spinal surgery.[5, 12-15]

There is an unmet need for an intraoperative surgical solution that improves accuracy of screw placement, minimizing the need for revision surgery and the clinical and economic burden associated with spine surgery complications, and reduces radiation exposure to patients and staff during procedures.

Image guidance techniques can be used during instrumented spine surgery to ensure accuracy of pedicle screw placement, with or without surgical navigation.[13, 14, 65] Commonly used image guidance techniques include intraoperative 2D fluoroscopy (e.g. C-arm), intraoperative computed tomography (CT), and cone-beam CT (e.g. O-arm).[5, 39, 66]

Accurate pedicle screw placement is critical for avoiding post-operative complications, revision surgery and patient morbidity associated with screw misplacement. However, there is currently no consensus on the definition of clinically relevant pedicle screw misplacement. Most studies define safe screw placement when pedicle violation is ≤2 mm.[14, 25, 31, 67]

While intraoperative 2D fluoroscopy is the most common image guidance technique used in the absence of surgical navigation,[5, 12] screw placement accuracy is limited due to a lack of 3D information.[7, 13] Additionally, due to the observed partial sterility of its drape covering, an intraoperative C-arm imaging system is a potential source of contamination of the operative field (for example, while maneuvering the device to acquire various radiographic projections), and may carry a risk of surgical wound infection.[23]

Surgical navigation allows implantable instrumentation tracking in real-time, virtually overlaying information on patient anatomy and implants in the navigation system display, without this, surgeons are unable to identify and correct misplaced screws during the surgery.[13] Screw placement accuracy is reduced with non-navigated vs navigated instrumented spine surgery, potentially leading to complications and the need for revision surgery (**Figure 5**).[5, 12-15] Despite the benefits of surgical navigation, its use is not yet common practice for instrumented spine surgery.[15]

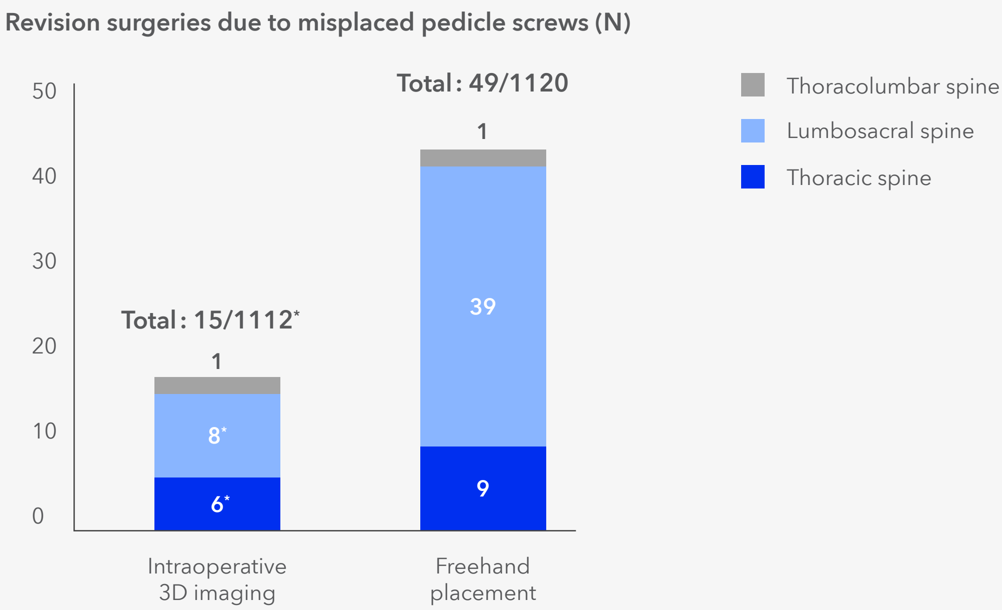
In addition, the exposure of patients and surgical staff to ionizing radiation during fluoroscopy-guided spinal surgeries remains a concern.[8] Repeated exposure of surgical staff to radiation during multiple surgeries can increase the long-term risk of cancer and cataract formation.[27, 38] Therefore, to avoid exceeding occupational radiation dose limits, surgical staff can only perform a limited number of procedures per year.

There is an unmet need for an intraoperative surgical system that:

- improves accuracy of screw placement and enables intraoperative correction of misplaced screws, minimizing the need for revision surgery and the clinical and economic burden associated with spine surgery complications, and
- reduces radiation exposure to patients and staff during procedures.

Figure 5.

Number of revision surgeries due to misplaced screws in freehand vs navigated instrumented spine surgery



*p<0.05 vs freehand placement.

Adapted from Fitchner et al 2018.[15]

Medtronic O-arm™ intraoperative imaging and StealthStation™ surgical navigation

The O-arm™ surgical imaging and StealthStation™ navigation systems provide an easy-to-use and complete solution for instrumented spine surgery. The O-arm™ system is a multidimensional, intraoperative surgical imaging system that produces real-time 3D and multiplane 2D images to facilitate clinical decision-making. The StealthStation™ system is an advanced navigation system integrating real-time intra-procedural images and displaying them on a screen to facilitate instrument navigation.

The O-arm™ surgical imaging and StealthStation™ navigation systems offer a streamlined workflow for the entire surgery. Automatic registration and data transfer, memory position of the robotic gantry, and full integration of Medtronic instruments and powered tools simplify the navigation process in order to increase screw placement accuracy and safety,[3, 7, 12, 24, 25] even in more complex cases.[2, 24] In addition, the O-arm™ surgical imaging and StealthStation™ navigation systems eliminate the need for fluoroscopy and reduce radiation exposure for surgeons and surgical staff.[26-29]

Product overview

The O-arm™ system is a multidimensional, intraoperative surgical system designed to provide surgeons with real-time 3D and multiplane 2D images during surgery (Figure 6). The 1st generation O-arm™ 1000 imaging system received 510(k) pre-market approval from the US Food and Drug Administration (FDA) in 2005 and CE mark approval in 2006. The 2nd generation O-arm™ O2 intraoperative imaging system has been available since April 2015 and provides a new low radiation dose algorithm, advanced imaging protocols (e.g. for Stereotaxis), an expanded field of view (FoV), and the option to preview the FoV. Since 2022, the O-arm™ surgical imaging system allows a 2D long film options which captures anteroposterior and lateral images up to 48 cm in length.

The StealthStation™ system is an advanced surgical navigation system that facilitates instrument navigation by integrating real-time, intraoperative images and displaying them on a screen (Figure 7, Figure 8). The current 8th generation, StealthStation™ S8, is reflecting 25 years of experience Medtronic in having in cranial, spinal, orthopedic, and ENT surgical navigation.

When used in combination, the O-arm™ surgical imaging and StealthStation™ navigation systems allow surgeons to navigate their instruments on the patient's unexposed anatomy. The combination of the two systems allows identification of the optimal incision point for MIS, facilitates surgical approach planning, and allows accurate screw placement and interbody fusions, while minimizing the risk of injury to neurovascular structures.[3, 7, 12, 24, 25] The combination of O-arm™ intraoperative imaging and StealthStation™ navigation systems provides easily accessible 3D image information to aid surgeons' decision-making, allowing clinicians to master more complex cases.[2, 24] When used together, the O-arm™ intraoperative imaging and StealthStation™ navigation systems provide a minimally invasive option for procedures that would normally require open surgery, while eliminating the need for fluoroscopy and reducing exposure to radiation for surgical staff.[26-29]

The O-arm™ surgical imaging system is a motorized device easily transported between operative rooms. Its O-shape forms a ring around the patient body while on the operating table, allowing the rotor in the gantry of the O-arm™ to rotate 360° around the patient to take 2D and 3D images without the risk of collision and, thanks to its tube cover, while remaining sterile. Its lateral opening (breakable gantry) allows the surgical staff lateral access to move around the patient, simplifying patient preparation and surgical workflow when compared with closed ring systems.

Figure 6.

O-arm™ intraoperative imaging system

Figure 7.

StealthStation™ S8 surgical navigation system

Figure 8.

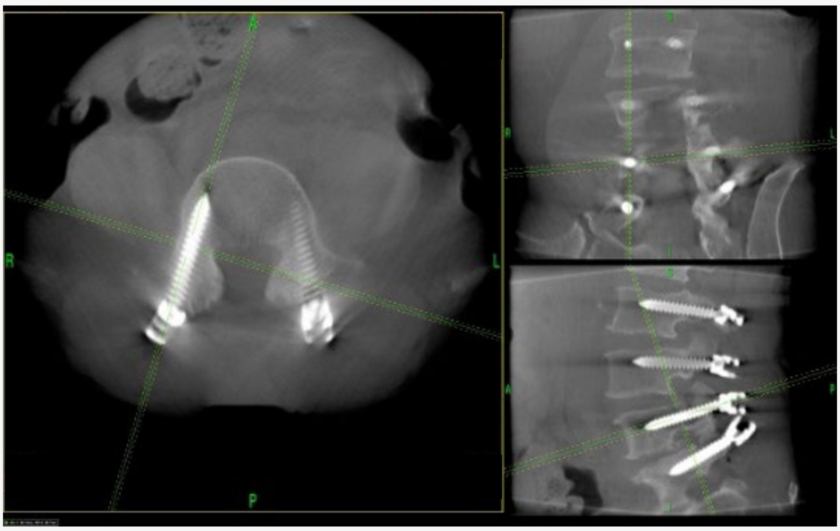
NavLock™ navigated spinal instrumentation

O-arm™ surgical imaging and StealthStation™ navigation workflow

Before surgery	
An alternative to CT or radiography	The O-arm™ surgical imaging system eliminates the need for pre-operative CT scans, leading to an overall reduction in patient radiation dose[8, 30, 39]
Intraoperatively	
An alternative to conventional, 2D or 3D fluoroscopy	When used in conjunction with the StealthStation™ navigation system, the O-arm™ intraoperative imaging system offers accurate and safe implant placement and use of associated instruments[8, 11, 12, 14, 25, 31]
Before closing	
To verify the accuracy of screw placement (Figure 9)	The O-arm™ intraoperative imaging and StealthStation™ navigation systems provide the opportunity to revise screw placement before leaving the operating room, potentially eliminating the need for revision surgery[2, 8, 24, 39, 68]
	The 2D long-film feature allows surgeons to verify implant placement and consider the functional alignment of the spine at the same time by accurately reconstructing ~12–16 vertebral levels in a single view[69, 70]

Figure 9.

O-arm™ intraoperative imaging system lumbar fusion confirmation scan



Abbreviations: CT, computed tomography.

Clinical value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

The O-arm™ surgical imaging and StealthStation™ navigation systems significantly improve screw placement accuracy in instrumented spine surgery compared with other current practice options.[8, 11, 14, 25, 28, 30-34] The O-arm™ intraoperative imaging and StealthStation™ navigation systems are associated with higher rates of safe (defined as pedicle violation <2 mm) screw placement (95.5–99.7%) compared with other current practice options (78.5–96.3%).[11, 14, 25, 28, 31, 32]

Misplaced screws can be corrected intraoperatively during the index procedure with the O arm™ surgical imaging and StealthStation™ navigation systems, thus avoiding the need for additional revision surgeries.[2, 8, 24, 35, 36]

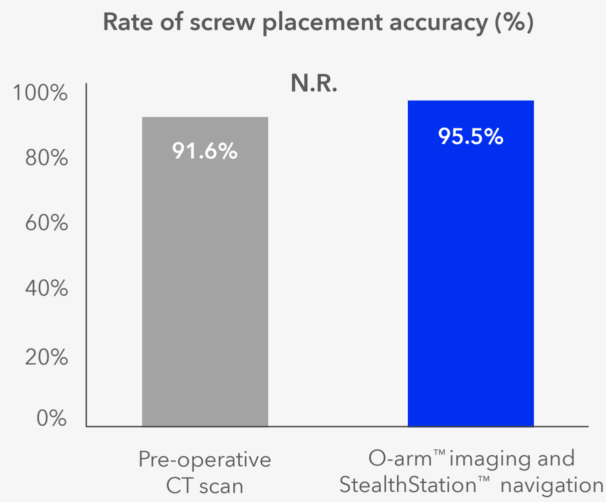
The O-arm™ surgical imaging and StealthStation™ navigation systems reduce radiation exposure for surgeons, staff,[27, 28, 37, 38] and patients[8, 39] by eliminating the need for fluoroscopy and minimizing the cumulative radiation dose.

Improved screw placement accuracy

The O-arm™ surgical imaging and StealthStation™ navigation systems significantly improve screw placement accuracy compared with current practice across multiple procedures, including overall instrumented spine surgery,[25, 30] MIS,[8, 31] posterior lumbar interbody fusion (PLIF),[14] transforaminal lumbar interbody fusion (TLIF),[11, 32] corrective scoliosis surgery,[28] and cervical spine fixation[33, 34] (**Figures 10–14 and Table 4**).

Figure 10.

Screw placement accuracy (no pedicle violation) in instrumented spine surgery with O-arm™ surgical imaging and StealthStation™ navigation vs pre-operative CT scan



Abbreviation: CT, computed tomography; N.R., p value not reported.

Data from Restelli et al 2022.[30]

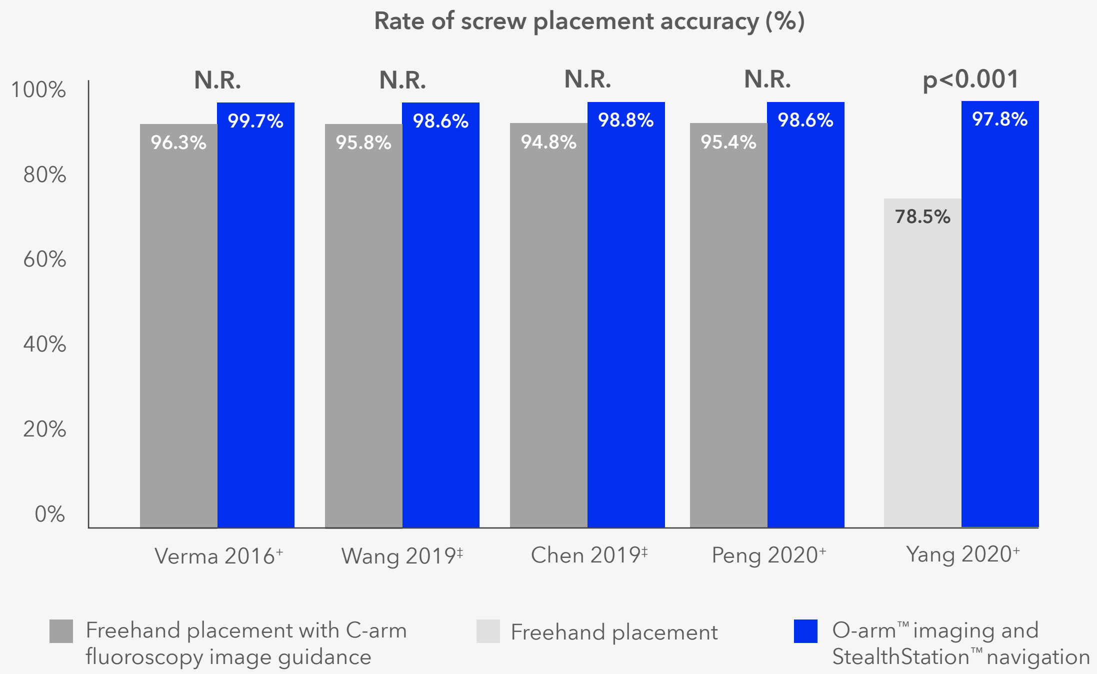
Note: Different accuracy rates might be reported in the literature. Such discrepancies are likely due to surgeon experience, level of training with the O-arm™ surgical imaging and StealthStation™ navigation systems, procedure type, indication and a lack of standardization between the grading scales used to assess pedicle screw placement.[5]

Higher pedicle screw placement accuracy in spine fixation surgery with the O-arm™ surgical imaging and StealthStation™ navigation systems (95.5–99.1%)[25, 30] was reported vs a pre-operative CT scan (91.6%, p value not reported)[30] (Figure 10 and Table 4) or C-arm fluoroscopy (96.3%, $p<0.05$)[25] (**Table 4**). The O-arm™ intraoperative imaging and StealthStation™ navigation systems were also associated with a higher rate of fully intrapedicular screws (96.9%) in patients undergoing PLIF compared with freehand screw placement using C arm fluoroscopy image guidance (88.7%, $p=0.004$) (**Table 4**).[14]

The O-arm™ surgical imaging and StealthStation™ navigation systems are consistently associated with significantly higher rates (97.8–99.7%)[25, 31] of clinically acceptable screw placement (pedicle violation <2 mm) in patients undergoing instrumented surgery compared with either freehand (78.5%, $p<0.001$)[31] or C-arm fluoroscopy-guided screw placement (96.3%, p value not reported)[25] (**Figure 11 and Table 4**). Higher rates of clinically acceptable screw placements were also reported in patients undergoing PLIF (98.6%)[14] or TLIF (98.8%)[32] with the O-arm™ surgical imaging and StealthStation™ navigation systems compared with C-arm fluoroscopy-guided screw placement (PLIF : 95.8%, TLIF: 94.8% ; p value not reported)[14, 32] (**Figure 11 and Table 4**).

Figure 11.

Rate of safely placed screws (pedicle violation <2 mm) with O-arm™ surgical imaging and StealthStation™ navigation vs freehand placement with or without C-arm fluoroscopy image guidance



Abbreviation : N.R., p value not reported.

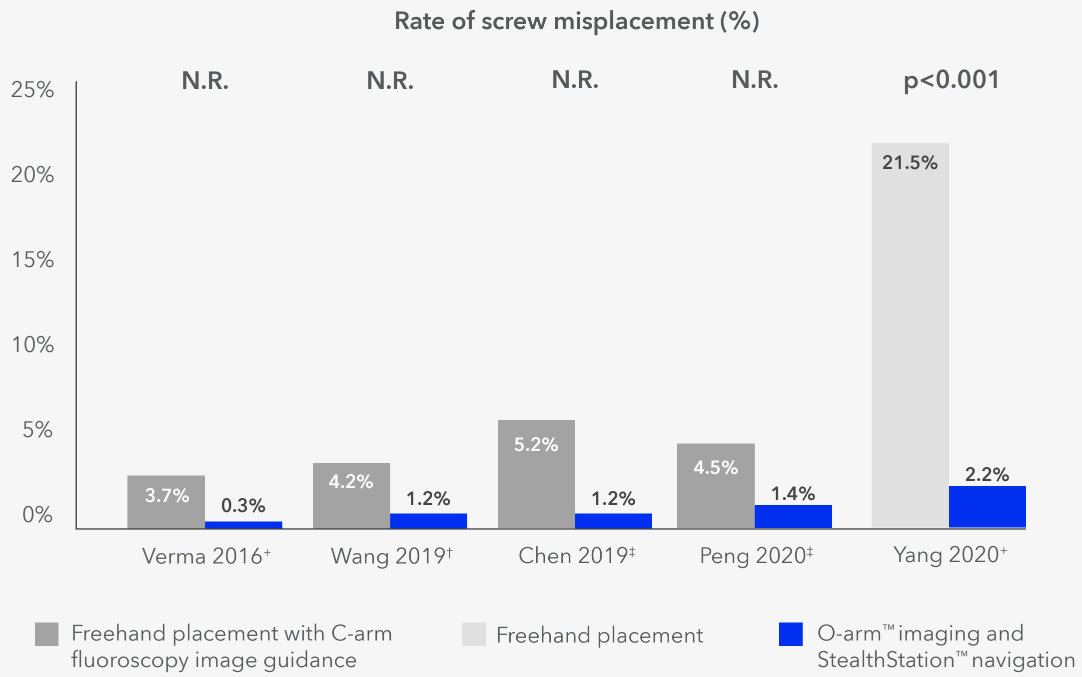
†Safe screw defined as pedicle violation <2 mm ; ‡ No definition of safe screw placement provided.

Sources : Verma et al 2016,[25] Chen et al 2019[32] Wang et al 2019,[14] Peng et al 2020[11] and Yang et al 2020[31].

Note : Different accuracy rates might be reported in the literature. Such discrepancies are likely due to surgeon experience, level of training with the O-arm™ surgical imaging and StealthStation™ navigation systems, procedure type, indication and a lack of standardization between the grading scales used to assess pedicle screw placement.[5]

Figure 12.

Rate of potentially harmful screw misplacement (pedicle violation ≥ 2mm) with O-arm™ surgical imaging and StealthStation™ navigation vs freehand placement with or without C-arm fluoroscopy image guidance



Abbreviation: N.R., p value not reported.

†Safe screw defined as pedicle violation <2 mm; ‡ No definition of safe screw placement provided.

Sources: Verma et al 2016,[25] Chen et al 2019,[32] Wang et al 2019,[14] Peng et al 2020[11] and Yang et al 2020[31].

Note: Different accuracy rates might be reported in the literature. Such discrepancies are likely due to surgeon experience, level of training with the O-arm™ surgical imaging and StealthStation™ navigation systems, procedure type, indication and a lack of standardization between the grading scales used to assess pedicle screw placement.[5]

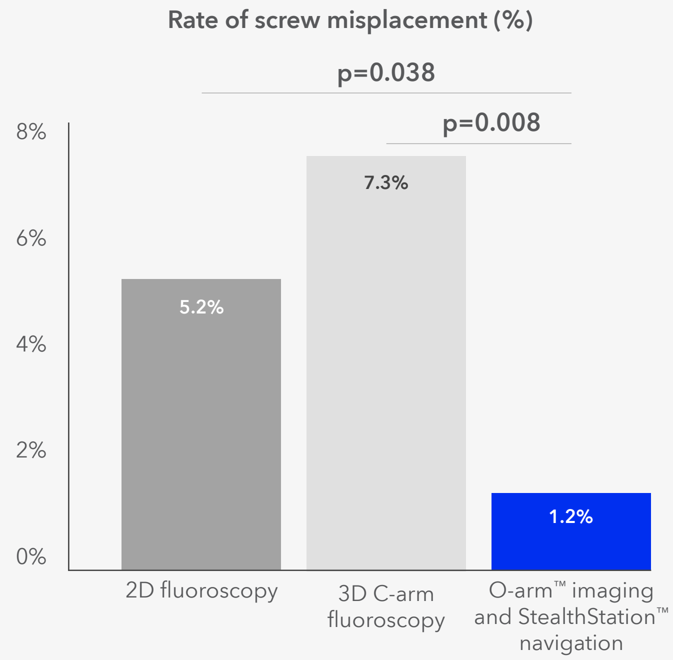
Compared with C-arm fluoroscopy guidance, a lower rate of potentially harmful pedicle violations of ≥2 mm may be associated with the use of O-arm™ surgical imaging and StealthStation™ navigation systems in studies assessing PLIF (1.2% vs 4.2%)14, TLIF (1.4% vs 4.5%)[11] or any instrumented spine surgery (0.3% vs 3.7%)[25] (**Figure 12 and Table 4**).

Minimally invasive surgery

The O-arm™ surgical imaging and StealthStation™ navigation systems are associated with improved accuracy during MIS.[8, 32] A significantly lower rate of screw misplacement (pedicle violation >0 mm) was observed with O-arm™ surgical imaging and StealthStation™ navigation (1.2%) compared with either 2D fluoroscopy (5.2%, p=0.038) or 3D C-arm fluoroscopy (7.3%, p=0.008) in a study assessing MIS in thoracic and lumbosacral surgeries (**Figure 13 and Table 4**).[8] Significantly fewer pedicle breaches were observed with the O-arm™ surgical imaging and StealthStation™ navigation systems also when the lumbar pedicle screws subgroup was assessed separately (p<0.05).[8] The rate of potentially harmful screw misplacement (pedicle violation ≥2 mm) may be lower when MIS was performed with the O-arm™ surgical imaging and StealthStation™ navigation systems (1.2%) for TLIF, compared with freehand screw placement with C-arm fluoroscopy image guidance (5.2%, p value not reported) (**Figure 12 and Table 4**), [32] and for thoracolumbar burst fractures fixation (MIS: 2.2%), compared with an open freehand posterior approach (21.5%, p<0.001) (**Figure 12 and Table 4**)[31].

Figure 13.

Screw misplacement in MIS for thoracic and lumbar spine fixation with O-arm™ surgical imaging and StealthStation™ navigation, 2D C-arm fluoroscopy, or 3D C-arm fluoroscopy



Abbreviation: MIS, minimally invasive surgery.

Data from Tajsic et al 2018.[8]

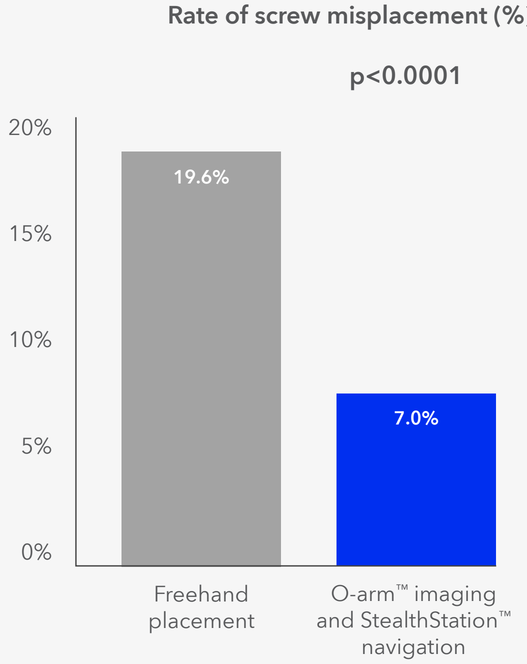
Note: Different accuracy rates might be reported in the literature. Such discrepancies are likely due to surgeon experience, level of training with the O-arm™ surgical imaging and StealthStation™ navigation systems, procedure type, indication and a lack of standardization between the grading scales used to assess pedicle screw placement[5]

Corrective scoliosis surgery

The O-arm™ surgical imaging and StealthStation™ navigation systems led to a significantly lower rate of misplaced cannulated pedicle screws (7%) compared with freehand placement (19.6%, p<0.0001) in adolescent and young adult patients with idiopathic, congenital or neuromuscular scoliosis (**Figure 14 and Table 4**).[28] The O-arm™ surgical imaging and StealthStation™ navigation systems also led to reduced rates of pedicle perforation on the convexity (4.8%) and concavity (2.2%) compared with freehand placement (convexity: 8.8%; concavity: 10.8%).[28]

Figure 14.

Rate of potentially harmful screw misplacement (pedicle violation ≥2 mm) with O-arm™ surgical imaging and StealthStation™ navigation vs freehand placement combined with C-arm fluoroscopy in patients with scoliosis



Data from Li et al 2023.[28]

Note: Different accuracy rates might be reported in the literature. Such discrepancies are likely due to surgeon experience, level of training with the O-arm™ surgical imaging and StealthStation™ navigation systems, procedure type, indication and a lack of standardization between the grading scales used to assess pedicle screw placement.[5]

Cervical spine surgery

Use of the O-arm™ surgical imaging and StealthStation™ navigation systems reduces pedicle perforation in cervical screw fixation.[9, 34] Additionally, use of the StealthMidas™ navigated drill along with the O-arm™ surgical imaging and StealthStation™ navigation systems has been shown to reduce lateral pedicle perforations, which are associated with a high risk of complications compared with a navigated probe.[9, 71]

A systematic review analyzed accuracy in lateral mass and cervical pedicle screw placement in 60 studies describing the placement of 16,669 screws in 4,165 patients. Navigated screw placement was associated with a significantly lower risk of complications compared with non-navigated approaches (odds ratio [OR] 5.3, 95% CI: 2.03–13.78).[72]

The O-arm™ surgical imaging and StealthStation™ navigation systems were associated with a significantly lower rate of pedicle wall perforations in pediatric and adult patients who underwent cervical pedicle screw fixation compared with freehand placement (1.2% vs 6.7%, respectively, $p<0.05$).[34] Cervical pedicle violations with the StealthStation™ system were all <2 mm (Grade 1), with no perforation ≥2 mm reported.[9, 71]

By avoiding unwanted rotational motion during drilling,[9] the StealthMidas™ navigated drill stable tip significantly reduced lateral pedicle perforations (2/16, 12%) compared with a navigated probe (14/17, 82%; $p<0.01$).[71] Reducing the incidence of lateral perforations is an important outcome in cervical surgery, as lateral breaches are more likely to lead to vertebral artery injury and are thus associated with a higher risk of complication compared with medial pedicle perforations.[71]

Reduced risk of revision surgery

The O-arm™ surgical imaging and StealthStation™ navigation systems enable surgeons to identify and correct misplaced screws before completion of the index surgery, minimizing the need for revision surgery.[24, 35, 68] In some studies, use of the O-arm™ surgical imaging and StealthStation™ navigation systems was shown to completely eliminate the need for revision surgery (**Figure 15 and Table 4**).[2, 8, 36]

In patients who underwent instrumented spine surgery with the O-arm™ surgical imaging and StealthStation™ navigation systems, only 1.8% of the screws needed intraoperative revision and no patients needed revision surgery due to screw misplacement (**Figure 15 and Table 4**).[36] Similarly, amongst pediatric patients undergoing instrumented spine surgery with the O-arm™ surgical imaging and StealthStation™ navigation systems, none required revision surgery due to screw misplacement, compared with 3.6% of patients in the freehand pedicle screw placement group ($p<0.05$) (**Figure 15 and Table 4**).[2]

The need for revision surgery was eliminated when the O-arm™ surgical imaging and StealthStation™ navigation systems were used for MIS over a 5-year period, compared with five and two patients requiring reoperation for nerve root irritation or pain in the 2D fluoroscopy and 3D C arm fluoroscopy groups, respectively (**Figure 15 and Table 4**).[8]

Figure 15.

Revision surgeries avoided with O-arm™ surgical imaging and StealthStation™ navigation

Van de Kelft 2012[36] 1,922 screws in 353 patients	47 screws misplaced **(2.5%)**	34 corrections required and performed in the index procedure **(1.8%)**	**No patient needed revision surgery** due to **screw misplacement**
Baky 2019[2] 206 screws in 105 patients	Severely misplaced screws **(1.0%)**	NR	
Tajsic 2018[8] 162 screws in 27 patients	2 screws misplaced **(1.2%)**	NR	

Abbreviation: NR, not reported.

Sources: Van de Kelft et al 2012,[36] Tajsic et al 2018,[8] and Baky et al 2019[2].

The O-arm™ surgical imaging and StealthStation™ navigation systems were associated with a significantly lower rate of reoperation due to screw misplacement compared with the combined freehand and fluoroscopy procedures (1.6% vs 4.2%, respectively, p<0.01) in a study of adult patients who underwent thoracolumbar spinal fusion.[68] Significantly more patients in the O-arm™ surgical imaging and StealthStation™ navigation group (98.2%) experienced 2-year freedom from reoperation due to screw misplacement compared with either the freehand (94.4%) or fluoroscopy (94.2%) groups (each p<0.02). A lower risk of reoperation was also observed in patients undergoing PLIFs (0.39 [95% CI: 0.21–0.72]; p<0.01) or complex procedures involving ≥5 spine levels (0.44 [95% CI: 0.23–0.84]; p=0.01).[68]

A lower rate of revision surgery was reported with 3D O-arm™ surgical imaging and StealthStation™ navigation (0.52%) compared with C-arm fluoroscopy (1.55%) in adults who underwent instrumented spine surgery.[24] Screw placement was corrected intraoperatively during the index procedure for five screws,[24] highlighting the value of the O-arm™ surgical imaging and StealthStation™ navigation systems for intraoperative revision and therefore avoiding the need for revision surgery.

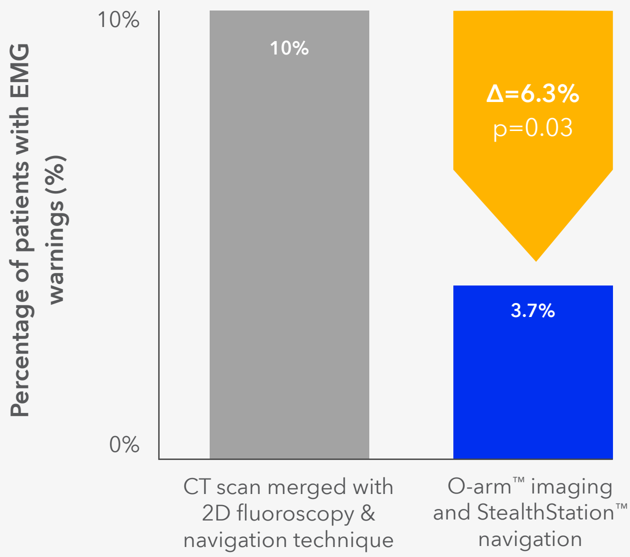
The same study reported no revision surgery due to screw misplacement amongst the 24 navigated cervical spine procedures performed.[24] Additionally, a second study reported that no patient needed revision surgery for cervical spine fixation when the O-arm™ surgical imaging and StealthStation™ navigation systems were used in combination, while one (0.12%) reoperation was reported in patients who underwent non-navigated surgery.[35]

Reduced frequency of electromyographic warnings of neuromuscular injury

Electromyographic (EMG) warnings indicate neuromuscular injury when the pedicle wall has been breached due to a misplaced screw. The O-arm™ surgical imaging and StealthStation™ navigation systems were associated with a significant reduction in EMG warnings vs CT scans merged with 2D fluoroscopy and navigation techniques, (10.0% vs 3.7%, respectively, p=0.03) in adults undergoing MIS, confirming improved pedicle screw placement accuracy (**Figure 16 and Table 4**).[73]

Figure 16.

EMG warnings with O-arm™ surgical imaging and StealthStation™ navigation vs CT scan merged with 2D fluorography and navigation techniques in patients undergoing MIS-TLIF and PLIF



Abbreviations: CT, computed tomography; EMG, electromyographic warnings; PLIF, posterior lumbar interbody fusion; TLIF, transforaminal lumbar interbody fusion.

Adapted from Wood et al 2011.[73]

Reduced radiation exposure

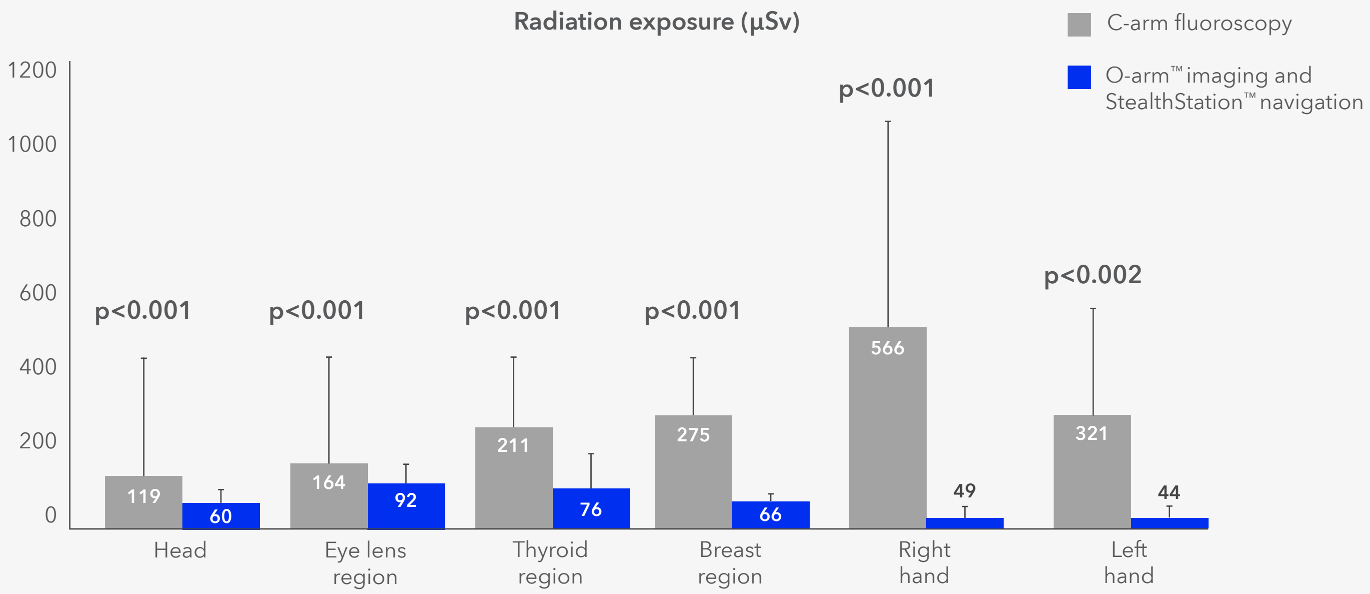
Surgical staff exposure

The O-arm™ surgical imaging and StealthStation™ navigation systems in combination minimize the cumulative exposure of medical staff to radiation during instrumented spine surgery (**Figure 17 and Table 4**).[27, 28, 37, 38]

The O-arm™ surgical imaging and StealthStation™ navigation systems led to significantly lower radiation exposure to the operating surgeon in all body regions assessed, including eye lens and thyroid regions (each p<0.001), compared with C-arm fluoroscopy (**Figure 17 and Table 4**), in a study of posterior instrumented surgeries. Significantly lower mean radiation doses were also measured for other surgical staff members (assistant surgeon, nurse, and radiology technician) for eye lens, thyroid, and breast regions (all p<0.05).[27] When using the O-arm™ surgical imaging and StealthStation™ navigation systems, surgeons can step back from the radiation source not only while acquiring images prior to navigation and after pedicle screw placement, but also during intraoperative scanning. Implementation of such protocols can lead to exposure doses for surgeon's hand, torso, and neck of <10 µSv.[74]

Figure 17.

Radiation exposure during spinal surgery for different body regions of the surgeon with O-arm™ surgical imaging system and StealthStation™ navigation vs C-arm fluoroscopy



Error bars represent the SD.
Abbreviation: SD, standard deviation.
Adapted from Bratschitsch et al 2019.[27]

The O-arm™ surgical imaging and StealthStation™ navigation systems significantly reduced surgeon exposure to radiation also during percutaneous vertebroplasty when compared with C-arm fluoroscopy (O-arm™ 912.29±412.72 mGy/cm2 vs C-arm 1722.13±884.90 mGy/cm2, p<0.001).[37] Further reductions in surgeon and patient radiation exposure during bone cement injection were reported when the standard setting on the O-arm™ intraoperative imaging system was adapted to follow the 'as low as reasonably achievable' (ALARA) principle (i.e. the standard 3D protocol was combined with low-dose 2D imaging and navigation through a FoV of 20 cm). Using the ALARA protocol, the mean effective dose was reduced to 4.34 mSv from 9.94 mSv with the standard setting ($p<0.01$). No between-group differences were observed in surgery time and cement leakage, and while the rate of satisfactory results (Garnier classification) was higher with the standard protocol (95%) than the ALARA protocol (84%), the difference was not statistically significant.[75]

During 3D image acquisition with the O-arm™ intraoperative imaging system, surgical staff can move behind a shield door or leave the operating theater, reducing their radiation exposure to zero.[28, 38, 76] In one study, the mean number of X-rays shot for each screw placement with C-arm 2D fluoroscopy was 8.9, while there was no radiation exposure during screw placement procedures with the O-arm™ surgical imaging and StealthStation™ navigation systems.[76]

Patient exposure - Thoracolumbar spine fixation

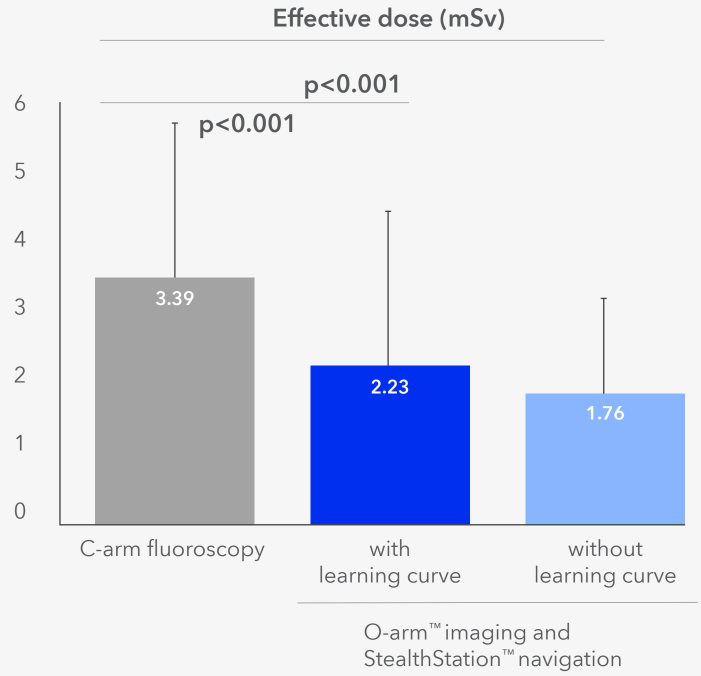
The O-arm™ surgical imaging and StealthStation™ navigation systems in combination minimize patient exposure to radiation during instrumented spine surgery (**Figure 18 and Table 4**).[8, 39]

A significantly lower mean effective radiation dose (2.23±1.96 mSv) was measured with the Oarm™2 surgical imaging and StealthStation™ 7 navigation systems compared with C-arm fluoroscopy (3.39±2.32 mSv, $p=0.002$) in adult patients undergoing PLIF.[39] The O-arm™ 2 surgical imaging system used in this study offers low radiation dose protocols that maintain image quality and resolution while reducing patient exposure (**Figure 18 and Table 4**).

Although a higher intraoperative radiation dose was reported with O-arm™ surgical imaging and StealthStation™ navigation compared with either 3D C-arm fluoroscopy (0.4 mSv) or 2D fluoroscopy (3.24 mSv vs 1.5 mSv, respectively) during MIS for spinal instability, when the cumulative dose (including post-operative imaging) was assessed, O-arm™ surgical imaging was associated with a lower effective radiation dose (8.1 mSv) compared with either 3D C-arm (9.4 mSv) or 2D (10.5 mSv) fluoroscopy (p values not reported).[8] The estimated additional cancer risk associated with each imaging-guidance modality during spinal fixation surgery was 1:1,800 for 2D fluoroscopy, 1:2,000 for 3D C-arm fluoroscopy, and 1:2,200 for the O-arm™ surgical imaging and StealthStation™ navigation systems.[8]

Figure 18.

Patient radiation exposure during spinal surgery with O-arm™ surgical imaging and StealthStation™ navigation vs C-arm fluoroscopy



Error bars represent the SD.
Abbreviation: SD, standard deviation.
Adapted from Rohe et al 2022.[39]

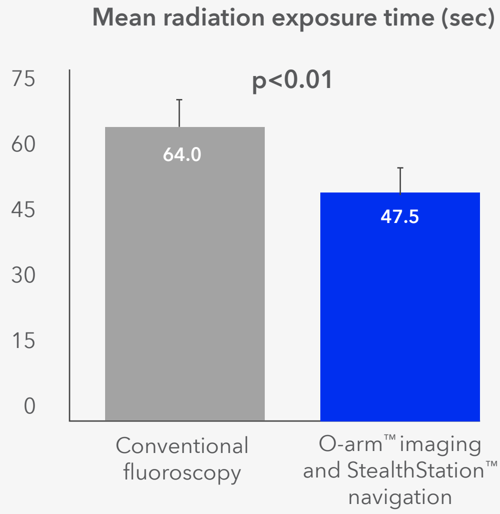
Patient exposure- cervical spine fixation

In patients undergoing cervical spine fixation procedures, use of the O-arm™ surgical imaging and StealthStation™ navigation systems lead to a reduction in radiation exposure to both patients and staff (**Figure 19 and Table 4**).[77, 78]

A significantly shorter average radiation exposure time was reported with the O-arm™ 3D surgical imaging and StealthStation™ navigation systems (47.5±1.5 sec), compared with conventional fluoroscopy (64.0±3.0 sec, $p<0.001$), in adult patients undergoing C1 lateral mass and C2 pedicle screw placement (**Figure 19 and Table 4**).[78] Similarly, pre-operative CT scans were associated with a higher mean effective radiation dose (2.18±1.90 mSv) compared with intraoperative confirmation scans with the O-arm™ surgical imaging system (1.57±0.82 mSv) during cervical pedicle screw placement in pediatric patients (p value not reported).[77]

Figure 19.

Mean radiation exposure time in patients undergoing instrumented surgery for atlantoaxial instability with O-arm™ surgical imaging and StealthStation™ navigation vs conventional fluoroscopy



Adapted from Yang et al 2013.[78]

Humanistic value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

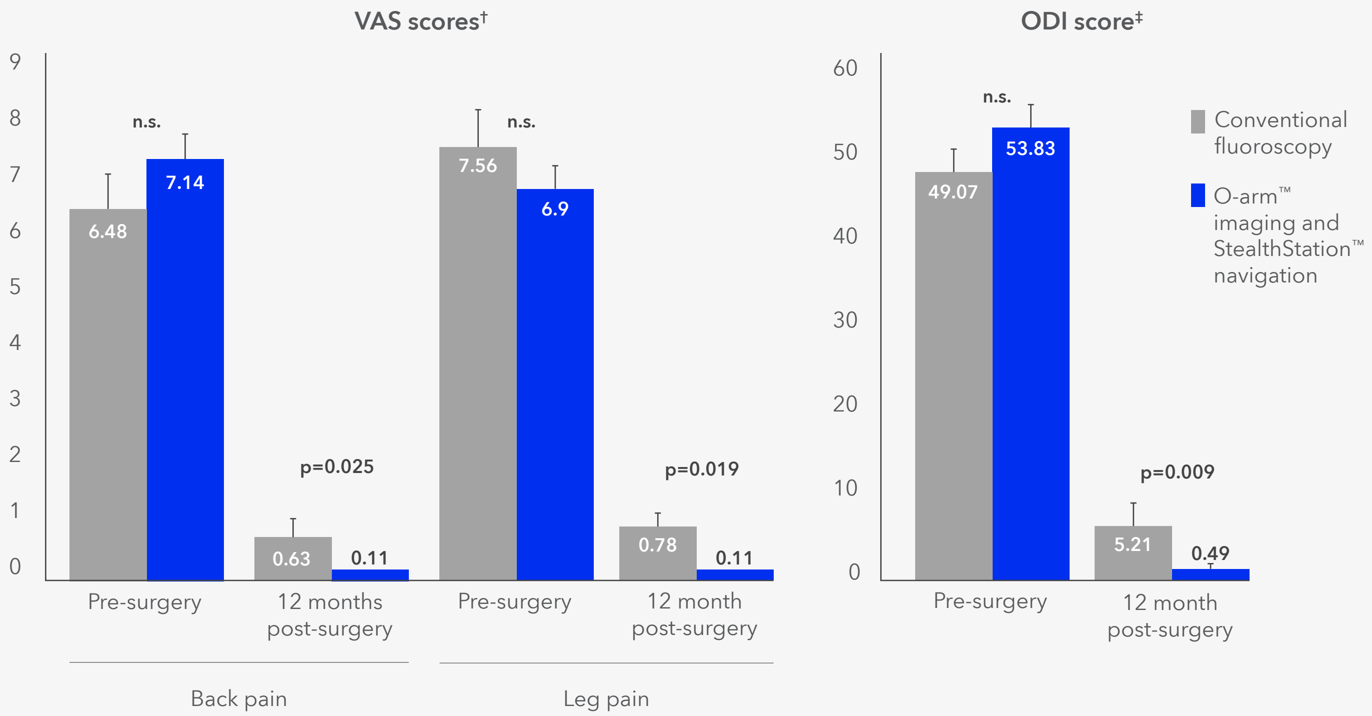
More accurate screw placement with the O-arm™ surgical imaging and StealthStation™ is associated with reduced back pain and disability compared with fluoroscopy.[7, 31, 40]

Use of the O-arm™ surgical imaging and StealthStation™ navigation systems was associated with greater improvements in post-operative patient reported outcomes (PROs) compared with C-arm or conventional fluoroscopy in patients with thoracolumbar fractures[18] or undergoing MIS-TLIF[7] or OLIF[40] (**Figures 20-21 and Table 4**).

Mean (±SE) Oswestry disability index (ODI) score was significantly lower (0.49±0.49) in patients who underwent surgery with the O-arm™ surgical imaging and StealthStation™ navigation systems vs the fluoroscopy group (5.21±1.69, $p<0.01$) 12 months after MIS-TILF, indicating a greater reduction in disability (**Figure 20**).[7] In the same patient population, use of the O-arm™ surgical imaging and StealthStation™ navigation systems was associated with significantly lower mean VAS scores for leg (0.11±0.11) and back (0.11±0.11) pain vs fluoroscopy (leg pain: 0.78±0.26; back pain: 0.63±0.20, each $p\leq0.02$) (**Figure 20 and Table 4**), supporting a greater reduction in pain in the O-arm™ surgical imaging and StealthStation™ navigation group.[7]

Figure 20.

Changes in ODI and pain VAS scores following MIS-TILF with O-arm™ surgical imaging and StealthStation™ navigation vs conventional fluoroscopy



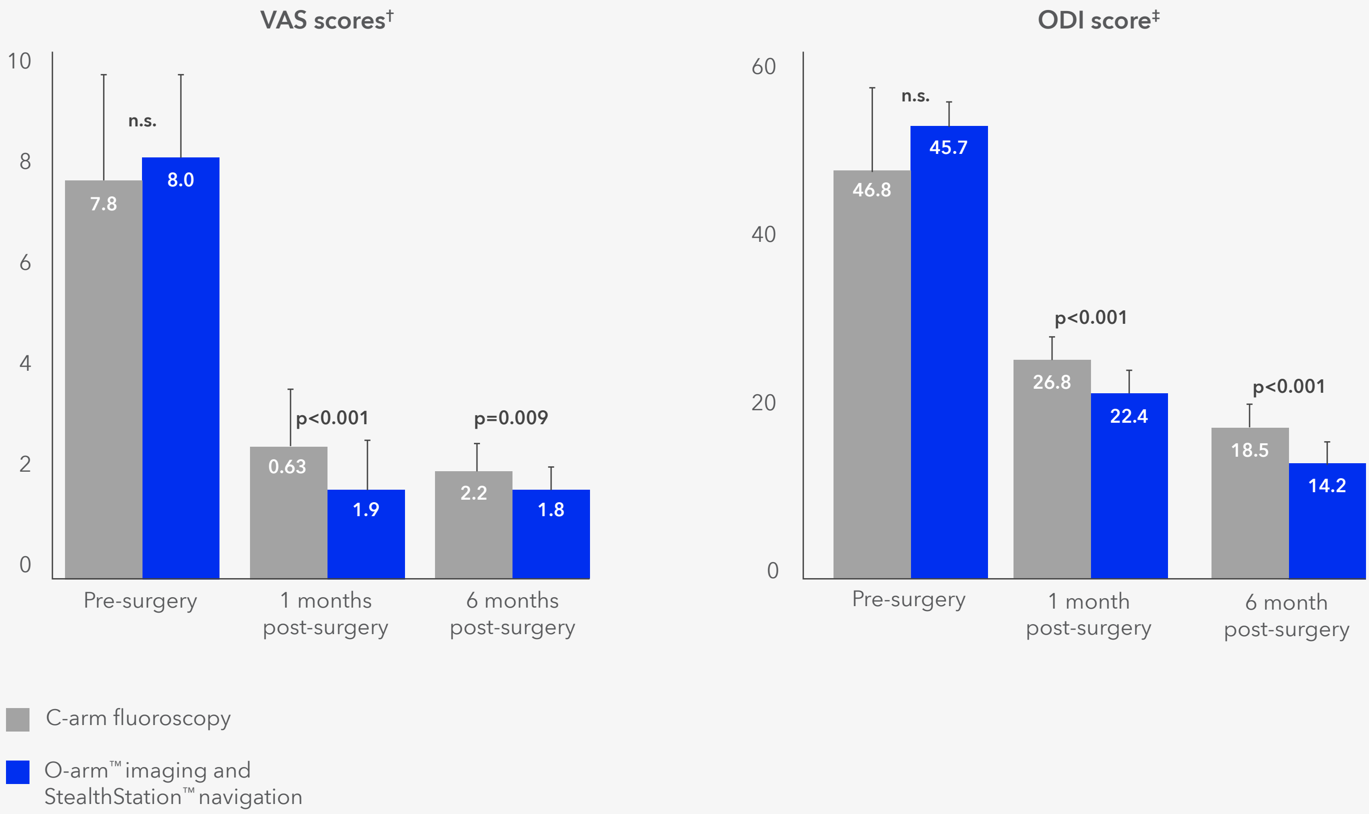
Error bars represent the SE. Abbreviation: MIS-TILF, minimally invasive transforaminal lumbar interbody fusion; n.s., not significant; ODI, Oswestry disability index; SE, standard error; VAS, visual analogue scale. †A reduction in VAS score corresponds to a reduction in severe pain; ‡Lower ODI scores correspond to a reduction in disability. Adapted from Singhatanadgige et al 2022.[7]

Patients with thoracolumbar fractures reported significantly lower post-operative mean ODI scores (p<0.001) and VAS scores (p<0.01) for pain with the O-arm™ surgical imaging and StealthStation™ navigation systems, compared with C-arm fluoroscopy, at both 1-month and 6-months post-surgery (**Figure 21 and Table 4**).[31]

Patients who underwent OLIF with the O-arm™ surgical imaging and StealthStation™ navigation systems reported not only a significantly greater reduction in disability (ODI score) vs the C-arm fluoroscopy group (p=0.015), but also significantly higher 36 item short form survey (SF-36) physical and mental component scores (p<0.001), indicating better physical and mental health (**Table 4**).[40]

Figure 21.

Changes in ODI and pain VAS scores following OILF with O-arm™ surgical imaging and StealthStation™ navigation vs C-arm fluoroscopy



Error bars represent the SD.

Abbreviation: OLIF, oblique lateral interbody fusion; n.s., not significant; ODI, Oswestry disability index; SD, standard deviation; VAS, visual analogue scale.

†A reduction in VAS score corresponds to a reduction in severe pain; ‡Lower ODI scores correspond to a reduction in disability.

Adapted from Yang et al 2020.[31]

Economic value of Medtronic O-arm™ surgical imaging and StealthStation™ navigation

The O-arm™ surgical imaging and StealthStation™ navigation systems may provide a cost-saving investment for hospitals and healthcare systems by improving screw placement accuracy and minimizing the need for revision surgeries,[12, 41, 42] decreasing radiological expenditure,[30] and reducing procedure times.[14, 39, 43-45]

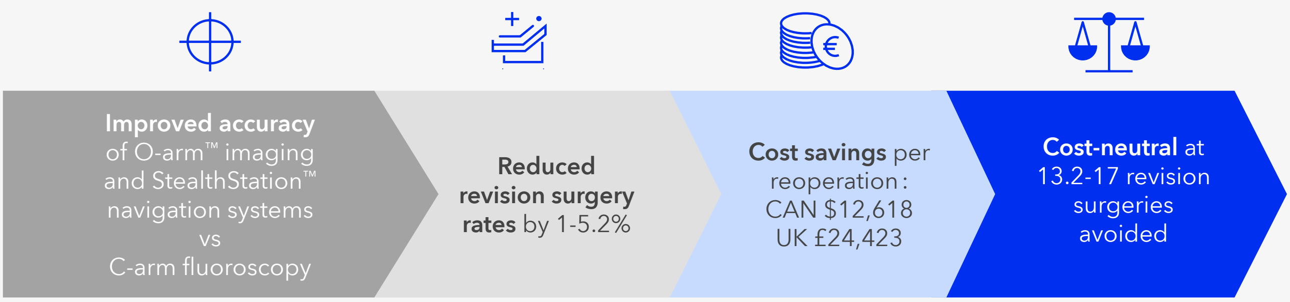
Cost-savings associated with improved surgical accuracy and reduced frequency of revision surgery

Hospital perspective

Cost-effectiveness analyses conducted in Canada and the UK quantified the return on investment achieved by improving accuracy and reducing the rate of revision surgery for patients undergoing instrumented spine procedures with the O-arm™ surgical imaging and StealthStation™ navigation systems.[12, 42] An absolute reduction in reoperation rates of 5.2% with O-arm™ surgical imaging and StealthStation™ navigation systems was observed in a single-center study in Canada (one revision surgery avoided every 20 patients) compared with conventional fluoroscopy. Based on an estimated reoperation cost of $12,618 (2013 prices), the O-arm™ surgical imaging and StealthStation™ navigation systems would become a cost-neutral investment at 13.2 reoperations avoided (**Figure 22**).[12] Similarly, the O-arm™ surgical imaging and StealthStation™ navigation systems would become cost-neutral at 17 reoperations avoided based on revision surgery rates of 0% and 1% for O-arm™ surgical imaging and StealthStation™ navigation and freehand screw placement, respectively, and estimated costs of £24,423 (2020 prices) for reoperation in the UK National Health Service (**Figure 22**).[42]

Figure 22.

Cost analyses of improved accuracy with O-arm™ surgical imaging and StealthStation™ navigation vs C-arm fluoroscopy



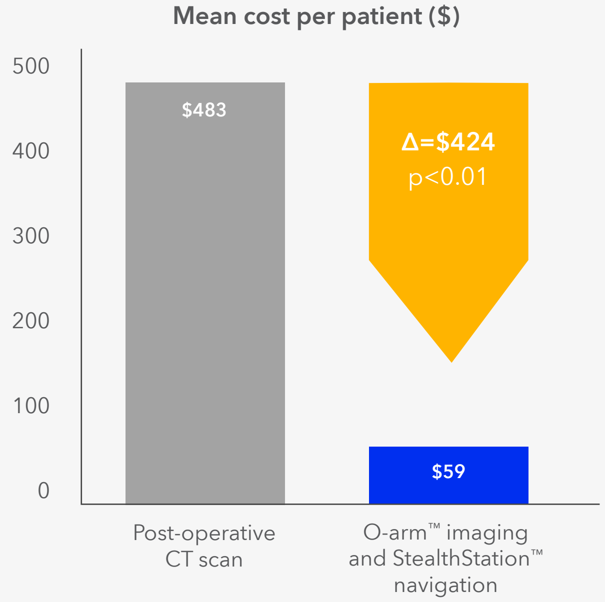
Data taken from Lee et al 2020[42] and Dea et al 2016[12].

Healthcare system perspective

A US cost-effectiveness model from a Medicare perspective estimated that the O-arm™ surgical imaging and StealthStation™ navigation systems were significantly less costly than post-operative CT scans to assess screw placement accuracy in patients undergoing at least 3-level lumbar fusion ($p<0.001$).[41] Mean costs per patient (2011 prices) were $483 with post-operative CT scan and $59 with the O-arm™ surgical imaging and StealthStation™ navigation systems (**Figure 23**). The savings were driven by the lower rate of reoperation reported with the O-arm™ surgical imaging and StealthStation™ navigation systems.[41]

Figure 23.

Comparison of the societal costs of using O-arm™ surgical imaging and StealthStation™ navigation vs post-operative CT scan to guide and verify screw placement (US$, 2011 prices)



Abbreviation: CT, computed tomography.
Adapted from Sanborn et al 2012.[41]

Cost-savings associated with shorter procedure times and reduced radiological examinations

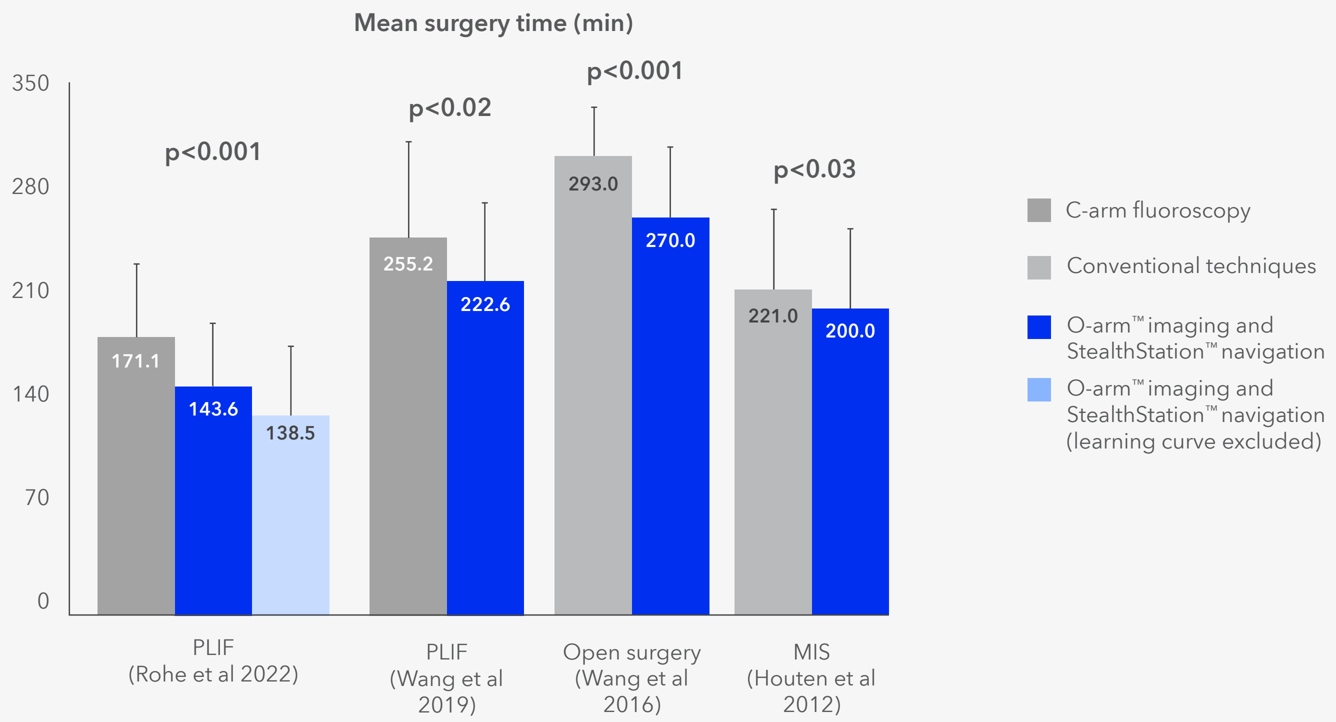
Thoraco-Lumbar spine Fixation

Use of the O-arm™ surgical imaging and StealthStation™ navigation systems is associated with shorter total operative times compared with conventional freehand techniques and C-arm fluoroscopy, which may provide cost savings and relieve the HCRU burden on hospitals (**Figure 24 and Table 4**).[14, 39, 44, 45]

Compared with C-arm fluoroscopy, using O-arm™ surgical imaging and StealthStation™ navigation for PLIFs led to time savings of 28 (p<0.001) and 33 minutes (p<0.02) in two clinical studies (**Table 4**).[14, 39] Similarly, in patients undergoing lumbar fusions, mean operative time was 23 minutes shorter (p=0.0013) using O-arm™ surgical imaging and StealthStation™ navigation instead of a freehand screw placement technique (**Figure 24**).[45] The time-saving associated with the O-arm™ surgical imaging and StealthStation™ navigation systems was maintained in minimally invasive 1-level fusions, with a mean operative time 21 minutes shorter (p<0.03) than conventional fluoroscopy (**Figure 24 and Table 4**).[44]

Figure 24.

Mean surgery time (min) with O-arm™ surgical imaging and StealthStation™ navigation, C-arm fluoroscopy and conventional techniques



Error bars represent the SD.

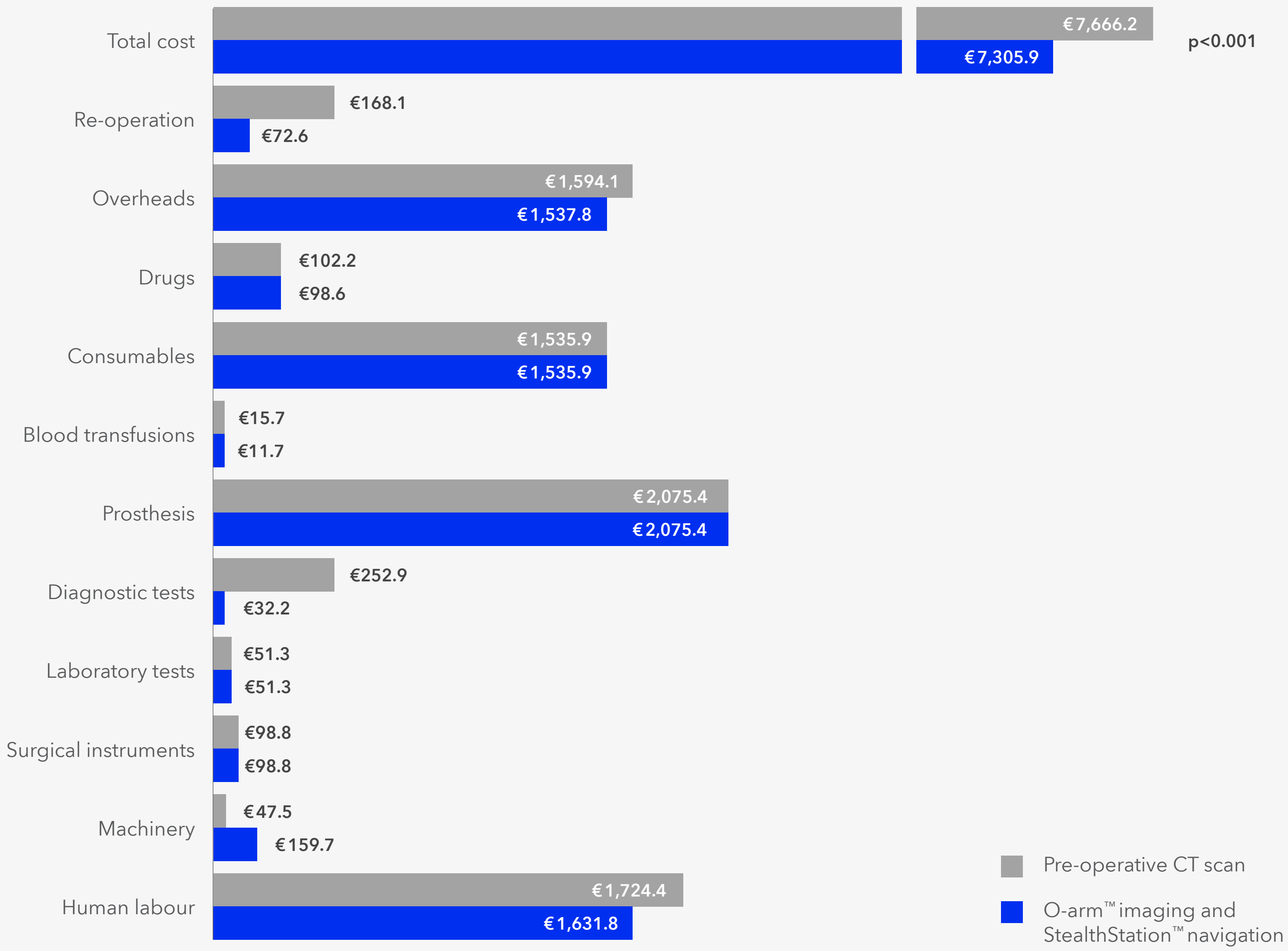
Abbreviation: MIS, minimally invasive surgery; PLIF, posterior lumbar interbody fusion; SD, standard deviation.

Sources: Houten et al 2012,[44] Khanna et al 2016,[45] Wang et al 2019,[14] and Rohe et al 2022[39].

A significantly shorter mean (±SD) spine fixation surgery time using the O-arm™ surgical imaging and StealthStation™ navigation systems, compared with pre-operative CT scan (120.25±43.68 min vs 125.77±34.17 min; p<0.05), was reported in a cost-effectiveness analysis from Italy.[30] The total mean cost per procedure incurred by the hospital between admission and discharge was significantly lower in the O-arm™ surgical imaging and StealthStation™ navigation group compared with the pre-operative CT group (€7,305.9 vs €7,666.2 [2018 prices]; p<0.001) in the period 2003–2013. Cost savings were driven by the higher screw placement accuracy observed with the O-arm™ surgical imaging and StealthStation™ navigation systems (**Figure 10**) and the avoidance of revision surgeries (**Figure 25 and Table 4**). O-arm™ surgical imaging eliminated the need for post-operative CT, reducing the radiological direct costs (diagnostic tests in **Figure 25**).[30] The reduction in costs associated with the O-arm™ surgical imaging and StealthStation™ navigation systems was maintained in the subset of patients who underwent surgery for lumbar degenerative spondylolisthesis between 2008 and 2010, with a non-significant total cost-saving of €255.83 (2010 prices).[79]

Figure 25.

Mean costs per procedure by resource category with O-arm™ surgical imaging and StealthStation™ navigation vs navigation based on pre-operative CT scan (Italy, 2018 prices)



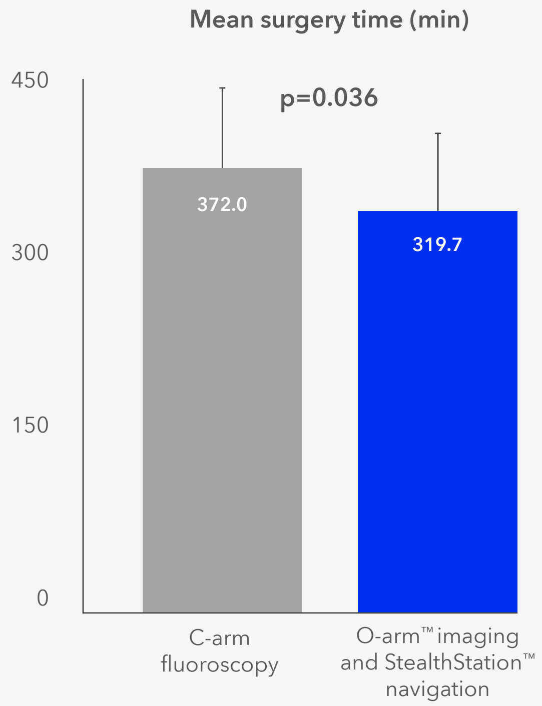
Abbreviation: CT, computed tomography.
Adapted from Restelli et al 2022.[30]

Cervical spine fixation

The O-arm™ surgical imaging and StealthStation™ navigation systems were associated with shorter procedure time in cervical spine fusion surgery, leading to a significant reduction of 52 min in mean surgery time compared with C-arm fluoroscopy (p=0.036) in patients who underwent C1–2 fusion spine surgery (**Figure 26 and Table 4**).[43]

Figure 26.

Mean surgery time in cervical spine fusion surgery when using O-arm™ surgical imaging and StealthStation™ navigation vs C-arm fluoroscopy



Data from Lee et al 2020.[43]

Learning curve

Surgical performance improves with experience, a process that is defined as a surgical learning curve. Repeated use of the O-arm™ surgical imaging and StealthStation™ navigation systems leads to reductions in surgery time, which may provide economic benefits to hospitals and healthcare systems.[39, 80]

Repeated use of the O-arm™ surgical imaging and StealthStation™ navigation systems reduced the mean surgery time by an additional five minutes (from 143.62±43.87 to 138.51±36.03 minutes), resulting in an overall time-saving of 33 minutes compared with procedures performed with C-arm fluoroscopy (p<0.001) in a retrospective study (**Figure 24 and Table 4**).[39] The effect of the learning curve was also observed on patient exposure to radiation, with the effective dose decreasing to 1.76±1.13 mSv from 2.23±1.96 mSv, when the learning period was excluded (**Figure 18 and Table 4**).[39]

Similarly, repeated use led to a large decrease in navigation time and radiation dose with the O-arm™ surgical imaging and StealthStation™ navigation systems in 1-level lumbar fusion procedures.[80] The 80 surgeries performed in the study were organized in 16 subgroups of five consecutive procedures. While no difference was observed in pedicle screw accuracy between the first and last five surgeries performed, average navigation time significantly decreased from 61±6 minutes in the first subgroup to 28±2 minutes in the last (p<0.0001). Average radiation dose was also significantly reduced from the first subgroup (919±225 mGy/cm) to the last (66±4 mGy/cm, p<0.0001) (**Table 4**).[80]

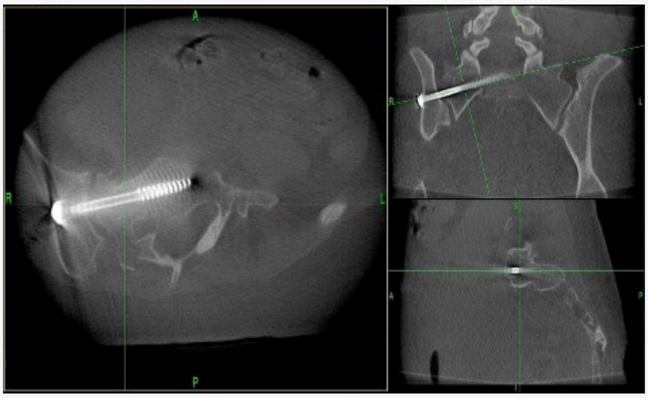
Appendix A – Clinical and economic value of O-arm™ surgical imaging and StealthStation™ navigation for the placement of sacroiliac screws

Clinical picture

Sacroiliac screws are used for the stabilization of the pelvic ring in patients with traumatic injury or degenerative diseases.[29, 65, 81] Accurate placement of sacroiliac and iliac instrumentation is necessary to avoid injury to the vertebral artery and the neurovascular structures localized at the sacroiliac joint and in the sciatic notch (Figure 27).[65, 81]

Figure 27.

Confirmation scan of sacroiliac screw fixation with the O-arm™ intraoperative imaging system



Burden of disease

In the absence of image guidance, a 5–16% misplacement rate for iliac screws has been reported.[82] Fluoroscopy images from multiple planes are often required to reduce the risk of iatrogenic injury during instrumented pelvic surgery,[29] highlighting the potential clinical value of 3D intraoperative imaging for sacroiliac screw placement.

Clinical value

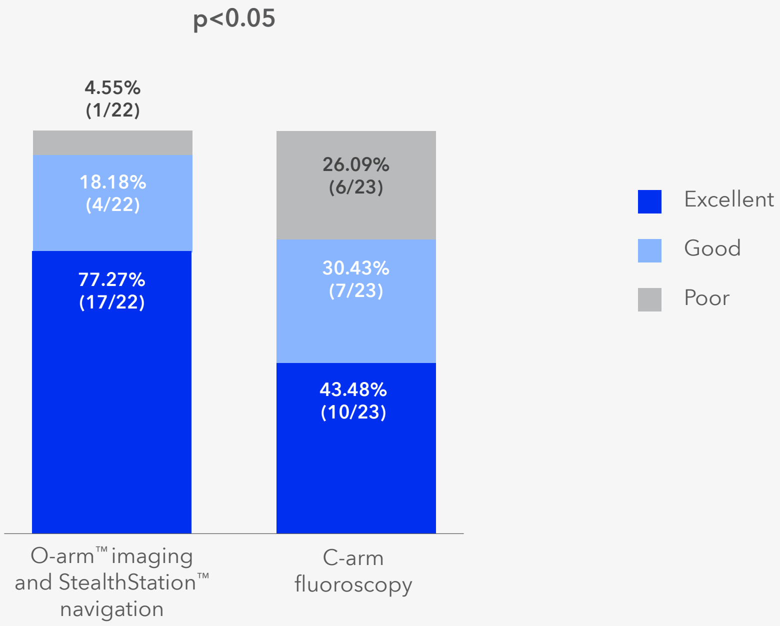
Improved screw placement accuracy

When used in combination, the O-arm™ surgical imaging and StealthStation™ navigation systems support accurate and safe placement of sacroiliac screws (Figure 28 and Table 4).[65, 81]

The O-arm™ surgical imaging and StealthStation™ navigation systems were associated with significantly higher accuracy of screw placement compared with C-arm fluoroscopy ($p<0.05$) (Figure 28 and Table 4) in a study of patients with posterior pelvic ring injury.[81] Full localization of the screw in the sacral pedicle (excellent outcome) was achieved in 17 of 22 screws (77.27%) in the O-arm™ surgical imaging and StealthStation™ navigation group vs 10 of 23 screws (43.48%) in the C-arm fluoroscopy group.[81] Only one of 22 screws (4.55%) was classified as misplaced and required intraoperative revision (poor outcome) in the O-arm™ surgical imaging and StealthStation™ navigation group compared with six of 23 screws (26.09%) in the C-arm fluoroscopy group.[81] Similarly, the rate of accurate iliac screw placement (no breach) was 96% with the O-arm™ surgical imaging and StealthStation™ navigation systems and 89% by freehand screw placement in a study of adult patients with degenerative disease who underwent posterior reconstruction (Table 4).[65]

Figure 28.

Outcomes of sacroiliac screw placement based on Richter method with O-arm™ surgical imaging and StealthStation™ navigation vs C-arm fluorography



Outcome definition: excellent, screw fully located in the sacral pedicle; good, screw extruded the cortex of the sacral pedicle by no more than one-fourth of the screw diameter; poor, screw extruded the cortex by more than one-fourth of its diameter.
Adapted from Lu et al 2021.[81]

Reduced radiation exposure

The O-arm™ surgical imaging and StealthStation™ navigation systems reduce radiation exposure for both surgical staff and patients during sacroiliac screw placement (Figure 29 and Table 4).[29]

Compared with C-arm fluoroscopy, the O-arm™ surgical imaging and StealthStation™ navigation systems were associated with a significantly lower mean (±SD) radiation dose to medical staff (80.1±72.3 mGy vs 25.1±35.8 mGy, p<0.01) and patients (80.1±72.3 mGy vs 39.0±35.8 mGy, p=0.01) during sacroiliac screw fixation (Table 4).[29] This result may be due to the significantly shorter time required for imaging during surgery with the O-arm™ surgical imaging system (66.9±79.9 sec) compared with C-arm fluoroscopy (204.1±117.7 sec, p<0.01) (Figure 29).[29]

Humanistic burden

Patients operated with the O-arm™ surgical imaging and StealthStation™ navigation systems had a significantly higher Majeed functional score 3 months post-surgery compared with patients in the C-arm fluoroscopy group (90.12±9.51 vs 81.31±7.08, p=0.002), indicating better pelvic function (Table 4).[81]

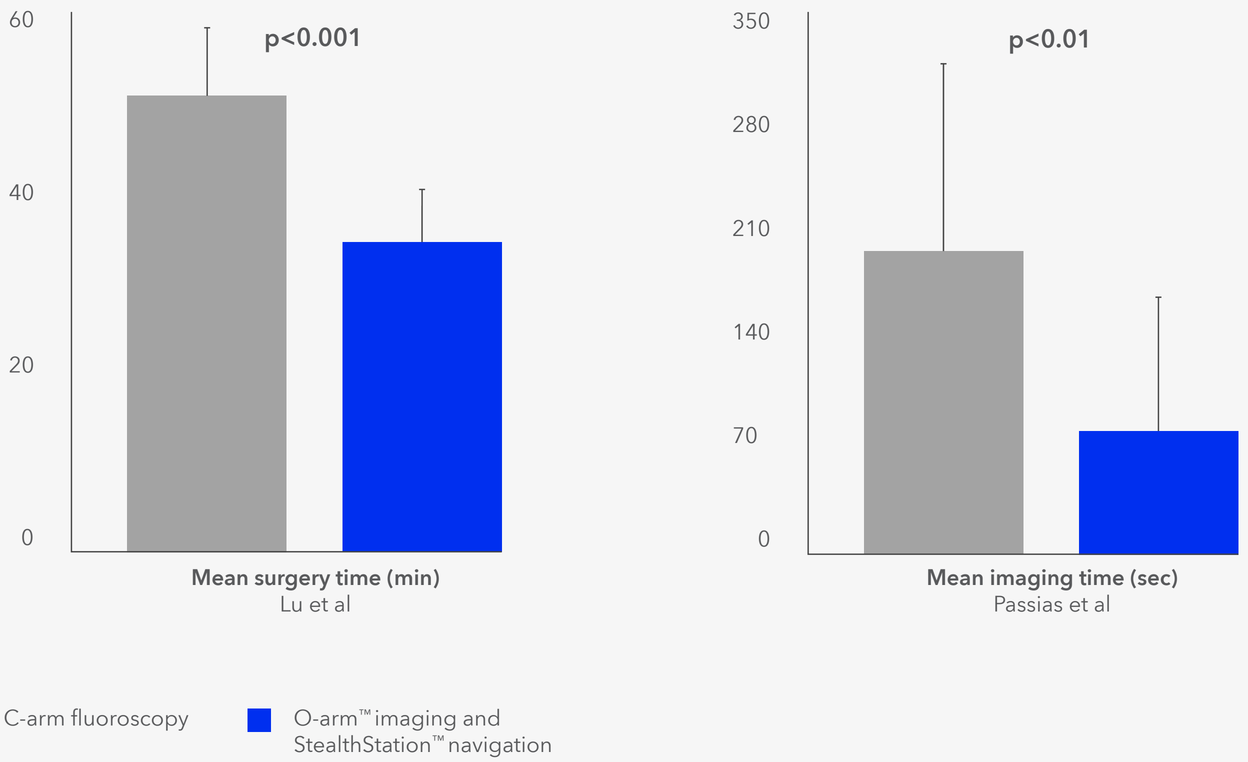
Economic value

Cost-saving potential associated with reduced procedure times

The O-arm™ surgical imaging and StealthStation™ navigation systems offer an efficient approach for sacroiliac screw fixation by reducing not only intraoperative imaging time,[29] but also overall surgery time.[81] Mean (±SD) surgery time was 33.19±3.14 minutes with the O-arm™ surgical imaging and StealthStation™ navigation systems and 48.35±4.38 minutes with C-arm fluoroscopy in a study evaluating sacroiliac screw insertion for pelvic ring injuries (**Figure 29 and Table 4**).[81]

Figure 29.

Mean surgery and imaging time for sacroiliac screw placement with O-arm™ surgical imaging and StealthStation™ navigation systems and C-arm fluorography



Data taken from Lu et al 2021[81] and Passias et al 2021[29].

Appendix B – Inclusion table

The studies included in the clinical and humanistic value sections were chosen based on the following criteria

- Publication date up to September 2023
- Studies including >30 patients
- A preference towards comparative studies of the O-arm™ surgical imaging and StealthStation™ navigation systems vs conventional techniques (i.e. C-arm, 2D fluoroscopy, freehand pedicle placement)

The main characteristics and outcomes of the studies included in the value summary are detailed in Table 4.

Table 4.

Studies supporting the key messages in the value summary

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Clinical value section					
Wood (2011)[73] A comparison of CT-based navigation techniques for minimally invasive lumbar pedicle screw placement	Retrospective comparative study (O-arm™ & StealthStation™ vs preoperative CT scan)	Patients: N=67 Screws: N=296 • O-arm™ & StealthStation™: n=43 patients/ n=186 screws • Preoperative scan: n=24 patients/ n=110 screws	Lumbar	Not reported	**Pedicle screws placed sub-optimally, n (%)** • O-arm™ & StealthStation™: 3 (1.6%) • Preoperative scan: 7 (6.4%) *p=0.03* **Positive EMG warnings, n (%)** • O-arm™ & StealthStation™: 7 (3.7%) • Preoperative scan: 11 (10.0%) *p=0.03*
Van der Kelft (2012)[36] A prospective multicenter registry on the accuracy of pedicle screw placement in the thoracic, lumbar, and sacral levels with the use of the O-arm imaging system and StealthStation Navigation	Prospective registry study	Patients : N=353 Screws : N=1,922 • All with O-arm™ & StealthStation™	Thoracic Lumbar Sacral	Degenerative diseases Trauma Tumor	**Intrapedicular screws, % :** 97.5% **Pedicle violation <2mm, % :** 98.2% No revision surgery

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Yang (2013)[78] Comparison of isocentric C-arm 3-dimensional navigation and conventional fluoroscopy for C1 lateral mass and C2 pedicle screw placement for atlantoaxial instability	Retrospective comparative study (O-arm™ & StealthStation™ vs fluoroscopy)	Patients : N=24 Screws : N=96 • O-arm™ & StealthStation™: n=12 patients/ n=48 screws • Fluoroscopy : n=12 patients/ n=48 screws	Cervical	Odontoid fracture Cervical spine injuries Degenerative diseases	**Intrapedicular screws, %** • O-arm™ & StealthStation™: 95.8% • Fluoroscopy: 83.3% *p value not reported* **Radiation time, mean (SD)** • O-arm™ & StealthStation™: 47.5±1.5 sec • Fluoroscopy: 64.0±3.0 sec *p<0.001*
Verma (2016)[25] O-arm with navigation versus C-arm: a review of screw placement over 3 years at a major trauma center	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm)	Patients : N=587 Screws : N=3,893 • O-arm™ & StealthStation™: n=278 patients/ n=1,720 screws • C-arm : n=309 patients/ n=2,173 screws	Lumbar Cervical	Odontoid fracture, Subaxial cervical spine injuries, Dorsolumbar fractures	**Intrapedicular screws, %** • O-arm™ & StealthStation™: 99.1 % • C-arm : 91.2% *p<0.05* **Pedicle violation <2mm, %** • O-arm™ & StealthStation™: 99.7 % • C-arm : 96.3% *p value not reported*
Xiao (2017)[68] Clinical outcomes following spinal fusion using an intraoperative computed tomographic 3D imaging system	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand vs fluoroscopy guidance)	Patients: N=614 Screws: N=92 • O-arm™ & StealthStation™: n=614 patients • Freehand: n=356 patients • Fluoroscopy guidance: n=238 patients	Thoracic Lumbar	Degenerative disease Spinal deformity	**Hazard risk of revision surgery** O-arm™ & StealthStation™ vs freehand and fluoroscopy-guidance combined • Any cause : 0.49 (95% CI: 0.32-0.7), *p<0.01* • Screw misplacement: 0.39 (95% CI : 0.19-0.80), *p<0.01*
Hlubek (2017)[65] Safety and Accuracy of Freehand Versus Navigated Iliac Screws: Results From 222 Screw Placements	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand)	Patients : N=111 Screws : N=222 • O-arm™ & StealthStation™: n=80 screws • Freehand : n=142 screws	Sacroilliac	Degenerative diseases	**Screw placement accuracy, %** • O-arm™ & StealthStation™: 96% • Freehand : 89% *p=0.12*

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Tajsic (2018)[8] Spinal navigation for minimally invasive thoracic and lumbosacral spine fixation: implications for radiation exposure, operative time, and accuracy of pedicle screw placement	Retrospective comparative study (O-arm™ & StealthStation™ vs 2D fluoroscopy vs C-arm & navigation)	Patients: N=152 Screws: N=858 • O-arm™ & StealthStation™: n=27 patients/ n=162 screws • 2D fluoroscopy: n=92 patients/ n=504 screws • C-arm & navigation: n=39 patients/ n=192 screws	Thoracic Lumbosacral	Trauma Tumor Degenerative disease	**Intrapedicular screws, %** • O-arm™ & StealthStation™: 98.8% • 2D fluoroscopy: 94.8% • C-arm & navigation: 92.7% *p value not reported* **Pedicle violation <2 mm, %:** • O-arm™ & StealthStation™: 99.4% • 2D fluoroscopy: 96.6% • C-arm & navigation: 93.7% *p value not reported* **Revision surgeries, n** • O-arm™ & StealthStation™: 0 • 2D fluoroscopy: 5 • C-arm & navigation: 2 **Patient radiation exposure, mean** During the procedure: • O-arm™ & StealthStation™: 3.2 mSv • 2D fluoroscopy: 1.5 mSv • C-arm & navigation: 0.4 mSv Cumulative (including post-operative scans): • O-arm™ & StealthStation™: 8.1 mSv • 2D fluoroscopy: 9.0 mSv • C-arm & navigation: 9.4 mSv
Bratschitsch (2019)[27] Radiation Exposure of Patient and Operating Room Personnel by Fluoroscopy and Navigation during Spinal Surgery	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients: N=37 Screws: not reported • O-arm™ & StealthStation™: n=19 patients • C-arm: n=18 patients	Not reported	Not reported	**Patient radiation exposure, mean (SD)** • O-arm™ & StealthStation™: 43.2±19.4 mSv • C-arm: 27.7±31.3 mSv *p=0.02* **Surgeon radiation exposure, mean (SD)** Thyroid • O-arm™ & StealthStation™: 76±72 µSv • C-arm: 211±95 µSv Eye lens • O-arm™ & StealthStation™: 92±41 µSv • C-arm: 164±74 µSv
Wang (2019)[14] Comparison between free-hand and O-arm-based navigated posterior lumbar interbody fusion in elderly cohorts with three-level lumbar degenerative disease	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand)	Patients: N=41 Screws: N=328 • O-arm™ & StealthStation™: n=20 patients/ n=160 screws • Freehand: n=21 patients / n=168 screws	Lumbar	Three-level lumbar degenerative diseases	**Intrapedicular screws, %** • O-arm™ & StealthStation™ : 96.9% • Freehand: 88.7% *p=0.004* **Pedicle violation <2 mm, %** • O-arm™ & StealthStation™: 98.6% • Freehand : 95.8% *p value not reported*

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Baky (2019)[2] Intraoperative Computed Tomography-Guided Navigation for Pediatric Spine Patients Reduced Return to Operating Room for Screw Malposition Compared With Freehand/ Fluoroscopic Techniques	Retrospective comparative study (O-arm™ & StealthStation™ vs fluoroscopy)	Patients: N=217 Screws: N=526 • O-arm™ & StealthStation™: n=105 patients/ n=206 screws • Fluoroscopy: n=112 patients/ n=323 screws	Thoracic Lumbar	Idiopathic scoliosis Tumor Trauma Degenerative diseases	**Pedicle violation <4 mm, %** • O-arm™ & StealthStation™: 99% • Fluoroscopy: 96.7% *p=0.027* **Revision surgeries, %** • O-arm™ & StealthStation™: 0% • Fluoroscopy: 3.6% *p<0.05*
Chen 2019[32] O-arm Navigation Combined With Microscope-assisted MIS-TLIF in the Treatment of Lumbar Degenerative Disease	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients: N=45 Screws: N=180 • O-arm™ & StealthStation™: n=21 patients/ n=84 screws • C-arm: n=24 patients/ n=96 screws	Lumbar	Degenerative diseases	**Intrapedicular screws, %** • O-arm™ & StealthStation™: 96.4% • C-arm: 86.5% *p=0.033* **Pedicle violation <2 mm, %** • O-arm™ & StealthStation™: 98.8 • C-arm: 94.7% *p value not reported* **Length of hospital stay:** • O-arm™ & StealthStation™: 10.61±2.52 days • C-arm: 13.83±3.89 min *p=0.002*
Roccucci (2019)[24] Real-time navigation in spinal surgery: what has changed in surgical practice?	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm & fluoroscopy)	Patients: N=421 Screws: N=1,924 • O-arm™ & StealthStation™: n=222 patients/ n=964 screws • C-arm: n=199 patients/ n=960 screws	Thoracic Lumbar	Trauma Tumors	**Screw misplacement, %** • O-arm™ & StealthStation™: 1.4% • C-arm: 5.8% *p<0.0001* **Revision surgeries, n (%)** • O-arm™ & StealthStation™: 1 patient (0.52%) • C-arm: 3 patients (1.55%) *p value not reported*

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Peng (2020)[11] Comparison of O-arm navigation and microscope-assisted minimally invasive transforaminal lumbar interbody fusion and conventional transforaminal lumbar interbody fusion for the treatment of lumbar isthmic spondylolisthesis	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm & fluoroscopy)	Patients : N=40 Screws : N=160 • O-arm™ & StealthStation™ : n=18 patients/ n=72 screws • C-arm : n=22 patients/ n=88 screws	Lumbar	Spondylolisthesis	**Intrapedicular screws, %** • O-arm™ & StealthStation™ : 95.8% • C-arm : 85.2% *p=0.0012* **Pedicle violation <2 mm, %** • O-arm™ & StealthStation™ : 98.6% • C-arm : 95.4% *p value not reported* **Operating time :** • O-arm™ & StealthStation™: 201.67±29.15 min • C-arm : 132.27±23.64 min *p<0.0001* **Length of hospital stay :** • O-arm™ & StealthStation™: 10.33±2.47 days • C-arm : 13.64±3.91 min *p=0.004*
Towner (2020)[35] Retrospective Review of Revision Surgery After Image-guided Instrumented Spinal Surgery Compared With Traditional Instrumented Spinal Surgery	Retrospective comparative study (O-arm™ & StealthStation™ vs fluoroscopy-assisted or freehand)	Patients: N=529 Screws: N=4,804 • O-arm™ & StealthStation™ : n=110 patients/ n=1,115 screws • Fluoroscopy-assisted or freehand : n=419 patients/ n=3,689 screws	Cervical Thoracic Lumbar	Degenerative diseases Spinal deformities Trauma Tumors	**Malposition screws requiring revision surgery, n** • O-arm™ & StealthStation™ : 1 • Fluoroscopy-assisted or freehand : 15 *p value not reported*
Wada (2020)[9] Cervical Pedicle Screw Insertion Using O-Arm-Based 3D Navigation : Technical Advancement to Improve Accuracy of Screws	Retrospective study	Patients : N=64 Screws : N=317 All with O-arm™ & navigation	Cervical	Degenerative diseases Trauma Tumor Spinal deformities	**Intrapedicular screws, %** • Overall : 96.2% • With drill : 93.0% • With StealthMidas™ : 98.8%

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Yang (2020)[31] Percutaneous short-segment pedicle instrumentation assisted with O-arm navigation in the treatment of thoracolumbar burst fractures	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand)	Patients : N=72 Screws : N=352 • O-arm™ & StealthStation™ : n=36 patients/ n=180 screws • Freehand : n=36 patients/ n=172 screws	Thoracic Lumbar	Burst fractures	**Safely placed screws (pedicle violation <2 mm), %** • O-arm™ & StealthStation™ : 97.8% • Freehand : 78.5% *p<0.001* **VAS score, mean (SD)** Pre-operative, *p=0.598* : • O-arm™ & StealthStation™ : 8.0±1.5 • Freehand : 7.8±1.7 1-month post-surgery, *p<0.001* : • O-arm™ & StealthStation™ : 1.9±0.8 • Freehand : 2.7±0.8 6-months post-surgery, *p=0.009*: • O-arm™ & StealthStation™ : 1.8±0.6 • Freehand : 2.2±0.8 **ODI score, mean (SD)** Pre-operative, *p=0.581* : • O-arm™ & StealthStation™ : 45.7±7.8 • Freehand : 46.8±9.0 1-month post-surgery, *p<0.001* : • O-arm™ & StealthStation™ : 22.4±2.5 • Freehand : 26.8±3.1 6-months post-surgery, *p<0.001* : • O-arm™ & StealthStation™ : 14.2±2.7 • Freehand : 18.5±2.5
Wojdyn (2021)[37] Use of O-arm with neuronavigation in percutaneous vertebroplasty reduces the surgeon's exposure to intraoperative radiation	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients : N=64 Screws : not reported • O-arm™ & StealthStation™ : n=29 patients • C-arm fluoroscopy : n=35 patients	Thoracic Lumbar	Degenerative diseases Trauma	**Patient radiation dose, mean** • O-arm™ & StealthStation™ : 919.29 mGy/cm2 • C-arm : 1772.13 mGy/cm2 *p<0.0001*

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Lu (2021)[81] O-arm navigation for sacroiliac screw placement in the treatment for posterior pelvic ring injury	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients : N=40 Screws : N=43 • O-arm™ & StealthStation™ : n=19 patients/ n=22 screws • C-arm fluoroscopy : n=21 patients/ n=23 screws	Sacroiliac	Pelvic ring traumatic injury	**Pedicle screw placement graded excellent, n (%)** • O-arm™ & StealthStation™ : 17 (77.3%) • C-arm : 10 (43.5%) **Surgery time, mean (SD)** • O-arm™ & StealthSttion™ : 33.2±3.1 min • C-arm : 48.3±4.4 min **Majeed score, mean (SD)** Pre-operative, *p=0.368*: • O-arm™ & StealthStation™ : 37.2±4.5 • C-arm : 38.4±4.2 1-month post-surgery, *p<0.001* : • O-arm™ & StealthStation™ : 73.8±5.2 • C-arm : 62.3±5.0 6-months post-surgery, *p=0.002* : • O-arm™ & StealthStation™ : 90.1±9.5 • C-arm : 81.3±7.1
Passias (2021)[29] Use of 3D Navigation Versus Traditional Fluoroscopy for Posterior Pelvic Ring Fixation	Retrospective comparative study (O-arm™ & StealthStation™ vs conventional fluoroscopy)	Patients : N=134 Screws : not reported • O-arm™ & StealthStation™ : n=28 patients • Fluoroscopy : n=106 patients	Sacroiliac	Pelvic ring traumatic injury	**Radiation dose, mean (SD)** Patient • O-arm™ & StealthStation™ : 39.0±35.8 mGy • Fluoroscopy : 80.1±72.3 mGy *p=0.01* Staff • O-arm™ & StealthStation™ : 25.1±35.8 mGy • Fluoroscopy : 80.1±72.3 mGy *p<0.01* **Imaging duration, mean (SD)** • O-arm™ & StealthStation™ : 66.9±79.9 sec • Fluoroscopy : 204.1±117.7 sec *p<0.01*
Restelli (2022)[30] An observational analysis of costs and effectiveness of an intraoperative compared with a preoperative image-guided system in spine surgery fixation : analysis of 10 years of experience	Retrospective comparative study (O-arm™ and S7 StealthStation™ vs preoperative CT scan)	Patients : N=875 Screws : N=4,441 • O-arm™ & StealthStation™ : n=577 patients/ n=2,918 screws • Pre-operative scan : n=298 patients/ n=1,523 screws	Cervical Thoracic Lumbar	Degenerative disease Revision surgery Trauma	**Pedicle screw accuracy, %** • O-arm™ & StealthStation™ : 95.5% • Pre-operative scan : 91.6% **Cost per procedure, mean** • O-arm™ & StealthStation™ : €7305.9 • Pre-operative scan : €7666.2

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Rohe (2022)[39] Cone-Beam Navigation Can Reduce the Radiation Exposure and Save Fusion Length-Dependent Operation Time in Comparison to Conventional Fluoroscopy in Pedicle-Screw-Based Lumbar Interbody Fusion	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients: N=214 Screws: not reported • O-arm™ & StealthStation™: n=108 patients • C-arm: n=106 patients	Lumbar	Degenerative diseases	**Surgery time, mean (SD)** • O-arm™ & StealthStation™: 142.6±43.8 min • O-arm™ & StealthStation™ (learning excluded): 138.5±36.0 min • C-arm: 171.1±48.9 min **Patient radiation effective dose, mean (SD)** • O-arm™ & StealthStation™: 2.23±1.96 min • O-arm™ & StealthStation™ (learning excluded): 1.76±1.13 min • C-arm: 3.39±2.32 min
Li (2023)[28] Safety and accuracy of cannulated pedicle screw placement in scoliosis surgery: a comparison of robotic-navigation, O-arm-based navigation, and freehand techniques	Prospective comparative study (O-arm™ & StealthStation™ vs freehand placement)	Patients: N=106 Screws: 2,035 • O-arm™ & StealthStation™: n=34 patients n=632 screws • Robotic surgery with O-arm™ & StealthStation™: n=32 patients/ n=627 screws • Freehand: n=40 patients/ n=776 screws	Not reported	Scoliosis	**Pedicle violation <2 mm, %** • O-arm™ & StealthStation™: 93.0% • Robotic surgery with O-arm™ & StealthStation™: 96.7% • Freehand: 80.4% *p<0.0001 (O-arm™ & StealthStation™ vs freehand)* **Pedicle violation ≥2 mm, %** • O-arm™ & StealthStation: 7.0% • Robotic surgery with O-arm™ & StealthStation™: 3.3% • Freehand: 19.6% *p<0.0001 (O-arm™ & StealthStation™ vs freehand)*
Takigawa (2023)[71] Application of a Navigated Drill for Cervical Pedicle Screw Insertion at C3-6	Retrospective comparative study (SteathMidas™ vs navigated probe)	Patients: N=106 Screws: N=370 • StealthMidas™: n=52 patients/ n=200 screws • Navigated probe: n=54 patients/ n=170 screws	Cervical	Degenerative diseases Trauma Tumor	**Intrapedicular screws, %** StealthMidas™: 92% • Medial perforation: 88% • Lateral perforation: 12% *p<0.01* Navigated probe: 90% • Medial perforation: 18% • Lateral perforation: 82% *p<0.01*
Soliman (2023)[72] Complications associated with subaxial placement of pedicle screws versus lateral mass screws in the cervical spine (C2-T1): systematic review and meta-analysis comprising 4,165 patients and 16,669 screws	Systematic review and meta-analysis (navigation vs non-navigation)	Patients: N=4,165 Screws: N=16,669	Cervical spine	Not reported	**Rate of complications:** • OR=5.3, 95% CI: 2.03-13.78 (decreased rate of complications in navigated surgeries)

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Humanistic value					
Singhatanadgige (2022)[7] Comparative Radiographic Analyses and Clinical Outcomes Between O-Arm Navigated and Fluoroscopic-Guided Minimally Invasive Transforaminal Lumbar Interbody Fusion	Retrospective comparative study (O-arm™ & StealthStation™ vs conventional fluoroscopy)	Patients: N=97 Screws: N=442 • O-arm™ & StealthStation™: n=36 patients/ n=172 screws • Fluoroscopy: n=61 patients/ n=270 screws	Lumbar Sacral	Degenerative diseases	**VAS score for back pain, mean (SD)** Pre-operative, *p=0.312*: • O-arm™ & StealthStation™: 7.14±0.45 • Fluoroscopy: 6.48±0.43 1 year post-surgery, *p=0.025*: • O-arm™ & StealthStation™: 0.11±0.11 • Fluoroscopy: 0.63±0.20 **VAS score for leg pain, mean (SD)** Pre-operative, *p=0.261*: • O-arm™ & StealthStation™: 7.56±0.39 • Fluoroscopy: 6.90±0.38 1 year post-surgery, *p<0.001*: • O-arm™ & StealthStation™: 0.11±0.11 • Fluoroscopy: 0.78±0.26 **ODI score, mean (SD)** Pre-operative, *p=0.123*: • O-arm™ & StealthStation™: 53.83±1.91 • Fluoroscopy: 49.07±2.06 1 year post-surgery, *p=0.009*: • O-arm™ & StealthStation™: 0.49±0.49 • Fluoroscopy: 5.21±1.69
Kim (2022)[40] Single-Position Oblique Lumbar Interbody Fusion and Percutaneous Pedicle Screw Fixation under O-Arm Navigation: A Retrospective Comparative Study	Retrospective comparative study (O-arm™ & StealthStation™ vs C-arm fluoroscopy)	Patients: N=56 Screws: N=224 • O-arm™ & StealthStation™: n=36 patients/ n=144 screws • C-arm fluoroscopy: n=20 patients/ n=80 screws	Lumbar	Degenerative disease	**ODI score, mean (SD)** Post-surgery, *p=0.015*: • O-arm™ & StealthStation™: 18.81±10.99 • Fluoroscopy: 28.20±17.06 **SF-36 PCS, mean (SD)** Post-surgery, *p<0.001*: • O-arm™ & StealthStation™: 62.22±14.09 • Fluoroscopy: 47.63±15.03 **SF-36 MCS, mean (SD)** Post-surgery, *p<0.001*: • O-arm™ & StealthStation™: 74.17±13.82 • Fluoroscopy: 52.89±15.68

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Economic value					
Houten (2012)[44] Clinical assessment of percutaneous lumbar pedicle screw placement using the O-arm multidimensional surgical imaging system	Retrospective comparative study (O-arm™ & StealthStation™ vs fluoroscopy)	Patients: N=94 Screws: N=346 • O-arm™ & StealthStation™: n=52 patients/ n=205 screws • Fluoroscopy: n=42 patients/ n=141 screws	Lumbar	Degenerative diseases Tumor	**Overall pedicle violation, %** • O-arm™ & StealthStation™: 3.0% • Fluoroscopy: 12.8% *p<0.01* **Surgery time, mean (range)** • O-arm™ & StealthStation™: 200 (153-241) min • Fluoroscopy: 221 (178-302) min *p<0.03*
Sanborn (2012)[41] Cost-effectiveness of confirmatory techniques for the placement of lumbar pedicle screws	Cost-effectiveness study (O-arm™ & StealthStation™ vs post-operative CT)	Patients: N=236 Screws: not reported • O-arm™ & StealthStation™: n=105 patients • Post-operative CT: n=131 patients	Lumbar	Not reported	**Imaging cost per patient (2011 prices)** • O-arm™ & StealthStation™: $59±25 • Post-operative CT: $483±127 *p<0.001*
Dea (2016)[12] Economic evaluation comparing intraoperative cone beam CT-based navigation and conventional fluoroscopy for the placement of spinal pedicle screws: a patient-level data cost-effectiveness analysis	Prospective comparative cost-effectiveness study (O-arm™ & StealthStation™ vs fluoroscopy)	Patients: N=502 Screws: N=5,132 • O-arm™ & StealthStation™: n=253 patients/ n=2,682 screws • Fluoroscopy: n=249 patients/ n=2,450 screws	Not reported	Trauma Tumor Spinal deformities Degenerative diseases	**Reoperation rate, %** • O-arm™ & StealthStation™: 0.8% • Fluoroscopy: 6.0% **Cost of reoperation** $12,618 (2013 prices) **Cost neutrality achieved with** 13.2 reoperations avoided with O-arm™ & StealthStation™
Khanna (2016)[45] Effect of intraoperative navigation on operative time in 1-level lumbar fusion surgery	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand)	Patients: N=133 Screws: not reported • O-arm™ & StealthStation™: n=70 patients • Freehand: n=63 patients	Lumbar	Tumor removal excluded	**Surgery time, mean (SD)** • O-arm™ & StealthStation™: 293±39 min • Freehand: 270±42 min *p=0.0013*

Author (year) Title	Study design	Number of patients/screws inserted	Anatomic level	Indications	Outcomes
Balling (2018)[80] Learning curve analysis of 3D-fluoroscopy image-guided pedicle screw insertions in lumbar single-level fusion procedures	Prospective cohort study	Patients: N=80 Screws: N=320 All with O-arm™ & StealthStation™	Lumbar	Degenerative diseases Scoliosis Revision surgery	**Learning curve analysis** **Pedicle screw accuracy, %** • Surgeries 1-5: 100% • Surgeries 76–80: 100% *p=1.0* **Pre-surgical preparation time, mean (SD)** • Surgeries 1-5: 61±6 min • Surgeries 76–80: 28±2 min *p<0.001* **Radiation dose, mean (SD)** • Surgeries 1-5: 919±225 mGy/cm • Surgeries 76–80: 66±4 mGy/cm *p<0.001*
Lee (2020)[42] Image-guided pedicle screws using intraoperative cone-beam CT and navigation. A cost-effectiveness study	Retrospective cost-effectiveness study (O-arm™ & StealthStation™ vs freehand)	Patients: N=2,273 Screws: not reported • O-arm™ & StealthStation™: n=401 patients • Freehand: n=1,872 patients	Thoracic Lumbar		**Revision surgery rate, %** • O-arm™ & StealthStation™: 0% • Fluoroscopy: 1% **Cost of revision surgery** £24,423 (2020 prices) **Cost neutrality achieved with** 17 revision surgeries avoided with O-arm™ & StealthStation™
Lee (2020)[43] Comparative Analysis of Surgical Outcomes of C1-2 Fusion Spine Surgery between Intraoperative Computed Tomography Image Based Navigation-Guided Operation and Fluoroscopy-Guided Operation	Retrospective comparative study (O-arm™ & StealthStation™ vs freehand)	Patients: N=34 Screws: N=135 • O-arm™ & StealthStation™: n=19 patients/ n=72 screws • Freehand: n=15 patients/ n=63 screws	Not reported	Revision surgery	**Accuracy rate in C1-2 lesion, %** • O-arm™ & StealthStation™ : 94.7% • Freehand : 89.8% *p value not reported* **Operative time, mean (SD)** • O-arm™ & StealthStation™: 319.7±62.3 min • Freehand : 372.0±73.5 min *p=0.036*

Abbreviations: CI, confidence interval; CT, computed tomography; NF-1, neurofibromatosis type 1; MCS, mental component score; ODI, Oswestry disability index; OR, odds ratio; PCS, physical component score; SD, standard deviation; SF-36, 36 item short form survey; VAS, visual analogue scale.

Abbreviations and glossary

Acronym	Description
CAGR	Cumulative annual growth rate
CE	Conformité européenne (European conformity)
CI	Confidence interval
CT	Computed tomography
FDA	Food and Drug Administration
FoV	Field of view
HCRU	Healthcare resource utilization
IQR	Interquartile range
MCS	Mental component score
MIS	Minimally invasive surgery
ODI	Oswestry disability index
OLIF	Oblique lateral interbody fusion
PCS	Physical component score
PLIF	Posterior lumbar interbody fusion
PRO	Patient-reported outcome
PS	Pedicle screw
TLIF	Transforaminal lumbar interbody fusion
SF-36	36-Item short form survey
SD	Standard deviation
VAS	Visual analogue scale

Glossary	Description
Conservative management	Supportive therapy consisting of physical therapy and pharmacological pain management
Devices and aids	Devices such as walkers and wheelchairs to support the patient in recovery and everyday care
Inpatient	An individual who has been admitted to a hospital or other facility for diagnosis and/or treatment that requires at least an overnight stay
Instrumented spine surgery	Any surgical procedure that aims at stabilizing the spine or correcting spinal alignment using implantable hardware such as screws, wires, cages, hooks, and interbody devices
Ionizing radiation	Electromagnetic waves or subatomic particles with sufficient energy to detach electrons from atoms or molecules
Posterior lumbar interbody fusion (PLIF)	An instrumented surgery approach in which two or more spine levels in the lumbar region are accessed and fused from the back of the patient body
Outpatient	A patient who is receiving ambulatory care at a hospital or other healthcare facility without being admitted to the facility
Oblique lateral interbody fusion (OLIF)	A minimally invasive surgery technique in which the lumbar spine is accessed laterally from a single position, minimizing muscle dissection
Transforaminal lumbar interbody fusion (TLIF)	A surgical technique in which the lower spine is accessed through the space between the vertebra and the disc (intravertebral foramen); it can be performed as open surgery or with a minimally invasive approach

References

1. Ailon T, Smith JS, Shaffrey CI, Lenke LG, Brodke D, Harrop JS, et al. Degenerative Spinal Deformity. Neurosurgery. 2015 Oct;77 Suppl 4:S75-91.

2. Baky FJ, Milbrandt T, Echternacht S, Stans AA, Shaughnessy WJ, Larson AN. Intraoperative Computed Tomography-Guided Navigation for Pediatric Spine Patients Reduced Return to Operating Room for Screw Malposition Compared With Freehand/Fluoroscopic Techniques. Spine Deform. 2019 Jul;7(4):577-81.

3. Banat M, Wach J, Salemdawod A, Bahna M, Scorzin J, Vatter H. The Role of Intraoperative Image Guidance Systems (Three-Dimensional C-arm versus O-arm) in Spinal Surgery: Results of a Single-Center Study. World Neurosurg. 2021 Feb;146:e817-e21.

4. Bettany-Saltikov J, Turnbull D, Ng SY, Webb R. Management of Spinal Deformities and Evidence of Treatment Effectiveness. Open Orthop J. 2017;11:1521-47.

5. Crawford BD, Nchako CM, Rebehn KA, Israel H, Place HM. Transpedicular Screw Placement Accuracy Using the O-Arm Versus Freehand Technique at a Single Institution. Global Spine J. 2022 Apr;12(3):447-51.

6. Hubertus V, Wessels L, Fruh A, Tkatschenko D, Nulis I, Bohner G, et al. Navigation accuracy and assessability of carbon fiber-reinforced PEEK instrumentation with multimodal intraoperative imaging in spinal oncology. Sci Rep. 2022 Sep 22;12(1):15816.

7. Singhatanadgige W, Pholprajug P, Songthong K, Yingsakmongkol W, Triganjananun C, Kotheeranurak V, et al. Comparative Radiographic Analyses and Clinical Outcomes Between O-Arm Navigated and Fluoroscopic-Guided Minimally Invasive Transforaminal Lumbar Interbody Fusion. Int J Spine Surg. 2022 Feb;16(1):151-8.

8. Tajsic T, Patel K, Farmer R, Mannion RJ, Trivedi RA. Spinal navigation for minimally invasive thoracic and lumbosacral spine fixation: implications for radiation exposure, operative time, and accuracy of pedicle screw placement. Eur Spine J. 2018 Aug;27(8):1918-24.

9. Wada K, Tamaki R, Inoue T, Hagiwara K, Okazaki K. Cervical Pedicle Screw Insertion Using O-Arm-Based 3D Navigation: Technical Advancement to Improve Accuracy of Screws. World Neurosurg. 2020 Jul;139:e182-e8.

10. Zhang K, Chen H, Chen K, Yang P, Yang H, Mao H. O-Arm Navigated Cervical Pedicle Screw Fixation in the Treatment of Lower Cervical Fracture-Dislocation. Orthop Surg. 2022 Jun;14(6):1135-42.

11. Peng P, Chen K, Chen H, Zhang K, Sun J, Yang P, et al. Comparison of O-arm navigation and microscope-assisted minimally invasive transforaminal lumbar interbody fusion and conventional transforaminal lumbar interbody fusion for the treatment of lumbar isthmic spondylolisthesis. J Orthop Translat. 2020 Jan;20:107-12.

12. Dea N, Fisher CG, Batke J, Strelzow J, Mendelsohn D, Paquette SJ, et al. Economic evaluation comparing intraoperative cone beam CT-based navigation and conventional fluoroscopy for the placement of spinal pedicle screws: a patient-level data cost-effectiveness analysis. Spine J. 2016 Jan 1;16(1):23-31.

13. Du J, Gao L, Huang D, Shan L, Wang W, Fan Y, et al. Radiological and Clinical Differences between Tinavi Orthopedic Robot and O-Arm Navigation System in Thoracolumbar Screw Implantation for Reconstruction of Spinal Stability. Med Sci Monit. 2020 Sep 12;26:e924770.

14. Wang Y, Chen K, Chen H, Zhang K, Lu J, Mao H, et al. Comparison between free-hand and O-arm-based navigated posterior lumbar interbody fusion in elderly cohorts with three-level lumbar degenerative disease. Int Orthop. 2019 Feb;43(2):351-7.

15. Fichtner J, Hofmann N, Rienmuller A, Buchmann N, Gempt J, Kirschke JS, et al. Revision Rate of Misplaced Pedicle Screws of the Thoracolumbar Spine-Comparison of Three-Dimensional Fluoroscopy Navigation with Freehand Placement: A Systematic Analysis and Review of the Literature. World Neurosurg. 2018 Jan;109:e24-e32.

16. Anda S, Aakhus S, Skaanes KO, Sande E, Schrader H. Anterior perforations in lumbar discectomies. A report of four cases of vascular complications and a CT study of the prevertebral lumbar anatomy. Spine (Phila Pa 1976). 1991 Jan;16(1):54-60.

17. Fujita T, Kostuik JP, Huckell CB, Sieber AN. Complications of spinal fusion in adult patients more than 60 years of age. Orthop Clin North Am. 1998 Oct;29(4):669-78.

18. Jendrisak MD. Spontaneous abdominal aortic rupture from erosion by a lumbar spine fixation device: a case report.

Surgery. 1986 May;99(5):631-3.

19. Stewart JR, Barth KH, Williams GM. Ruptured lumbar artery pseudoaneurysm: an unusual cause of retroperitoneal hemorrhage. Surgery. 1983 Apr;93(4):592-4.

20. Deen HG, Birch BD, Wharen RE, Reimer R. Lateral mass screw-rod fixation of the cervical spine: a prospective clinical series with 1-year follow-up. Spine J. 2003 Nov-Dec;3(6):489-95.

21. Orchowski J, Bridwell KH, Lenke LG. Neurological deficit from a purely vascular etiology after unilateral vessel ligation during anterior thoracolumbar fusion of the spine. Spine (Phila Pa 1976). 2005 Feb 15;30(4):406-10.

22. Diaz JH, Lockhart CH. Postoperative quadriplegia after spinal fusion for scoliosis with intraoperative awakening. Anesth Analg. 1987 Oct;66(10):1039-42.

23. Biswas D, Bible JE, Whang PG, Simpson AK, Grauer JN. Sterility of C-arm fluoroscopy during spinal surgery. Spine (Phila Pa 1976). 2008 Aug 1;33(17):1913-7.

24. Roccucci P, Peron S, Minotti M, Stefini R. Real-time navigation in spinal surgery: what has changed in surgical practice? J Neurosurg Sci. 2019 Aug;63(4):402-10.

25. Verma SK, Singh PK, Agrawal D, Sinha S, Gupta D, Satyarthee GD, et al. O-arm with navigation versus C-arm: a review of screw placement over 3 years at a major trauma center. Br J Neurosurg. 2016 Dec;30(6):658-61.

26. Baumgart L, Ille S, Kirschke JS, Meyer B, Krieg SM. Radiation doses and accuracy of navigated pedicle screw placement in cervical and thoracic spine surgery: a comparison of sliding gantry CT and mobile cone-beam CT in a homogeneous cohort. J Neurosurg Spine. 2023 Sep 1;39(3):363-9.

27. Bratschitsch G, Leitner L, Stucklschweiger G, Guss H, Sadoghi P, Puchwein P, et al. Radiation Exposure of Patient and Operating Room Personnel by Fluoroscopy and Navigation during Spinal Surgery. Sci Rep. 2019 Nov 27;9(1):17652.

28. Li C, Wang Z, Li D, Tian Y, Yuan S, Wang L, et al. Safety and accuracy of cannulated pedicle screw placement in scoliosis surgery: a comparison of robotic-navigation, O-arm-based navigation, and freehand techniques. Eur Spine J. 2023 Sep;32(9):3094-104.

29. Passias BJ, Grenier G, Buchan J, Buchan DR, Scheschuk J, Taylor BC. Use of 3D Navigation Versus Traditional Fluoroscopy for Posterior Pelvic Ring Fixation. Orthopedics. 2021 Jul-Aug;44(4):229-34.

30. Restelli U, Anania CD, Porazzi E, Banfi G, Croce D, Fornari M, et al. An observational analysis of costs and effectiveness of an intraoperative compared with a preoperative image-guided system in spine surgery fixation: analysis of 10 years of experience. J Neurosurg Sci. 2022 Aug;66(4):350-5.

31. Yang P, Chen K, Zhang K, Sun J, Yang H, Mao H. Percutaneous short-segment pedicle instrumentation assisted with O-arm navigation in the treatment of thoracolumbar burst fractures. J Orthop Translat. 2020 Mar;21:1-7.

32. Chen K, Chen H, Zhang K, Yang P, Sun J, Mo J, et al. O-arm Navigation Combined With Microscope-assisted MIS-TLIF in the Treatment of Lumbar Degenerative Disease. Clin Spine Surg. 2019 Jun;32(5):E235-E40.

33. Gan G, Kaliya-Perumal AK, Yu CS, Nolan CP, Oh JY. Spinal Navigation for Cervical Pedicle Screws: Surgical Pearls and Pitfalls. Global Spine J. 2021 Mar;11(2):196-202.

34. Kotani Y, Abumi K, Ito M, Minami A. Improved accuracy of computer-assisted cervical pedicle screw insertion. J Neurosurg. 2003 Oct;99(3 Suppl):257-63.

35. Towner JE, Li YI, Singla A, Moquin R, Li YM. Retrospective Review of Revision Surgery After Image-guided Instrumented Spinal Surgery Compared With Traditional Instrumented Spinal Surgery. Clin Spine Surg. 2020 Aug;33(7):E317-E21.

36. Van de Kelft E, Costa F, Van der Planken D, Schils F. A prospective multicenter registry on the accuracy of pedicle screw placement in the thoracic, lumbar, and sacral levels with the use of the O-arm imaging system and StealthStation Navigation. Spine (Phila Pa 1976). 2012 Dec 1;37(25):E1580-7.

37. Wojdyn M, Pierzak O, Zapalowicz K, Radek M. Use of O-arm with neuronavigation in percutaneous vertebroplasty reduces the surgeon's exposure to intraoperative radiation. Arch Med Sci. 2021;17(1):113-9.

38. Kim JH, Jitpakdee K, Kotheeranurak V, Quillo-Olvera J, Choi KC, Kim YJ, et al. Is navigation beneficial for transforaminal endoscopic lumbar foraminotomy? A preliminary comparison study with fluoroscopic guidance. Eur Spine J. 2023 Aug;32(8):2808-18.

39. Rohe S, Strube P, Holzl A, Bohle S, Zippelius T, Lindemann C. Cone-Beam Navigation Can Reduce the Radiation Exposure and Save Fusion Length-Dependent Operation Time in Comparison to Conventional Fluoroscopy in Pedicle-Screw-Based Lumbar Interbody Fusion. J Pers Med. 2022 May 1;12(5).

40. Kim HC, Jeong YH, Oh SH, Lee JM, Lee CK, Yi S, et al. Single-Position Oblique Lumbar Interbody Fusion and Percutaneous Pedicle Screw Fixation under O-Arm Navigation: A Retrospective Comparative Study. J Clin Med. 2022 Dec 30;12(1).

41. Sanborn MR, Thawani JP, Whitmore RG, Shmulevich M, Hardy B, Benedetto C, et al. Cost-effectiveness of confirmatory techniques for the placement of lumbar pedicle screws. Neurosurg Focus. 2012 Jul;33(1):E12.

42. Lee YC, Lee R. Image-guided pedicle screws using intraoperative cone-beam CT and navigation. A cost-effectiveness study. J Clin Neurosci. 2020 Feb;72:68-71.

43. Lee JS, Son DW, Lee SH, Ki SS, Lee SW, Song GS. Comparative Analysis of Surgical Outcomes of C1-2 Fusion Spine Surgery between Intraoperative Computed Tomography Image Based Navigation-Guided Operation and Fluoroscopy-Guided Operation. J Korean Neurosurg Soc. 2020 Mar;63(2):237-47.

44. Houten JK, Nasser R, Baxi N. Clinical assessment of percutaneous lumbar pedicle screw placement using theO-arm multidimensional surgical imaging system. Neurosurgery. 2012 Apr;70(4):990-5.

45. Khanna AR, Yanamadala V, Coumans JV. Effect of intraoperative navigation on operative time in 1-level lumbar fusion surgery. J Clin Neurosci. 2016 Oct;32:72-6.

46. Kobayashi K, Sato K, Kato F, Kanemura T, Yoshihara H, Sakai Y, et al. Trends in the numbers of spine surgeries and spine surgeons over the past 15 years. Nagoya J Med Sci. 2022 Feb;84(1):155-62.

47. Clarivate. Spinal Implants. Market Insights. Europe. 2022.

48. Kalakoti P, Menger R, Hendrickson N, Shamrok A, Eisenberg J, Saifi C, et al. 156. Forecasting spinal deformity health care burden and operative utilization in the United States from 2015 to 2040: an epidemiological-based autoregressive integrated moving average (ARIMA) computation modeling. . The Spine Journal. 2019;19:S75-S6.

49. Sheikh SR, Thompson NR, Benzel E, Steinmetz M, Mroz T, Tomic D, et al. Can We Justify It? Trends in the Utilization of Spinal Fusions and Associated Reimbursement. Neurosurgery. 2020 Feb 1;86(2):E193-E202.

50. Sivasubramaniam V, Patel HC, Ozdemir BA, Papadopoulos MC. Trends in hospital admissions and surgical procedures for degenerative lumbar spine disease in England: a 15-year time-series study. BMJ Open. 2015 Dec 15;5(12):e009011.

51. Zhang Y, Liu H, He F, Chen A, Yang H, Pi B. Safety and efficacy of percutaneous kyphoplasty assisted with O-arm navigation for the treatment of osteoporotic vertebral compression fractures at T6 to T9 vertebrae. Int Orthop. 2020 Feb;44(2):349-55.

52. Al Jammal OM, Delavar A, Maguire KR, Hirshman BR, Wali AR, Kazzaz M, et al. National Trends in the Surgical Management of Lumbar Spinal Stenosis in Adult Spinal Deformity Patients. Spine (Phila Pa 1976). 2019 Dec 1;44(23):E1369-E78.

53. Beschloss A, Ishmael T, Dicindio C, Hendow C, Ha A, Louie P, et al. The Expanding Frontier of Outpatient Spine Surgery. Int J Spine Surg. 2021 Apr;15(2):266-73.

54. Malik AT, Yu E, Kim J, Khan SN. 30-day Outcomes in Primary vs. Revision Posterior Spinal Fusion for Pediatric Spinal Deformity. Clin Neurol Neurosurg. 2019 May;180:106-10.

55. Zhang H, Li T, Sun H, Zhang J, Hao D. Retrospective analysis of reasons and revision strategy for failed thoracolumbar fracture surgery by posterior approach: a series of 31 cases. Am J Transl Res. 2022 ;14(9):6323-31.

56. Diebo BG, Passias PG, Marascalchi BJ, Jalai CM, Worley NJ, Errico TJ, et al. Primary Versus Revision Surgery in the Setting of Adult Spinal Deformity: A Nationwide Study on 10,912 Patients. Spine (Phila Pa 1976). 2015 Nov;40(21):1674-80.

57. Dandurand C, Mashayekhi MS, McIntosh G, Street JT, Fisher CG, Finkelstein J, et al. Patient, clinical, surgical, and institutional factors associated with length of stay in scheduled degenerative thoracolumbar spine surgery: National Multicenter Cohort Analysis from the Canadian Spine Outcomes and Research Network. J Neurosurg Spine. 2023 Apr 1;38(4):446-56.

58. Jacob C, Annoni E, Haas JS, Braun S, Winking M, Franke J. Burden of disease of reoperations in instrumental spinal surgeries in Germany. Eur Spine J. 2016 Mar;25(3):807-13.

59. Jacobs K, Dewilde T, Vandoren C, Cardoen B, Vansteenkiste N, Scheys L, et al. Variability in Hospital Costs of Adult Spinal Deformity Care. Spine (Phila Pa 1976). 2020 Sep 1;45(17):1221-8.

60. Culler SD, McGuire KJ, Little KM, Jevsevar D, Shea K, Schlosser M, et al. Incremental Hospital Cost and Length-of-stay Associated With Treating Adverse Events Among Medicare Beneficiaries Undergoing Cervical Spinal Fusion During Fiscal Year 2013 and 2014. Spine (Phila Pa 1976). 2017 Oct 15;42(20):1578-86.

61. Ishii M, Ohnishi A, Yamagishi A, Ohwada T. Freehand screw insertion technique without image guidance for the cortical bone trajectory screw in posterior lumbar interbody fusion: what affects screw misplacement? J Neurosurg Spine. 2022 Jan 1;36(1):1-7.

62. Freire-Archer M, Sarraj M, Koziarz A, Thornley P, Alshaalan F, Alnemari H, et al. Incidence and Recurrence of Deep Spine Surgical Site Infections: A Systematic Review and Meta-analysis. Spine (Phila Pa 1976). 2023 Aug 15;48(16):E269-E85.

63. Wang JC, Mummaneni PV, Haid RW. Current treatment strategies for the painful lumbar motion segment: posterolateral fusion versus interbody fusion. Spine (Phila Pa 1976). 2005 Aug 15;30(16 Suppl):S33-43.

64. Avellanal M, Martin-Corvillo M, Barrigon L, Espi MV, Escolar CME. A 1-Year Cost Analysis of Spinal Surgical Procedures in Spain: Neurosurgeons Versus Orthopedic Surgeons. Neurospine. 2019 Jun;16(2):354-9.

65. Hlubek RJ, Almefty KK, Xu DS, Turner JD, Kakarla UK. Safety and Accuracy of Freehand Versus Navigated Iliac Screws: Results From 222 Screw Placements. Spine (Phila Pa 1976). 2017 Oct 15;42(20):E1190-E6.

66. Habib N, Filardo G, Distefano D, Candrian C, Reinert M, Scarone P. Use of Intraoperative CT Improves Accuracy of Spinal Navigation During Screw Fixation in Cervico-thoracic Region. Spine (Phila Pa 1976). 2021 Apr 15;46(8):530-7.

67. Li C, Li H, Su J, Wang Z, Li D, Tian Y, et al. Comparison of the Accuracy of Pedicle Screw Placement Using a Fluoroscopy-Assisted Free-Hand Technique with Robotic-Assisted Navigation Using an O-Arm or 3D C-Arm in Scoliosis Surgery. Global Spine J. 2022 Dec 1:21925682221143076.

68. Xiao R, Miller JA, Sabharwal NC, Lubelski D, Alentado VJ, Healy AT, et al. Clinical outcomes following spinal fusion using an intraoperative computed tomographic 3D imaging system. J Neurosurg Spine. 2017 May;26(5):628-37.

69. Ladd B, Jones K, Polly D, Jr. 2-Dimensional Long Film O-Arm Imaging, an Alternative When Intraoperative Fluoroscopy Is Inadequate. World Neurosurg. 2021 Jun;150:54-5.

70. Zhang X, Uneri A, Huang Y, Jones CK, Witham TF, Helm PA, et al. Deformable 3D-2D image registration and analysis of global spinal alignment in long-length intraoperative spine imaging. Med Phys. 2022 Sep;49(9):5715-27.

71. Takigawa T, Morita T, Kajiki Y, Ito Y. Application of a Navigated Drill for Cervical Pedicle Screw Insertion at C3-6. Cureus. 2023 Oct;15(10):e47710.

72. Soliman MAR, Aguirre AO, Khan S, Kuo CC, Ruggiero N, Mariotti BL, et al. Complications associated with subaxial placement of pedicle screws versus lateral mass screws in the cervical spine (C2-T1): systematic review and meta-analysis comprising 4,165 patients and 16,669 screws. Neurosurg Rev. 2023 Feb 28;46(1):61.

73. Wood M, Mannion R. A comparison of CT-based navigation techniques for minimally invasive lumbar pedicle screw placement. J Spinal Disord Tech. 2011 Feb;24(1):E1-5.

74. Burch S, Karahalios D, Mobasser J-P, Potts E. Comparison of radiation exposure to the spine surgeon during pedicle screw placement using the O-arm System and StealthStation Navigation vs. C-arm Standard fluoroscopy. Technical Monograph Medtronic. 2010.

75. Prod'homme M, Grasset D, Akiki A, Helfer L, Dietrich G, Muller JP, et al. Significant Reduction of Radiation Exposure Using Specific Settings of the O-Arm for Percutaneous Cementoplasty in Accordance With the ALARA Principle. Int J Spine Surg. 2023 Aug;17(4):534-41.

76. Shin MH, Ryu KS, Park CK. Accuracy and Safety in Pedicle Screw Placement in the Thoracic and Lumbar Spines : Comparison Study between Conventional C-Arm Fluoroscopy and Navigation Coupled with O-Arm(R) Guided Methods. J Korean Neurosurg Soc. 2012 Sep;52(3):204-9.

77. Verhofste BP, Glotzbecker MP, Hresko MT, MacDougall RD, Birch CM, O'Neill NP, et al. Intraoperative Use of O-arm in Pediatric Cervical Spine Surgery. J Pediatr Orthop. 2020 Apr;40(4):e266-e71.

78. Yang YL, Zhou DS, He JL. Comparison of isocentric C-arm 3-dimensional navigation and conventional fluoroscopy for C1 lateral mass and C2 pedicle screw placement for atlantoaxial instability. J Spinal Disord Tech. 2013 May;26(3):127-34.

79. Costa F, Porazzi E, Restelli U, Foglia E, Cardia A, Ortolina A, et al. Economic study: a cost-effectiveness analysis of an intraoperative compared with a preoperative image-guided system in lumbar pedicle screw fixation in patients with degenerative spondylolisthesis. Spine J. 2014 Aug 1;14(8):1790-6.

80. Balling H. Learning curve analysis of 3D-fluoroscopy image-guided pedicle screw insertions in lumbar single-level fusion procedures. Arch Orthop Trauma Surg. 2018 Nov;138(11):1501-9.

81. Lu S, Yang K, Lu C, Wei P, Gan Z, Zhu Z, et al. O-arm navigation for sacroiliac screw placement in the treatment for posterior pelvic ring injury. Int Orthop. 2021 Jul;45(7):1803-10.

82. Sargut TA, Hecht N, Xu R, Bohner G, Czabanka M, Stein J, et al. Intraoperative imaging and navigated spinopelvic instrumentation: S2-alar-iliac screws combined with tricortical S1 pedicle screw fixation. Eur Spine J. 2022 Oct;31(10):2587-96.

Further Information

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions and potential adverse events.

For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic
Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
(800) 876-3133

Customer Service:
(800) 933-2635

medtronic.com

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser.

For best results, use Adobe AcrobatTM Reader with the browser.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Medtronic