A COMPLETE SOLUTION FOR SPINAL SURGERY

Medtronic O-arm™ Intraoperative Imaging
& StealthStation™ Navigation

Value Summary

Medtronic
Further, Together

Note to the reader

The information provided in this document was updated in September 2016.

Evidence on clinical and economic value of Medtronic O-arm™ Imaging & StealthStation™ Navigation included in this document refer to all generations of the O-arm™ Imaging & StealthStation™ Navigation systems.

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EXECUTIVE SUMMARY

UP TO
99.7%
SCREW PLACEMENT ACCURACY WITH O-ARM™ & STEALTHSTATION™[3]

Burden and risks associated with instrumented spine surgery

Instrumented spine surgery consists of the stabilization of the spine using a variety of implantable hardware such as pedicle screws, rods, plates, cages or hooks.

Due to the proximity of the spinal cord, nerves and vascular structures, the main challenge associated with instrumented spine surgery is the accurate placement of surgical hardware, specifically pedicle screws, according to the patient's anatomy and in alignment with the surgical preoperative plan. Protecting themselves and patients from excessive radiation exposure is another issue to consider when using image-guidance techniques to facilitate accurate pedicle screw placement. Of these, a routinely used technique is intraoperative 2D fluoroscopy with technologies such as a C-arm imaging system[2,11]. However, due to the lack of information on the 3rd dimension, intraoperative 2D fluoroscopy as well as free-hand techniques are suboptimal and may lead to pedicle screw misplacement (8.9% to 16.9%)[12].

Screw misplacement represents a substantial humanistic and economic burden, especially when revision surgery is needed, and can result in complications such as pain, hematoma, infection, hemorrhage, pseudoaneurysm, perforations of the lung, the ureter, the gut or the esophagus, injury to the nerve root, spinal cord infarction and paralysis[18-24].

Advancements in surgical imaging & navigation - The Medtronic O-arm™ Imaging and StealthStation™ Navigation systems

The O-arm™ Imaging is a complete multidimensional intraoperative surgical imaging system that produces high-quality 3D images, as well as multiplane 2D views[29]. The StealthStation™ Navigation is an advanced navigation system integrating up-to-date intra-procedural images and displaying them on a screen to facilitate instrument navigation.

The combination of O-arm™ Imaging & StealthStation™ Navigation provides an easy-to-use and complete solution for instrumented spine surgery. The O-arm™ Imaging & StealthStation™ Navigation systems also offer a streamlined workflow in order to increase screw placement accuracy and safety[1,29-33,38].

Clinical value - O-arm™ Imaging & StealthStation™ Navigation

In comparison to current practice, the O-arm™ Imaging & StealthStation™ Navigation systems significantly improve screw placement accuracy[1,29-32,35,36,38-41]. Comparative studies have reported up to 9% absolute reduction of potentially harmful screw misplacement with the O-arm™ Imaging & StealthStation™ Navigation systems[1,29-32]. Additionally, high rates of safe screw placement, from 97.2% to 99.7%, have been consistently recorded with O-arm™ Imaging & StealthStation™ Navigation, whereas alternative current practice options were associated with accuracy rates ranging from 89.8% to 96.3%[1,29-32].

O-arm™ Imaging & StealthStation™ Navigation also significantly reduce surgeons' and patients' exposure to radiation[29,36,45-47] and offer the opportunity for intraoperative correction of misplaced screws during the index procedure, thus avoiding additional revision surgeries[41-44].

Economic value - O-arm™ Imaging & StealthStation™ Navigation

The O-arm™ Imaging & StealthStation™ Navigation systems have the potential to be a cost-saving investment due to the opportunity of performing minimally invasive procedures, the reduction of CT-scan needs, the improvement in screw placement accuracy, the subsequent reduced need of revision surgeries, and the shortened length of procedures[42,48-52].

CLINICAL PICTURE - SPINE SURGERY

Instrumented spine surgery consists of the stabilization of the spine using a variety of implantable hardware such as pedicle screws, rods, plates, cages or hooks. Children or adults who present with any of a variety of indications including deformities, degenerative diseases, trauma and tumors, may require instrumented spine surgery[1-3].

The main challenge associated with instrumented spine surgery is the accurate placement of surgical hardware due to the proximity of the spinal cord, nerves and vascular structures. Another challenge is the accurate placement of pedicle screws according to the patient's anatomy and in alignment with the surgical preoperative plan. Thanks to significant advancements in image-guidance technologies, safe pedicle screw placement can now be more easily achieved not only with conventional open surgery but also with minimally invasive techniques, thus reducing the risk of iatrogenically induced injury[8].

Instrumented spine surgery is indicated for the management of pathological conditions including deformities, degenerative diseases, trauma and tumors, in order to correct and maintain spine alignment **(Table 1)**[1-3]. Spinal instrumentation refers to implantable hardware such as screws, rods, plates, cages or hooks, which are used to ensure rigidity of a patient's spine. Among these different sorts of instruments, pedicle screws are the current mainstay of instrumented spine surgery **(Figure 1)**[4].

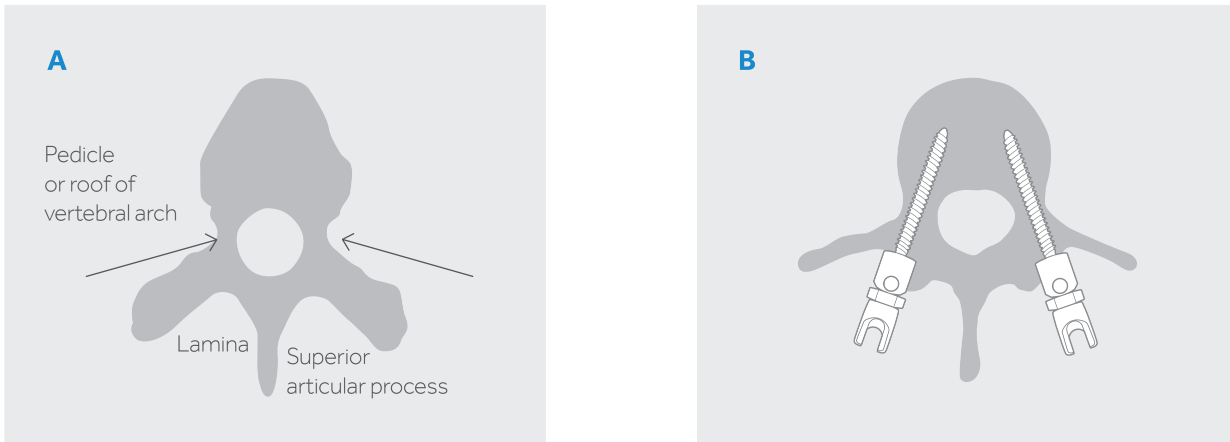
Pedicles are the short, thick processes that project dorsally from each side of a vertebra **(Figure 1)**. Due to their proximity to the spinal cord, nerves and vascular structures, the main challenge of instrumented spine surgery is therefore the accurate and injury-free placement of pedicle screws[5].

In such a complex anatomy, open surgery has been associated with substantial destructive effects, especially in terms of muscle dissection, leading to the advent of minimally invasive techniques over the last decade[6,7]. Minimally invasive spinal surgery aims to achieve the same clinical outcomes as conventional open surgery, while minimizing the risk of iatrogenic injury that may be incurred during the exposure process[8]. The foundation of minimally invasive surgery (MIS) for pedicle screw placement was laid with advancements in optics and video equipment as well as image guidance systems that provided visual information of unexposed anatomy[8]. Today, the majority of conventional open spinal procedures can be performed using a minimally invasive approach[8].

Table 1
Indications for instrumented spine surgery with pedicle screws[1-3]

Spinal deformities	Degenerative disc diseases	Trauma
▪ Scoliosis ▪ Kyphosis ▪ Kyphoscoliosis ▪ Lordosis ▪ Spondylolisthesis	▪ Slipped or herniated disc ▪ Stenosis ▪ Osteoarthiritis ▪ Spondyloarthrosis ▪ Spondylolisthesis	▪ Spinal fracture or dislocation ▪ Osteoporosis **Tumor**

Figure 1
Illustration of the pedicle of a vertebra (A), and pedicle screw insertion (B)



IMAGING & NAVIGATION - CURRENT PRACTICE & UNMET NEEDS

Current practice consists of various image-guidance techniques, with or without surgical navigation in order to facilitate accurate pedicle screw placement. Of these, a routinely used technique is intraoperative 2D fluoroscopy with technologies such as a C-arm imaging system[2,11].

However, with intraoperative 2D fluoroscopy, the procedure is limited by a lack of information on the 3rd dimension and on the relative positioning of surgical instruments according to the patient's anatomy[10]. There are also concerns about sterility[11] and risk of surgical wound infection as well as radiation exposure[13,14].

As intraoperative 2D fluoroscopy and free-hand techniques only provide suboptimal information, they may lead to pedicle screw misplacement (8.9% to 16.9%)[12], which results in humanistic and economic burden, especially when revision surgery is needed. In addition, reduced sterility may result in postoperative infections[11], and high radiation exposure increases the risk of malignancies among surgeons and patients[13,14]. All of these outcomes are preventable.

To facilitate accurate pedicle screw placement in the complex anatomy of the spine, available practices consist of various image-guidance techniques, with or without surgical navigation. Surgical navigation provides intraoperative visualization of anatomical structures which allows for real-time tracking of surgical instrumentation[9,10]. During a procedure, information about the relative positioning of implantable hardware and the patient's anatomy is virtually projected and continuously displayed on the surgical navigation system[10].

Surgical navigation, in combination with intraoperative imaging, allows surgeons to perform safer and minimally invasive procedures[10].

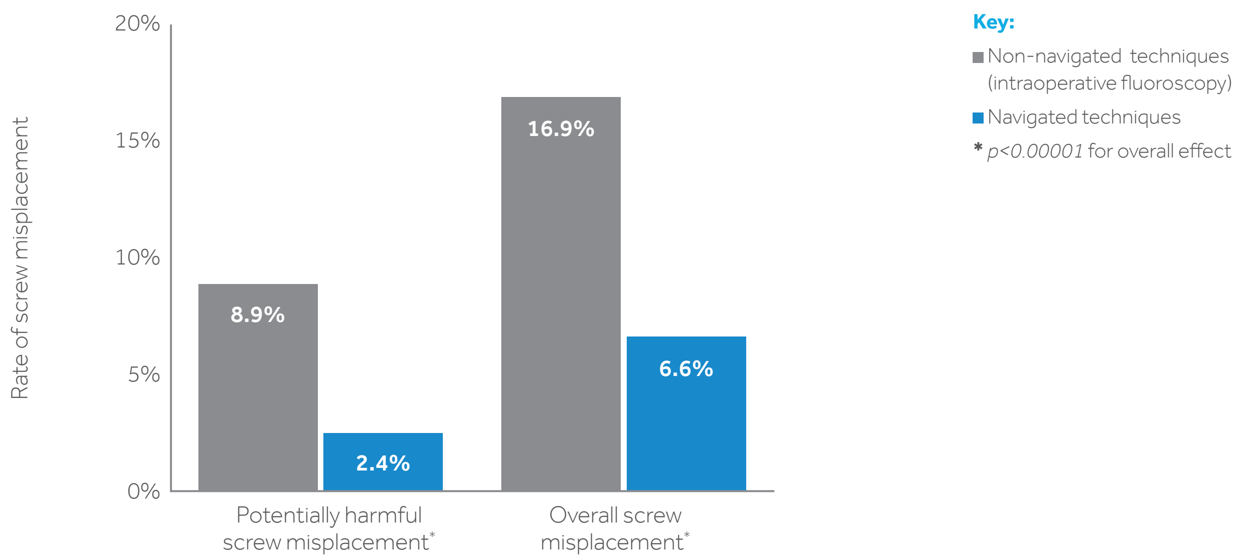
Currently, common practice does not necessarily integrate surgical navigation. A routinely used technique is intraoperative 2-dimensional (2D) fluoroscopy with technologies such as a C-arm imaging system[2,11]. Alternative options include other free-hand techniques with Computerized Tomography (CT) scans alone or paired with fluoroscopy[12].

Unmet needs with current practice

- Due to partial sterile drape covering, an intraoperative C-arm imaging system is a potential source of contamination of the operative field, especially while maneuvering the device to acquire various radiographic projections, and may carry a risk of surgical wound infection[11].
- With C-arm intraoperative 2D fluoroscopy, screw placement is guided with continuous X-ray imaging which exposes patients and surgeons to relatively high doses of radiation[13,14].
- Intraoperative fluoroscopy based on 2D projections is not optimal to precisely guide pedicle screw placement as the procedure is limited by a lack of information on the 3rd dimension.
- Non-navigated techniques have been associated with statistically higher pedicle screw misplacement with rates of 8.9% and 16.9% for both potentially harmful screw misplacement and overall screw misplacement[12,a]. In comparison, with surgical navigated techniques, rates were 2.4% and 6.6%, respectively **(Figure 2)**[12].

Figure 2

Comparison of image-guided pedicle screw placement accuracy with or without surgical navigation (Adapted from Tang 2014)[12,a]



a. Potentially harmful screw misplacement defined as pedicle violation either ≤2mm or ≤3mm or <1/4 of screw diameter; Overall screw misplacement defined as pedicle violation ≤0mm.

HUMANISTIC & ECONOMIC **BURDEN OF COMPLICATIONS**

Screw misplacement can result in complications such as pain, hematoma, infection, hemorrhage, pseudoaneurysm, perforations of the lung, the ureter, the gut or the esophagus, injury to the nerve root, spinal cord infarction and paralysis[18-24].

Revision procedures are the greatest cause of morbidity associated with screw misplacement as the risk of neurological deficits is 40% higher than in index procedures, and is significantly higher among children compared with adults[28].

The economic burden associated with the current practice in spinal surgery is mainly driven by the costs and consequences of reoperation[26]. Indeed, in a burden of illness study on reoperations in instrumented spine surgery conducted in Germany, it has been estimated that the aggregate annual costs of reoperations would reach approximately €59.3M (2010 €) from the perspective of the statutory health insurance[26].

Humanistic Burden

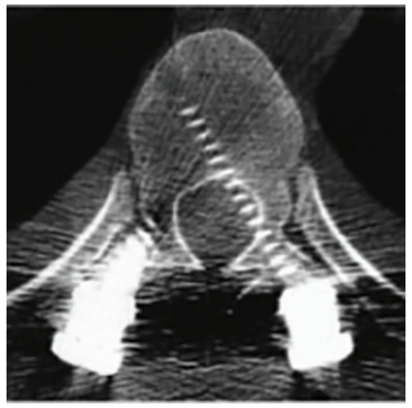
Due to the proximity to the spinal cord, nerves and vascular structures (the aorta, vena cava and branching vessels) inaccurate pedicle screw placement **(Figure 3)** can result in various and potentially severe complications[15,16]. Injuries occur because the course of the pedicle and screw positioning cannot be properly checked, which is mainly due to lack of visual access[17].

Screw misplacement complications such as injury to the nerve root has been reported in up to 14.3% of cases and spinal cord infarction in 0.75% of cases with the potential to result in para/quadripalsy[18-20]. Complications may be acute or delayed, temporary or permanent. If the aorta is ruptured, it can result in hemorrhage and a subsequent lethal decrease in blood volume or in pseudoaneurysm[21-24]. Other complications of screw misplacement include pain, hematoma, infection, perforations of the lung, the ureter, the gut and the esophagus as well as paralysis[20,22].

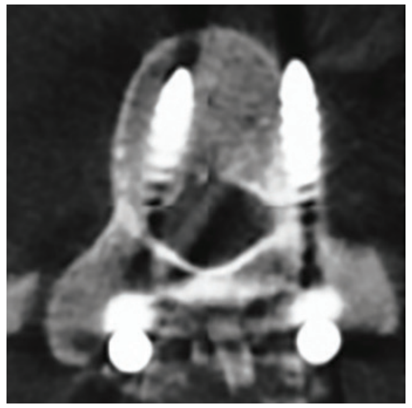
In the case of transpedicle instrumentation fixation, overall complication rates as high as 54% have been reported with a risk of deep tissue infection (4–5%), cerebrospinal fluid leak (4%), transient neuropraxia (2%), permanent nerve root injury (2%), and instrumentation failure (3–12%)[25,26]. These complications impose a considerable burden on patients due to persistent pain and the potential need for revision surgery[26].

If pedicle screw placement accuracy is not checked at the end of the index fusion procedure, a reoperation to revise screw position may be required[27]. Importantly, revision procedures are the greatest cause of morbidity associated with screw misplacement as the risk of neurological deficits is 40% higher than in index procedures, and is significantly higher among children compared with adults[28].

Figure 3
Examples of pedicle screw misplacement



A. Perforation of canal



B. Perforation of lateral pedicle

HUMANISTIC & ECONOMIC **BURDEN OF COMPLICATIONS**

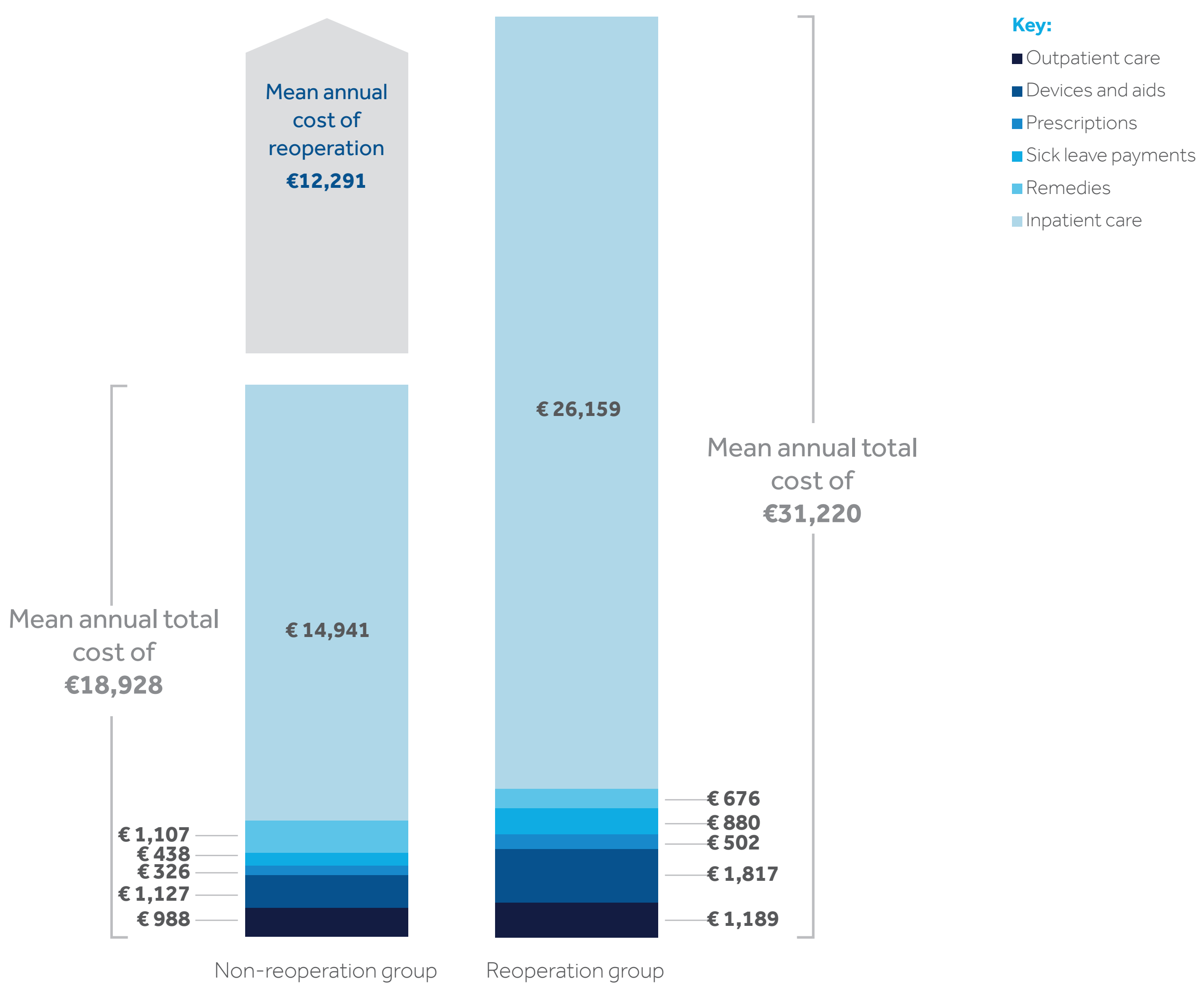
Economic Burden

The economic burden associated with the current practice in spinal surgery is mainly driven by the cost and consequences of reoperation[26]. When reoperations are necessary, to correct screw misplacement for instance, they could be associated with significant additional resource utilization and cost from the payer's perspective[26].

A burden of illness study on reoperations in instrumented spine surgery has highlighted that the costs of index procedures and subsequent reoperations (regardless of indication for spinal revision) have a significant impact on health insurances budgets in Germany[26]. In this study, the mean total cost of patients with a reoperation (combining both the cost of the index procedure and the reoperation) was €31,220 (2010 €) over the 12 months after primary surgery. In contrast, the mean annual total cost of patients without a reoperation was €18,928 (2010 €); a statistical significant difference of €12,291 (2010 €) **(Figure 4)**[26]. These cost increases in patients with reoperation were mainly driven by the need for additional devices and aids (+101%) and further inpatient care (+75%)[26]. In the end, considering 10% of reoperations nationwide, the aggregate annual costs were estimated to reach approximately €59.3M (2010 €) from the perspective of the statutory German Health Insurance[26].

Figure 4

Mean costs of resources used during 12 months after primary surgery in patients undergoing instrumented spine surgery with and without subsequent reoperation (2010 €) (Adapted from Jacob 2016)[26,b]



b. Remedies are services like massages or occupational therapy provided by medically trained personal. Devices and aids are devices such as walkers and wheel chairs to support the patient in recovery and every day care

MEDTRONIC O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

The combination of O-arm™ Imaging & StealthStation™ Navigation provides an easy-to-use and complete solution for instrumented spine surgery. The O-arm™ Imaging is a complete multidimensional intraoperative surgical imaging system that produces high-quality 3D images, as well as multiplane 2D views to enhance clinical decision-making[29]. The StealthStation™ Navigation is an advanced navigation system integrating up-to-date intra-procedural images and displaying them on a screen to facilitate instrument navigation.

The O-arm™ Imaging & StealthStation™ Navigation systems offer a streamlined workflow for the entire surgery with automatic registration and data transfer, memory position of the robotic gantry and full integration of Medtronic instruments and powered tools to simplify the navigation process in order to increase screw placement accuracy and safety[1,29-33,38]. Quality of and ease of access to full 3D data help surgeon's decision-making during the surgery and allow them to master more complex cases. In addition, the O-arm™ Imaging & StealthStation™ Navigation systems eliminate the need for fluoroscopy and reduce radiation exposure for surgeons and surgical staff[36,37].

The O-arm™ Imaging & StealthStation™ Navigation systems

The O-arm™ Imaging is a complete multidimensional intraoperative surgical imaging system that provides surgeons with real-time, high-resolution 3D imaging, as well as multiplane 2D views during surgery[29]. Medtronic received CE Mark approval for the 1st generation of the O-arm™ Imaging system in 2006. Since 2014, the 2nd generation of the O-arm™ Imaging system is available, providing innovative improvements such as large field of view (FoV) scans, a new low radiation dose algorithm and a FoV preview.

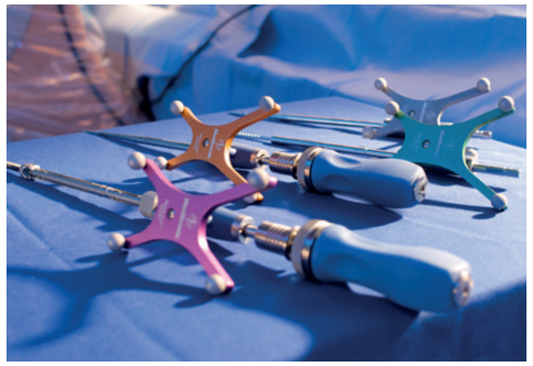
The StealthStation™ Navigation is an advanced navigation system integrating up-to-date intra-procedural images and displaying them on a screen to facilitate instrument navigation. The StealthStation™ Navigation system has been pioneering surgical navigation and the current 8th system generation, StealthStation™ S8, reflects Medtronic's experience over 25 years in cranial, spinal, orthopaedic and ENT (ear, nose and throat) surgery. When used with the O-arm™ Imaging, it offers a streamlined workflow with automatic registration of the patient's intraoperative 3D datasets and memory position of the robotic gantry to allow the surgeons to navigate their instruments on the patient's anatomy even if not, or only partially, exposed. The system supports the finding of the optimal incision point for minimal invasive surgery, planning the approach to the vertebra, accurate screw placement and interbody work.

The combination of O-arm™ Imaging & StealthStation™ Navigation provides an easy-to-use and complete solution for instrumented spine surgery. It allows for precise placement of pedicle screws, by navigating the screws in relation to the patient's anatomy so that unexposed nerves and vessels at risk of injury can be circumnavigated to reduce complications[1,29-33].

Figure 5
O-arm™ Intraoperative Imaging system

Figure 6
StealthStation™ S8 Navigation system

Figure 7
NavLock™ navigated spinal instrument system



MEDTRONIC O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Quality of and ease of access to full 3D data help surgeon's decision-making during the surgery and allow them to master more complex cases[34]. In addition, the O-arm™ Imaging & StealthStation™ Navigation systems provide a minimally invasive option for procedures that would normally require open surgery by orientating the surgeon around unexposed and complex anatomy in real-time[35]. Minimally invasive surgery can be done using the O-arm™ Imaging & StealthStation™ Navigation systems along with the navigated instruments, eliminating the need for fluoroscopy and reducing radiation exposure to surgeons and surgical staff[36,37].

The StealthStation™ Navigation supports the most important spinal systems from the Medtronic portfolio such as the CD Horizon™ Solera™ and the CD Horizon™ Legacy™ family of products including the CD Horizon Longitude™, CD Horizon™ Longitude® II, CD Horizon™ Sextant™ II Rod insertion System, Vertex™ Max and the Vertex™ Select™ Reconstruction System. The CD Horizon™ Solera™ family of products could all be used in conjunction with the PowerEase™ system. The Capstone and Clydesdale devices are fully integrated with the navigation software for accuracy in placement of interbody devices. This compatibility ensures that all instruments are optimized for navigation and that the surgical workflow is streamlined at every step.

O-arm™ Imaging & StealthStation™ Navigation workflow

- The O-arm™ Imaging system can be used before surgery as an alternative to CT or radiography.
- The O-arm™ Imaging system can be used intraoperatively as an alternative to conventional or 2D fluoroscopy, and in combination with the StealthStation™ Navigation to accurately and safely place instruments[1,29-33,38]. It provides up-to-date 3D information of the patient's anatomy at any moment during surgery, with real-time adjustments in case of anatomical changes, and uses this data for navigation.
- O-arm™ images can be taken prior to closing the incision to verify the accuracy of pedicle screw placement, potentially eliminating the need for post operative CT scans/radiography and providing an opportunity for revision of screw misplacement before leaving the operative room.

As a motorized mobile unit, the O-arm™ Imaging is easily transported between operative rooms. Its O-shape forms a ring around the patient's body while in the operative position, allowing O-arm™'s gantry to freely rotate 360° around the patient to take 2D fluoroscopy (real-time moving x-rays) and 3D images, without risk of collision, and to remain fully sterile. It can be opened laterally to get around the patient, largely simplifying patient preparation and surgical workflow when compared to closed ring systems.

Table 2
Features and benefits of the O-arm™ Imaging & StealthStation™ Navigation complete solution

O-arm™ & StealthStation™ features	Improved accuracy of instrument placement	Enhanced decision -making	Ease of use/ workflow	Improved sterility	Reduced radiation exposure
Intraoperative 3D images	✓	✓	✓		✓
5 multiplane views	✓	✓	✓		✓
Intraoperative 2D fluoroscopy	✓	✓	✓		
360° rotation around patient		✓ (image quality)			
3 components in 1 unit: 2D, 3D, multiplane views		✓	✓	✓	
Robotic positioning to acquire additional images			✓	✓	✓
Automatic return to pre-set conditions			✓	✓	✓
Updated Information of patient intraopertively	✓	✓			✓
Multi-directional, real-time display	✓	✓			
System components enclosed in gantry			✓	✓	
Automatic registration & image transfer on seamless navigation interface	✓	✓	✓	✓	
Motorised control of movement			✓	✓	
Fast scan times		✓	✓		
Single-use customised drape			✓		
Fully mobile unit			✓		
Optimized navigation workflow		✓	✓		
Medtronic spinal instruments prestored in navigation software	✓	✓	✓		

CLINICAL VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

The O-arm™ Imaging & StealthStation™ Navigation systems significantly improve screw placement accuracy in comparison with current practice[1,29-32]. Comparative studies have reported up to 9% absolute reduction of potentially harmful screw misplacement with the O-arm™ Imaging & StealthStation™ Navigation systems[1,29-32]. Additionally, high rates of safe screw placement, from 97.2% to 99.7%, have been consistently recorded with O-arm™ Imaging & StealthStation™ Navigation whereas alternative current practice options were associated with accuracy rates ranging from 89.8% to 96.3%[1,29-32].

O-arm™ Imaging & StealthStation™ Navigation offer the opportunity for intraoperative correction of misplaced screws during the index procedure, thus avoiding additional revision surgeries[41-44].

O-arm™ Imaging & StealthStation™ Navigation reduce radiation exposure for surgeons, staff and patients by eliminating the need for fluoroscopy[29,36,45-47].

Improved accuracy of screw placement

Improvement in pedicle screw placement accuracy is the key clinical endpoint to reducing complications and patient morbidity associated with screw misplacement.

However, despite a lack of standardized evaluation, there is currently no consensus on the definition of clinically relevant pedicle screw misplacement. In most of the studies, pedicle screw position is usually considered safe and accurate when pedicle violation is ≤2-3mm[12].

According to a recent meta-analysis, the clinical value of intraoperative 3D imaging and navigation in improving screw placement accuracy is now well established[33]. Results of this meta-analysis, which included 30 studies and pooled data from 1973 patients in whom 9310 screws were inserted, have reported significantly higher rates of screw placement accuracy with 3D fluoroscopic navigation (95.5%) in comparison with both 2D fluoroscopic navigation (84.3% ; $p=2.77x10^{-35}$) and conventional fluoroscopy without the aid of computer navigation (68.1% ; $p=1.09x10^{-248}$) **(Figure 8)**[33]. Moreover, among the two 3D fluoroscopic navigated techniques used in the studies included, significantly higher pedicle screw placement accuracy has been reported with the O-arm™ Imaging system in comparison with a 3D C-arm imaging system ($p=3.94x10^{-11}$)[33]. O-arm™ Imaging was associated with 2.9% screw misplacement whereas 3D C-arm was associated with 7.3% screw misplacement, an absolute difference of 4.4% and a relative reduction of 60% of screw misplacement achieved with the O-arm™ Imaging sytem **(Figure 9)**[33].

Figure 8

Rate of screw placement accuracy with 3D fluoroscopic navigation in comparison with 2D fluoroscopic navigation and conventional fluoroscopy (Adapted from Mason 2014)[33]

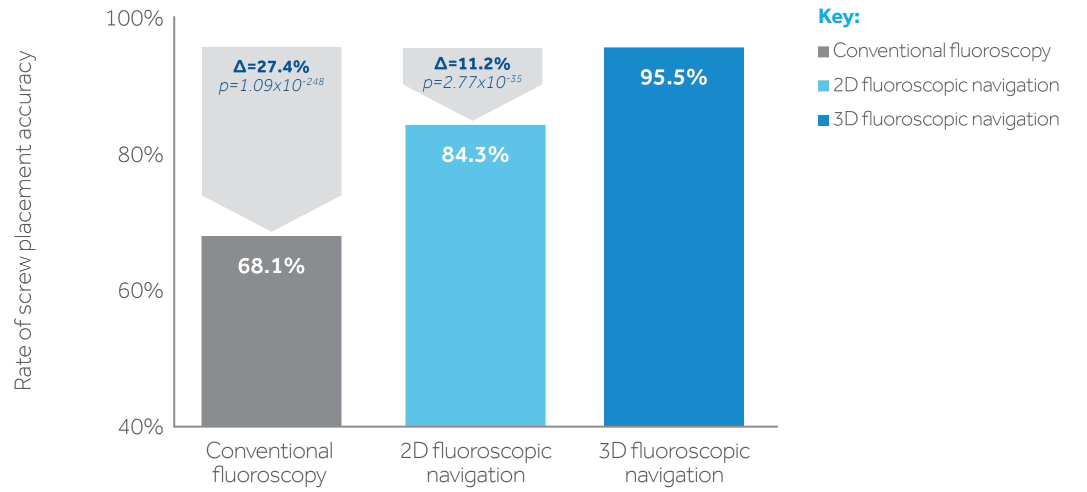
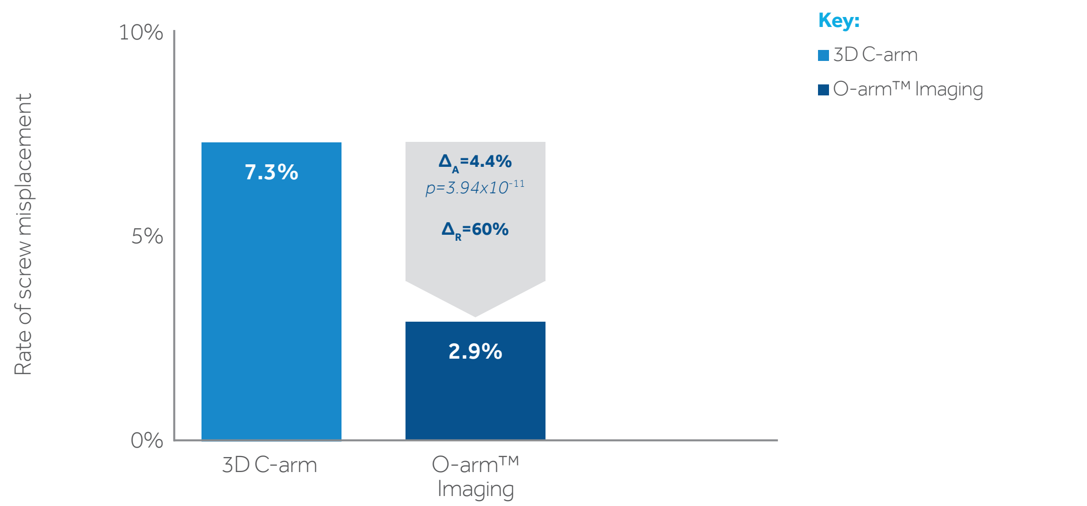


Figure 9

Reduced rate of screw misplacement with the O-arm™ Imaging system in comparison with 3D C-arm imaging system (Adapted from Mason 2014)[33,c]



c. Absolute change (Δ_A) has been calculated as the absolute difference in the rate of screw misplacement between the two groups (O-arm™ Imaging versus 3D C-arm). Relative change (Δ_R) has been calculated as the absolute change divided by the rate of screw misplacement reported for the comparator (3D C-arm).

CLINICAL VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Additionally, high rates of safe screw placement (pedicle violation ≤2-3mm) with the O-arm™ Imaging & StealthStation™ Navigation systems have been consistently recorded in the literature, ranging from 97.2% to 99.7% **(Figure 10 & Appendix)**[1,29-32]. Results of comparative studies have reported that the absolute reduction in potentially harmful screw misplacement achieved with O-arm™ Imaging & StealthStation™ Navigation ranged from 3.1% to 9.2% in comparison with C-arm 2D fluoroscopy **(Figure 11)**[1,29-32].

O-arm™ Imaging & StealthStation™ Navigation have also been associated with up to 99.1% of perfect screw positioning (pedicle violation =0mm) and up to 15% absolute reduction of overall screw misplacement in comparison with C-arm 2D fluoroscopy **(Figure 12 & Appendix)**[1,29-32].

Figure 10

Percentage of safe screw placement (pedicle violation ≤2-3mm) with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with C-arm 2D fluoroscopy (Adapted from Silbermann 2011, Shin 2012, Allam 2013, Shin 2015, Verma 2016)[1,29-32]

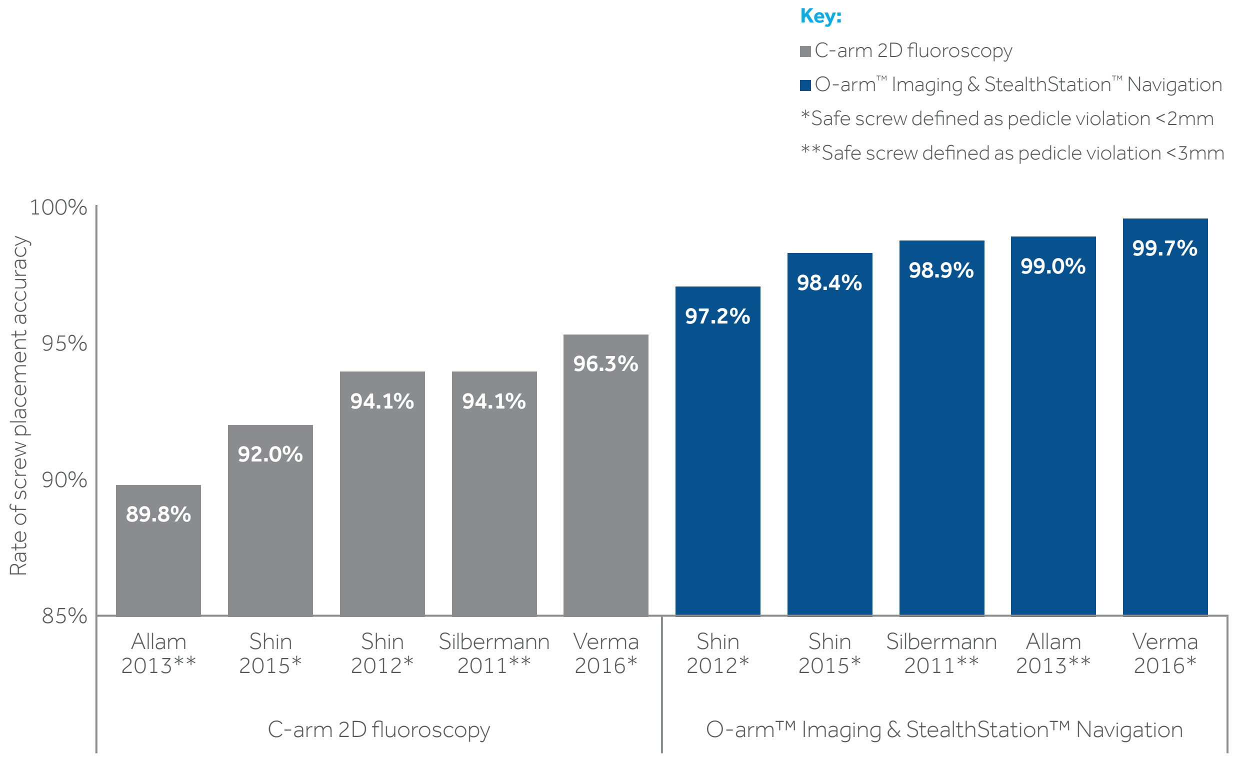


Figure 11

Decreased rates of potentially harmful screw misplacement (pedicle violation ≥2-3mm) with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with C-arm 2D fluoroscopy (Adapted from Silbermann 2011, Shin 2012, Allam 2013, Shin 2015, Verma 2016)[1,29-32,d]

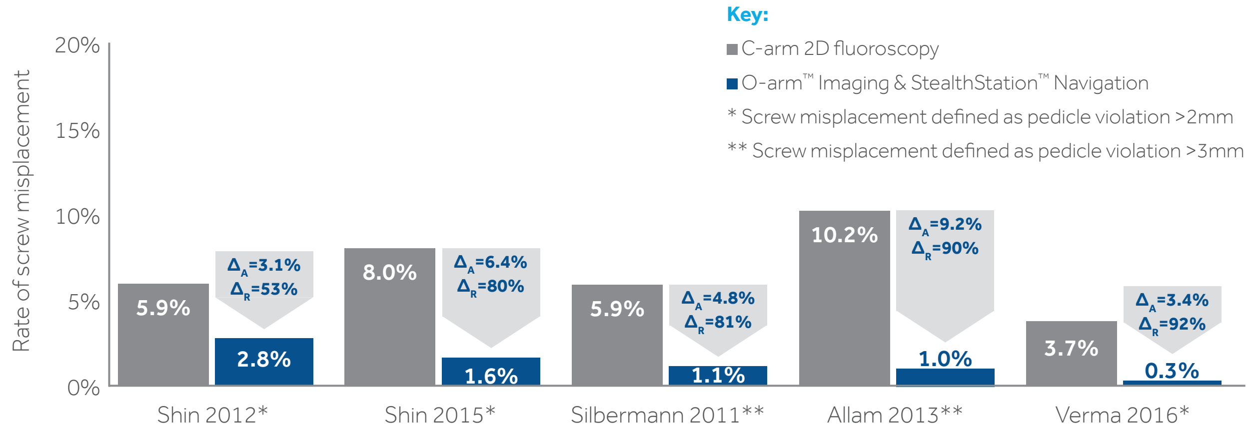
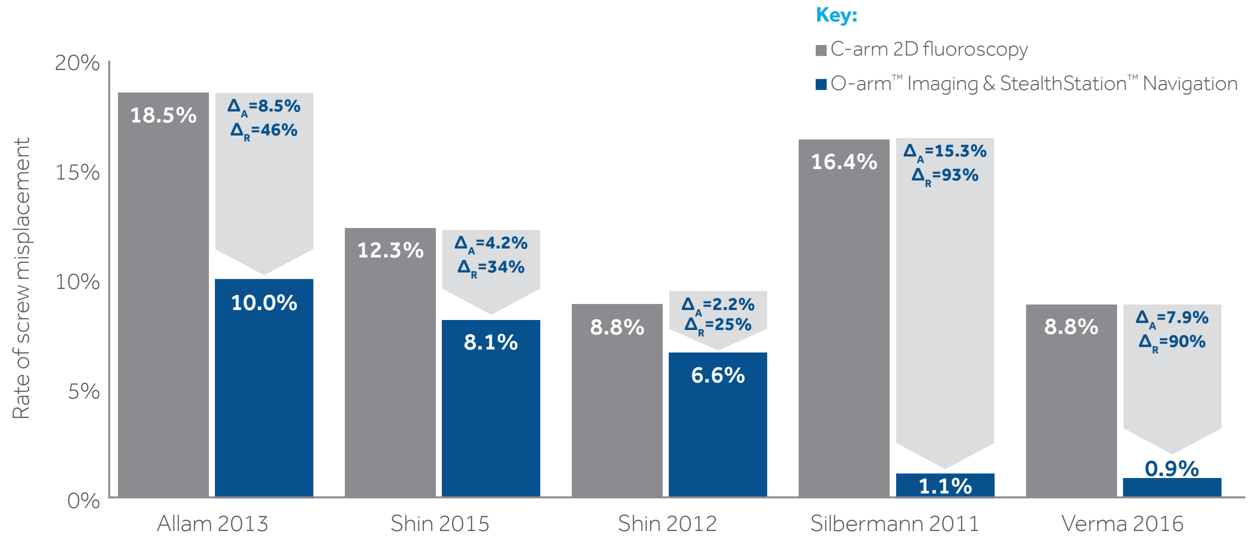


Figure 12

Decreased rates of overall screw misplacement (pedicle violation >0mm) with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with C-arm 2D fluoroscopy (Adapted from Silbermann 2011, Shin 2012, Allam 2013, Shin 2015, Verma 2016)[1,29-32,d]



d. Absolute change (Δ_A) has been calculated as the absolute difference in the rate of screw misplacement between the two groups (O-arm™ Imaging & StealthStation™ Navigation versus C-arm 2D fluoroscopy). Relative change (Δ_R) has been calculated as the absolute change divided by the rate of screw misplacement reported for the comparator (C-arm 2D fluoroscopy).

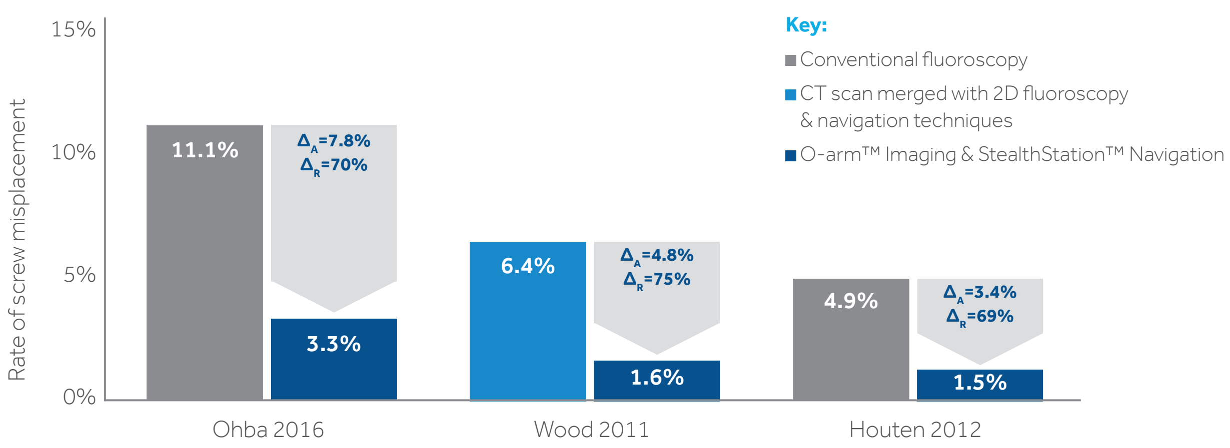
CLINICAL VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Minimally invasive procedures

According to three observational comparative studies, improved screw placement accuracy with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with other techniques has also been confirmed in minimally invasive instrumented spine surgeries **(Figure 13)**[35,36].

Figure 13

Decreased rates of potentially harmful screw misplacement (pedicle violation ≥2mm) in minimally invasive procedures with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with other techniques (Adapted from Ohba 2016, Houten 2012, Wood 2011)[35,36,38,e]



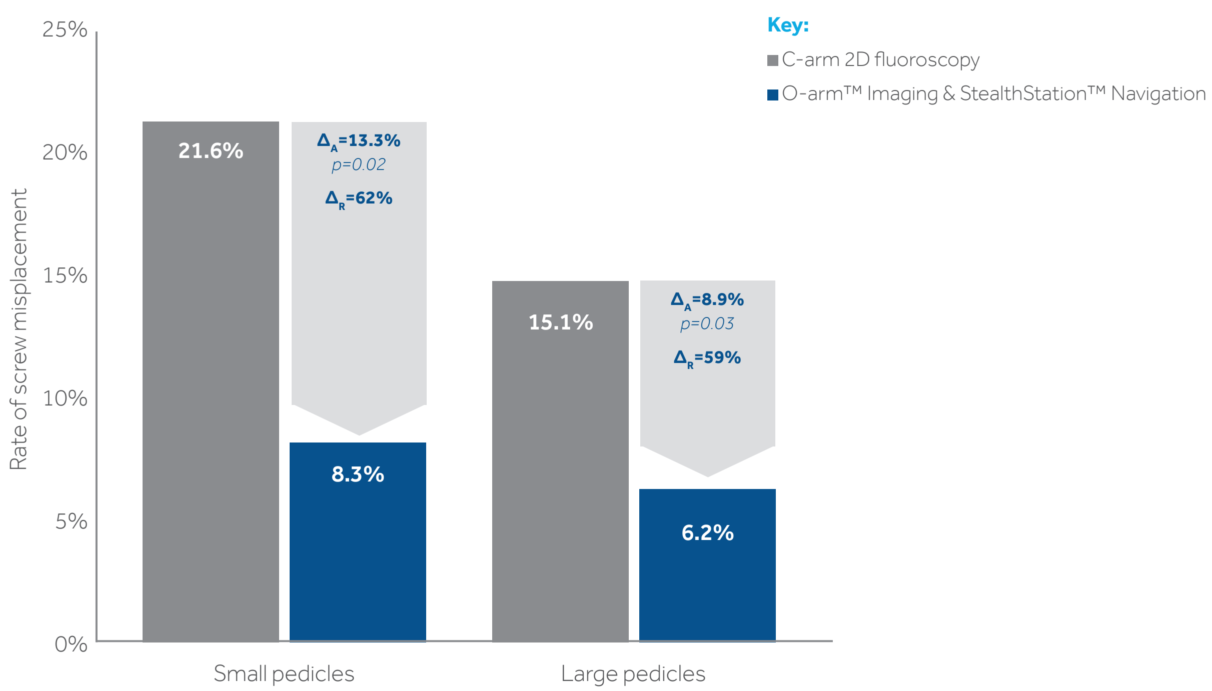
Adolescent with idiopathic scoliosis

In a pediatric population of adolescents with idiopathic scoliosis, results of a comparative study have reported a significant improvement in screw placement accuracy with the O-arm™ Imaging system (97%) in comparison with C-arm (91%) (*p<0.001*)[39].

In addition, results of another comparative study have consistently shown a lower risk of screw misplacement with the O-arm™ Imaging & StealthStation™ Navigation systems than with C-arm 2D fluoroscopy, in both small and large pedicles **(Figure 14)**[40].

Figure 14

Decreased rates of potentially harmful screw misplacement (pedicle violation ≥2mm) in small and large pedicles with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with C-arm 2D fluoroscopy in adolescents with idiopathic scoliosis (Adapted from Liu 2016)[40,e]



e. Absolute change (Δ_A) has been calculated as the absolute difference in the rate of screw misplacement between the two groups (O-arm™ Imaging & StealthStation™ Navigation versus other techniques). Relative change (Δ_R) has been calculated as the absolute change divided by the rate of screw misplacement reported for the comparator.

CLINICAL VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Focus on real world clinical practice

A European prospective, post-marketing, clinical registry has been conducted in Belgium and Italy and included 353 patients who underwent instrumented spine surgery with the O-arm™ Imaging & StealthStation™ Navigation systems over a 16-month period[41].

The primary objective of this study was to assess screw placement accuracy and need for revision surgery in common practice. In addition, surgeons' confidence in screw placement and actual screw positioning were assessed and compared.

Screw placement accuracy and revision surgery

In this study, screw misplacement was defined as cortical perforation in axial and/or sagittal views. When screw misplacement was classified as unacceptable (i.e. misplacement exceeding half the screw diameter and screws with medial cortical perforation, endplate perforation or foraminal perforation), screws were revised during the same procedure. A total of 1922 screws have been placed in the 353 patients included in this registry. Screw placement accuracy reached 97.5% (N=1834) and only 1.8% (N=34) of the screws placed needed to be intraoperatively corrected. The use of the O-arm™ Imaging & StealthStation™ Navigation systems allowed for all corrections to be carried out during the index procedure, eliminating the need for additional revision surgeries **(Figure 15)**.

Surgeons' confidence in screw placement

The level of surgeons' confidence in achieving correct screw placement has been recorded during each surgery. In 91.3% of the cases, surgeons were confident in screw placement prior to acquire the O-arm™ Imaging 3D scan. When surgeons reported confidence in achieving correct screw placement, their assemement was confirmed in 98.5% of the cases. Thus, results show that with the O-arm™ Imaging & StealthStation™ Navigation systems, surgeons' perception of the accuracy of screw placement was consistent with actual screw positioning.

Figure 15

Revision surgery avoided with the O-arm™ Imaging & StealthStation™ Navigation systems (Adapted from Van de Kelft 2012)[41]

Revision surgery avoided

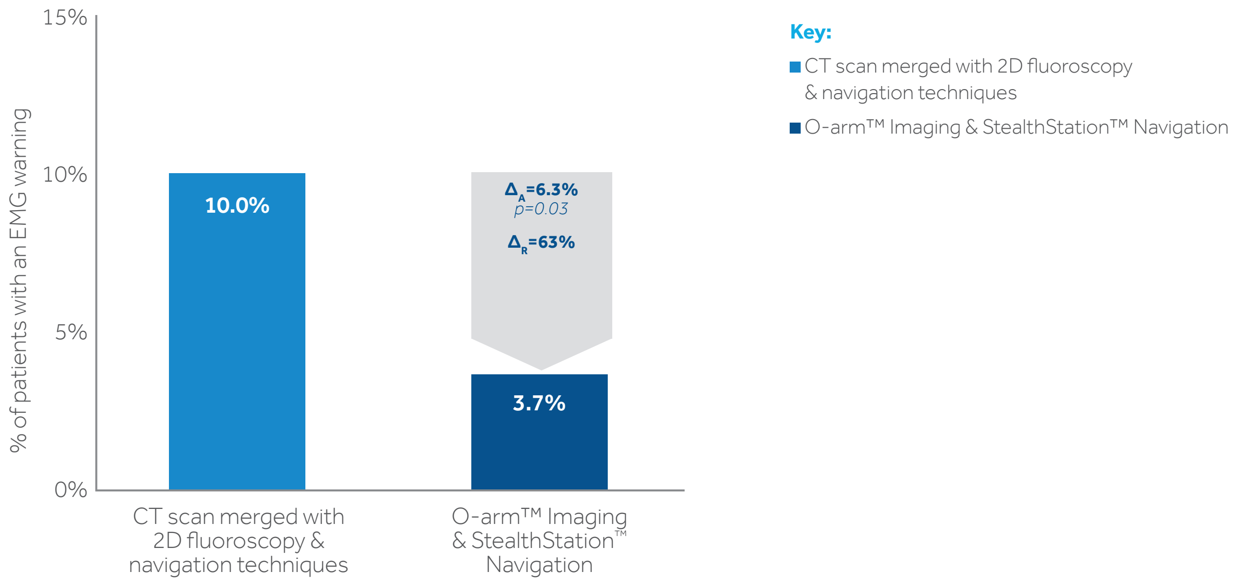
In addition to the results reported in the European registry (cf box), observational studies have also consistently shown that the O-arm™ Imaging & StealthStation™ Navigation systems allow for screw misplacement correction during the index procedure and reduce the need for revision surgery[42-44]. With C-arm 2D fluoroscopy and conventional non-navigated techniques, reoperation rates of 1% and 1.2% have been reported, respectively[42,43].

Reduced frequency of electromyographic warnings

Electromyographic (EMG) warnings allow for detection of neuromuscular injuries when the pedicle wall has been breached. In comparison with CT scans merged with 2D fluoroscopy & navigation techniques, the O-arm™ Imaging & StealthStation™ Navigation systems have been associated with significant reductions of positive EMG monitoring signals, thus confirming improved pedicle screw placement accuracy **(Figure 16)**[38].

Figure 16

EMG warnings with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with CT scan merged with 2D fluoroscopy & navigation techniques (Adapted from Wood 2011)[38,f]



f. Absolute change (Δ_A) has been calculated as the absolute difference in the rate of EMG warnings between the two groups (O-arm™ Imaging & StealthStation™ Navigation versus CT scan merged with 2D fluoroscopy & navigation techniques). Relative change (Δ_R) has been calculated as the absolute change divided by the rate of EMG warnings reported for the comparator (CT scan merged with 2D fluoroscopy & navigation techniques).

CLINICAL VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Reduced radiation exposure

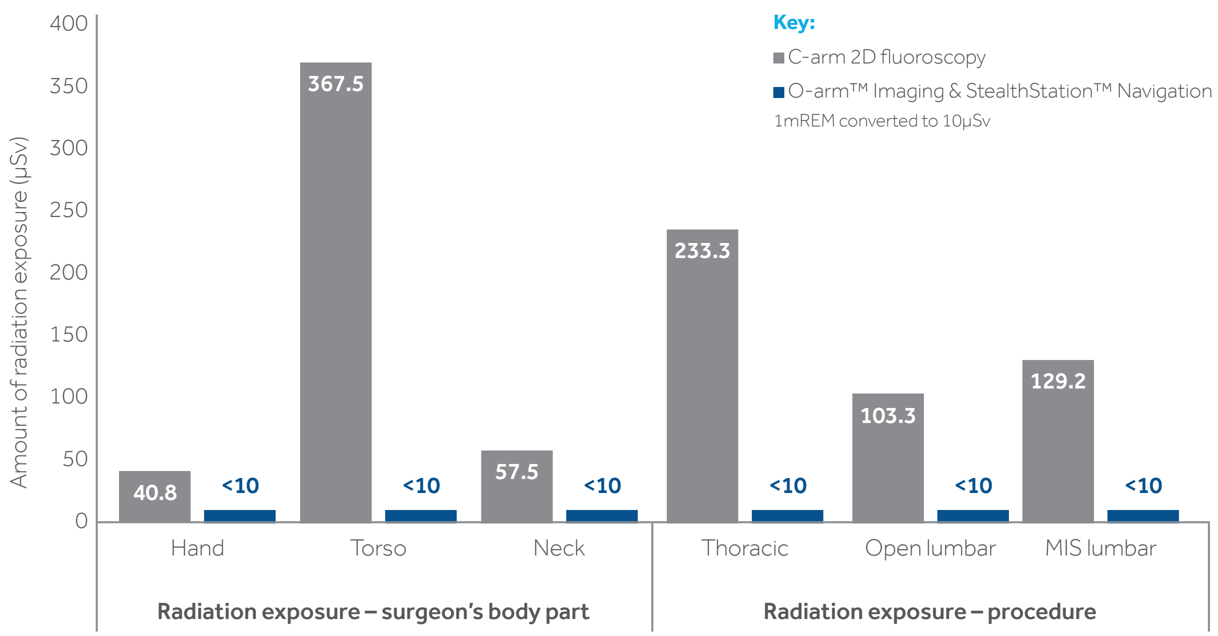
With the O-arm™ Imaging & StealthStation™ Navigation systems, literature suggests that spine surgeons are to reduce their radiation exposure during instrumented spine surgery **(Figure 17)**[45]. When registration is being accomplished or when intraoperative images are obtained to check screw placement, the surgeon and operating room staff can stand back from the radiation source and protect themselves behind a lead shield[46]. Indeed, using O-arm™ Imaging & StealthStation™ Navigation can result in minimal to no radiation exposure to the surgeon or operating room staff[46].

In minimally invasive surgery, results from a study have reported that the average exposure dose with C-arm 2D fluoroscopy was 12 µSv on the thorax, 1168 µSv on the hand and 179 µSv on the lens of the surgeon, whereas, with the O-arm™ Imaging & StealthStation™ Navigation systems, the radiation dose was below the detection treshold of the dosimeter[36]. Additionally, in another study, the mean number of X-rays shot for each screw placement reported with C-arm 2D fluoroscopy was 8.9, while there was no radiation exposure during the screw placement procedure with the O-arm™ Imaging & StealthStation™ Navigation systems[29].

Results from a dosimetry study have also reported that with O-arm™ Imaging (standard protocol), the radiation dose for the patient was similar to half the dose of a 64 multislice CT scan[47].

Figure 17

Reduced radiation exposure during pedicle screw placement with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with C-arm standard fluoroscopy (Adapted from: Burch 2011)[45]



ECONOMIC VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

The O-arm™ Imaging & StealthStation™ navigation systems have the potential to be a cost-saving investment for hospitals due to the opportunity of performing MIS procedures, the reduction of CT-scan needs, the improvement in screw placement accuracy, the subsequent reduced need of revision surgeries, and the shortened length of procedures[42,48-52].

Cost-saving potential associated with improved accuracy and reduced revision surgery

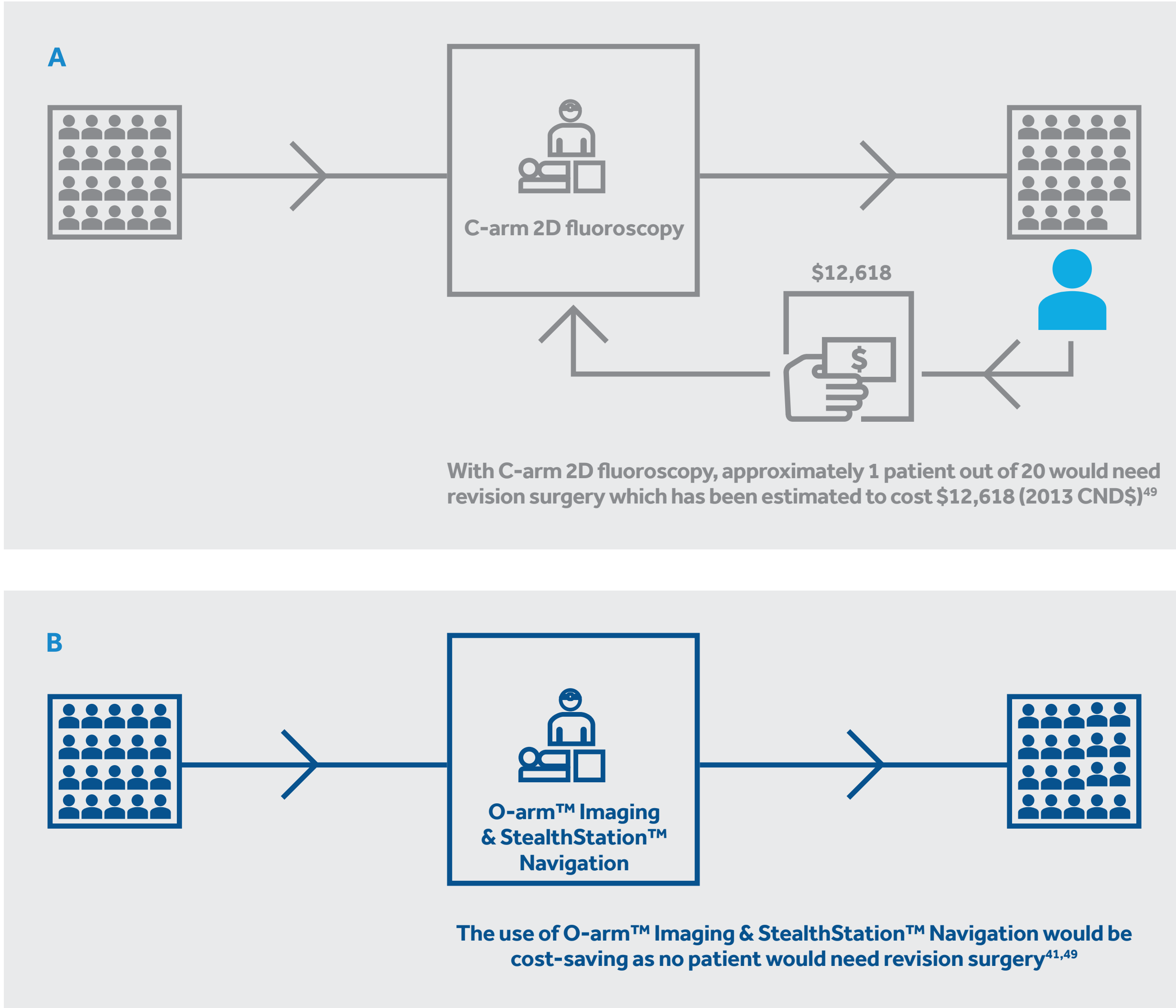
Hospital perspective

A study conducted in a spine center in Canada has quantified the return on investment achieved by improving accuracy and reducing the rate of reoperation[g] for patients undergoing instrumented spine surgery with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison to C-arm 2D fluoroscopy[49].

This study reported a reoperation rate reduction of 5.2% with the O-arm™ Imaging & StealthStation™ Navigation systems, which corresponds to 1 reoperation avoided in every 20 patients **(Figure 18)**[49]. Considering the incremental costs for both acquisition and service contract fees of O-arm™ Imaging & StealthStation™ Navigation in comparison with a mobile C-arm, and based on an estimated reoperation cost of $12,618 (2013 CND$), it was calculated that the O-arm™ Imaging & StealthStation™ Navigation systems would become a cost-neutral investment for this center at 13.2 reoperations avoided[49].

A US retrospective analysis of a clinical database of posterior lumbar fusion cases reported a 1% rate of revision surgery within 6 weeks of the index procedure with intraoperative C-arm fluoroscopy (N=4/386 patients), whereas with the O-arm™ Imaging & StealthStation™ Navigation systems, no patients required reoperation (N=0/331 patients)[42]. According to these results, the annual projected number of revision surgeries for symptomatic screw misplacement that could potentially be avoided with the O-arm™ Imaging & StealthStation™ Navigation systems would reach 2,300 nationwide. Considering an estimated reoperation cost of $17,650 (2010 US$) for the hospital, avoiding these surgeries would translate into a savings of approximately $40,595,000 (2010 US$) from a nationwide hospital perspective[42].

Figure 18
Patients' pathways and related costs with the O-arm™ Imaging & StealthStation™ Navigation systems (B) in comparison with C-arm 2D fluoroscopy (A) (Adapted from Van de Kelft 2012, Dea 2016)[41,49]



g. In this study, reoperation was defined as a revision procedure for symptomatic misplaced screws occurring either during the index admission or in a subsequent readmission within 1 year of the index surgery[49].

ECONOMIC VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

Healthcare system perspective

A US economic model has shown that, from a social insurance perspective (Medicare), the O-arm™ Imaging & StealthStation™ Navigation systems were significantly less costly (*p<0.001*) than postoperative CT scans for checking screw placement accuracy in patients undergoing at least 3-level lumbar fusion **(Figure 19)**[50]. The model included the costs related to each technique as well as the cost for reoperations, but excluded the cost of the index procedures which was the same for all cases. The savings associated with the O-arm™ Imaging & StealthStation™ Navigation systems were driven by the lower rate of reoperation reported with O-arm™ Imaging & StealthStation™ Navigation in comparison with postoperative CT scan, which therefore is to impose higher costs on the US society[50].

Cost-saving potential associated with reduced procedure time and reduced radiological examinations

Articles in the literature suggest that the use of the O-arm™ Imaging & StealthStation™ Navigation systems may be associated with shorter total operative time compared to conventional free-hand techniques[51,52].

A US single center retrospective study of 133 patients undergoing 1-level lumbar fusions reported that the operative time was 23 minutes shorter (*p=0.0013*) when using O-arm™ Imaging & StealthStation™ Navigation instead of a free-hand technique **(Figure 20)**[51]. Additionally, a substantial decrease of the operative time with O-arm™ Imaging & StealthStation™ Navigation was reported over the study timeframe, supporting the idea of a "learning curve" process[51].

The time-saving potential of O-arm™ Imaging & StealthStation™ Navigation has also been shown in minimally invasive surgery. According to another US single center retrospective study on 94 patients, minimally invasive 1-level fusion procedures with O-arm™ Imaging & StealthStation™ Navigation were 21 minutes shorter (*p<0.03*) than procedures with conventional fluoroscopy **(Figure 20)**[36].

Figure 19

Comparison of the societal costs of using O-arm Imaging & StealthStation Navigation versus post-operative CT scan to guide and check screw placement (2011 US$) (Adapted from Sanborn 2012)[50]

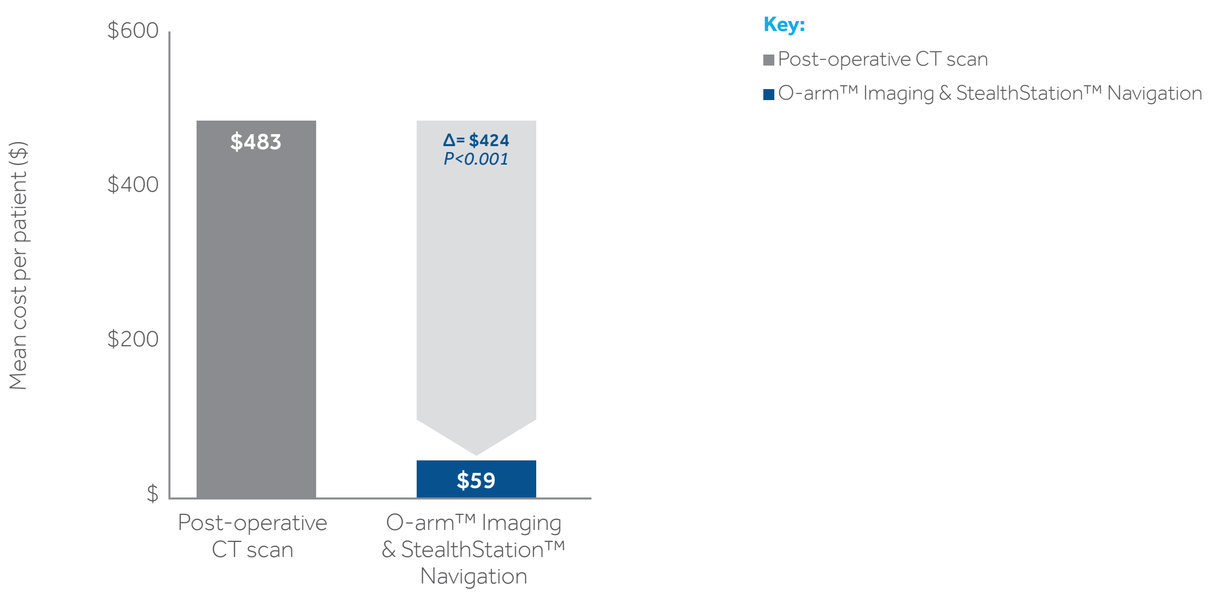
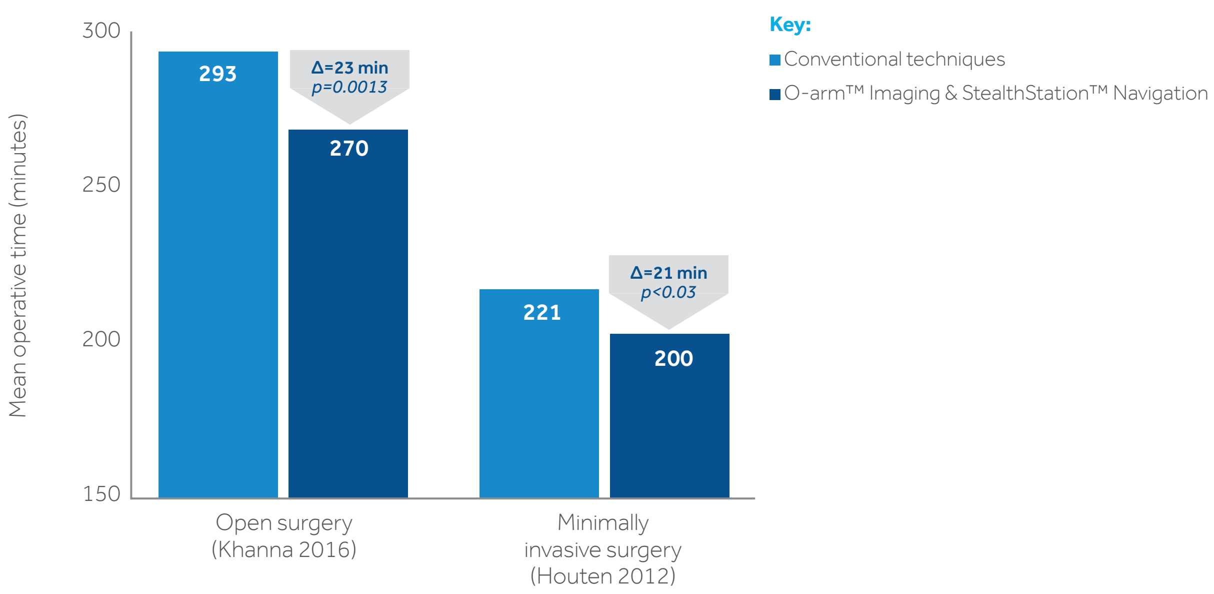


Figure 20

Mean operative time of 1-level lumbar fusion procedures with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with conventional techniques (Adapted from Khanna 2016 and Houten 2012)[36,51]



ECONOMIC VALUE - O-ARM™ IMAGING & STEALTHSTATION™ NAVIGATION

An Italian economic analysis based on a single center data collection also reported shortened operative time and reduced hospital costs with the O-arm™ Imaging & StealthStation™ Navigation systems compared to preoperative CT scan and navigation[52]. All the costs incurred by the hospital between admission and hospital discharge, including acquisition cost of capital equipment, as well as the length of surgery were collected in 499 patients with degenerative spondylolisthesis undergoing lumbar pedicle screw fixation. Compared with preoperative CT scan and navigation, the intraoperative use of O-arm™ Imaging & StealthStation™ Navigation systems was associated with statistically significant shorter mean surgical time, as well as shorter mean time to acquire images and to insert pedicle screws (*p=0.000*) **(Figure 21)**[52]. Even if equipment costs were higher for O-arm™ Imaging & StealthStation™ Navigation, the reduced need for radiology examinations and the reduced time required to complete the procedure (with consequences on the costs of human resources and anesthesia drugs) resulted in an overall cost equivalence with preoperative CT scan and navigation **(Figure 22)**[52]. Total costs were €6,738 per patient who underwent lumbar pedicle screw insertion with preoperative CT scan and navigation, and €6,482 with the O-arm™ Imaging & StealthStation™ Navigation systems (2010 €), leading to a 3.8% non-significant cost reduction[52].

Figure 21

Mean time for pedicle screw placement procedures with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with preoperative CT scan and navigation (Adapted from Costa 2014)[52,h]

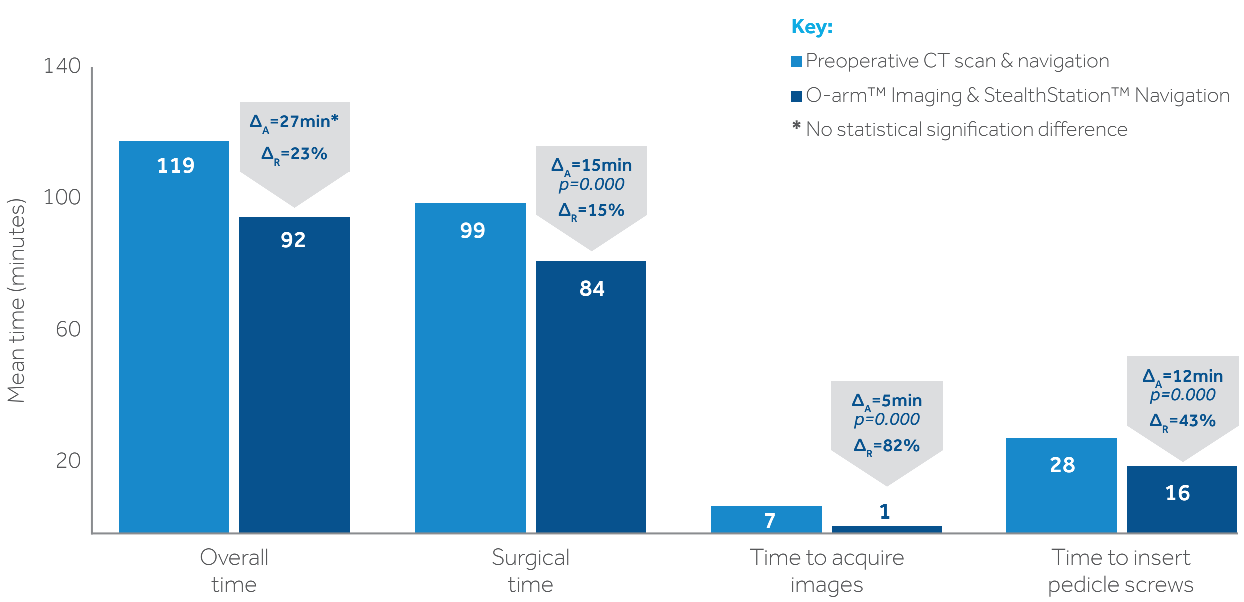
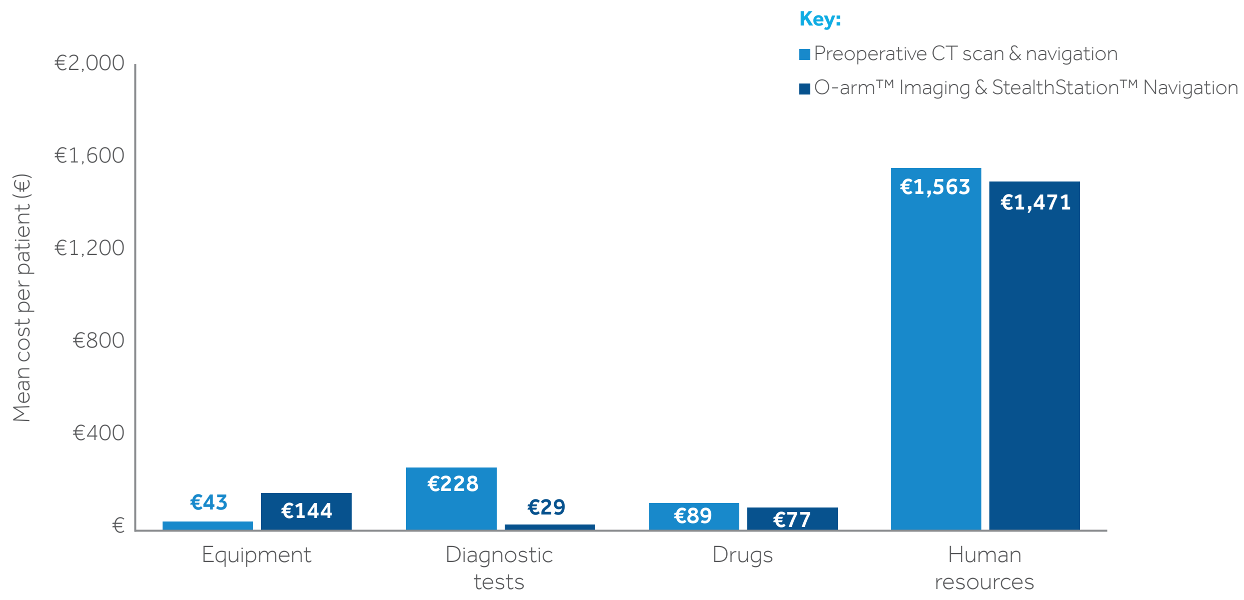


Figure 22

Mean costs (2010 €) per patient with the O-arm™ Imaging & StealthStation™ Navigation systems in comparison with preoperative CT scan and navigation (Adapted from Costa 2014)[52,h]



h. Absolute change (Δ_A) has been calculated as the absolute difference in time between the two groups (O-arm Imaging & StealthStation Navigation versus preoperative CT scan and navigation). Relative change (Δ_R) has been calculated as the absolute difference divided by the time reported for the comparator (preoperative CT scan and navigation).

APPENDIX

This table presents the main characteristics and results of comparative studies included in the clinical value section and selected based on the following criteria:

- Publication date: 2011 onwards
- Comparative studies of O-arm™ Imaging & StealthStation™ Navigation versus conventional techniques (C-arm)
- Number of patients included >30

Author (year) Title	Type of study	Number of patients / screws inserted	Anatomic level	Indications	Screw placement accuracy	
					Screws perfectly placed	Screws safely placed
Verma (2016)[32] 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™ & Navigation vs C-arm)	N=587 patients n=3893 screws 1. O-arm™ & Navigation: N=278 patients / n=1720 screws 2. C-arm: N=309 patients / n=2173 screws	Lumbar Cervical	Odontoid fracture, subaxial cervical spine injuries, dorsolumbar fractures	1. O-arm™ & Navigation: 99.1% 2. C-arm: 91.2% *p<0.05*	Pedicle violation <2mm 1. O-arm™ & Navigation: 99.7% 2. C-arm: 96.3%
Shin (2015)[31] Prospective Comparison Study between the Fluoroscopy-guided and Navigation Coupled with O-arm™ - Guided Pedicle Screw Placement in the Thoracic and Lumbosacral Spines	Prospective randomized comparative study (O-arm™ & Navigation vs C-arm)	N=40 patients n=262 screws 1. O-arm™ & Navigation: 20 patients / 124 screws 2. C-arm: 20 patients / 138 screws	Thoracic Lumbar	Degenerative spine diseases, metastatic spine tumor	1. O-arm™ & Navigation: 91.9% 2. C-arm: 87.7% *p<0.05*	Pedicle violation <2mm 1. O-arm™ & Navigation: 98.4% 2. C-arm: 92.0%
Allam (2013)[1] Computer tomography assessment of pedicle screw placement in thoracic spine: comparison between free-hand and a generic 3D-based navigation techniques	Retrospective comparative study (O-arm™ & Navigation vs C-arm & post-op CT scan)	N=45 patients n=208 screws 1. O-arm™ & Navigation: 27 patients / 100 screws 2. C-arm & post-op CT scan: 18 patients / 108 screws	Thoracic	Fractures, tumors, spondylodiscitis of the thoracic spine, degenerative lumbar scoliosis	1. O-arm™ & Navigation: 90.0% 2. C-arm: 81.5%	Pedicle violation <3mm 1. O-arm™ & Navigation: 99.0% 2. C-arm & post-op CT scan: 89.8%
Shin (2012)[29] Accuracy and Safety in Pedicle Screw Placement in the Thoracic and Lumbar Spine : Comparison Study between Conventional C-Arm Fluoroscopy and Navigation Coupled with O-arm™ Guided Methods	Retrospective comparative study (O-arm™ & Navigation vs C-arm)	N=69 patients n=310 screws 1. O-arm™ & Navigation: 24 patients / 106 screws 2. C-arm: 45 patients / 204 screws	Thoracic Lumbar	Degenerative spine diseases, metastatic spine tumors, traumas	1. O-arm™ & Navigation: 93.4% 2. C-arm: 91.2% *p<0.05*	Pedicle violation <2mm 1. O-arm™ & Navigation: 97.2% 2. C-arm: 94.1%
Slibermann (2011)[30] Computer tomography assessment of pedicle screw placement in lumbar and sacral spine: comparison between free-hand and O-arm™ based navigation techniques	Retrospective comparative study (O-arm™ & Navigation vs C-arm)	N=67 patients n=339 screws 1. O-arm™ & Navigation: 37 patients / 187 screws 2. C-arm: 30 patients / 152 screws	Lumbar Sacral	Degenerative spine diseases, metastatic spine tumors, traumas	1. O-arm™ & Navigation: 98.9% 2. C-arm: 83.6%	Pedicle violation <3mm 1. O-arm™ & Navigation: 98.9% 2. C-arm: 94.1%

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GLOSSARY & ACRONYMS

GLOSSARY	
Devices and aids	Devices such as walkers and wheel chairs to support the patient in recovery and every day 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
Outpatient	A patient who is receiving ambulatory care at a hospital or other facility without being admitted to the facility
Remedies	Services like massages or occupational therapy provided by medically trained personal

ACRONYMS	
2D/3D	2-dimensional/3-dimensional
CT	Computerized Tomography
EMG	Electromyography
FoV	Field of View
MIS	Minimally Invasive Surgery
MRI	Magnetic Resonance Imaging
OR	Operating Room
Vs	Versus

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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