STILLE imagiQ2 dose study

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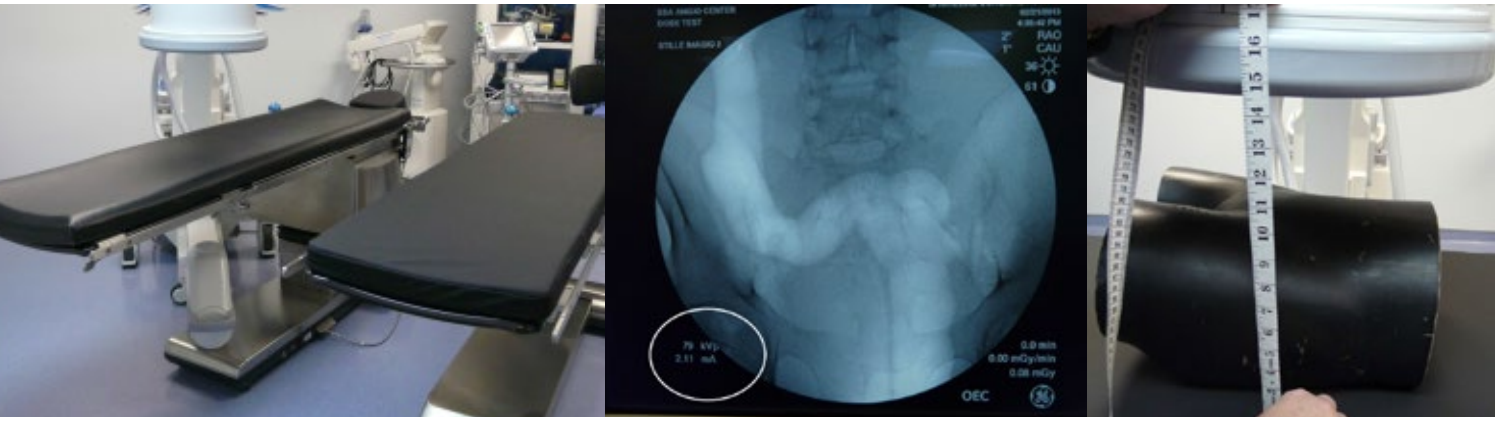
STILLE imagiQ2 surgical table reduces C-arm radiation exposure up to 20% relative to STILLE imagiQ



A comparative study to verify the new imagiQ2 low-dose table top conducted at Shoreline Surgical Associates Clinic, Middletown, CT.

Abstract

The aim was to study how the new imagiQ2 surgical table with a low-dose table top may help to reduce radiation exposure relative to the industry standard table top of the first generation imagiQ table.

An abdominal phantom and a GE OEC 9900 C-arm unit were used to compare the table tops. A standard one-pulse fluoroscopy exposure was made. The C-arm unit recorded 0.10 mGy radiation exposure on the imagiQ and 0.08 mGy on the new imagiQ2. The comparative study proved that the Stille imagiQ2 table required 20% lower exposure than the Stille imagiQ table holding all else factors constant.

As compared to published dose rates in EVAR procedures, a 20% reduction in radiation can be equivalent to more than 5.0 mSv of reduced mean effective dose. To put into perspective, this reduction equals the radiation exposure affecting the body from more than 250 conventional chest X-ray procedures.

It was observed that the new Stille imagiQ2 table can be a key contributor to help reduce harmful radiation exposure and can be an important contributor of keeping dose exposure according to the ALARA principle (as low as reasonably achievable).

As the frequency of image guided/interventional procedures continues to grow, so does the need for low dose radiation technology.

Cardiovascular disease has been broadly described concerning its complications and consequences. Abdominal aortic aneurysm (AAA) ranks as one of the most significant cardiovascular diseases in the world. It has been estimated that in the United States, 1.1 million individuals between the ages of 50 and 84 have an AAA.[1]

In the last decade, X-ray guided interventions have emerged as the new gold-standard treatment of diseases such as AAA. The drawback of X-ray guided procedures as EVAR, renal and iliac angioplasty, kidney stent placement, ERCP and other interventions is that they expose the patient and clinicians to harmful radiation. Fluoroscopic imaging is extensively used in these interventional procedures to target the lesion, and monitor the procedures.

In recent years, there has been increasing concern regarding the radiation risks to both the patient[2] and operator[3] for fluoroscopically based interventional procedures. Radiation exposure is known to cause cancer and also leads to acute skin injury.[4]

With the increase of more complex endovascular approach cases along with better outcomes, prolonged and excessive fluoroscopy times are frequently observed. Mean fluoroscopy time in EVAR procedures have been reported in published studies to be in the range of 13-39.4 minutes. Procedures requiring large fluoroscopy times are associated with a significant radiation hazard.[5]

Significant reduction in patient radiation dose can be achieved by changing radiological procedures, radiological equipment or both. Any reduction of the attenuation between the patient and the image receptor will have a beneficial effect on patient dose.[6]

Globally established guidelines and regulations by institutions as the IAEA (International Atomic Energy Agency, as part of the United Nations) stipulate the fundamental principles of radiation safety which is to keep occupational radiation exposures As Low As is Reasonably Achievable (ALARA) and that equipment should be operated at the lowest fluoroscopic dose rate that yields adequate images. [7]

Innovations in medical technology shall therefore be constantly evaluated to what extent they can help to improve the vascular disease treatment, fulfilling the ALARA principle in order to reduce the patient and clinical team risks

Materials and methods

The study set-up was to compare and prove the differences between the Stille imagiQ table and the new Stille imagiQ2 tables in regards to table top attenuation and its effects on C-arm radiation exposure.

The Stille imagiQ tables are developed in Sweden and produced and marketed by Stille AB, Sweden. The imagiQ2 table was introduced in 2012 and includes a new patent pending carbon fiber table top, and a patent pending free float. The attenuation of the new Stille imagiQ2 tabletop has been tested by Intertek Semko AB according to the European Committee for Electrotechnical Standarization (CENELEC) regulations[8] using a 100kV detector.

The attenuation equivalence was measured and certified to be 0,4 mm Al.

The comparative study was conducted at the office based lab at Shoreline Surgical Associates, Middletown, CT. A mobile GE OEC 9900 MD C-Arm was used for standard fluoroscopy at 80 kVp and 2.2 mA. The study was conducted using an abdomen phantom with human bone surrounded by acrylic plastic.

The phantom was placed in the center of the fluoroscopy field on both surgical tables. The image intensifier was placed 15 inches from the table tops. A standard fluoroscopy exposure was made and data recorded.

Results

The C-arm unit recorded 0.10 mGy radiation exposure on the imagiQ and 0.08 mGy on the imagiQ2. Image pictures were equal in resolution. The comparative study showed that the Stille imagiQ2 table required 20% lower exposure than the Stille imagiQ table at constant standard fluoroscopy set-up.

All features, such as translucency, True Free Float and isocentric roll along with a mobile Hybrid OR, can help to minimize procedural time, therefore reducing patient and medical staff radiation exposure.

Discussion

Reducing radiation in conjunction with endovascular procedures is paramount to ensure patient and caregiver safety. Reducing the table top attenuation is proven in this study to be a key contributor of dose reduction as part of the overall clinical and technical set-up in the OR.

Industry standard surgical imaging tables report to have table top attenuation levels of 0.7-1.5 mm Al, a variable which should be measured according to the medical device directives of the CENELEC[8]. The Stille imagiQ2 is developed with a patent pending carbon fiber technology that has proven its extremely low attenuation.

A number of key industrial, technological and clinical drivers support the use of low-dose mobile operating tables.

Imaging equipment adjusts automatically

Modern fluoroscopy systems operate in automatic exposure control (AEC) mode which requires that a certain amount of radiation reaches the detector in order to produce clinically useful images. Most units are also equipped with automatic exposure control systems. The more attenuation caused by the imaging table and patient, the more the C-arm increases the exposure factors (kV, mA) in order to compensate, resulting in higher radiation doses for patient and clinical staff.

Increasing the utilization rate of the C-arm's low-dose mode

Modern imaging equipment includes dose reduction technology such as variable-rate pulsed fluoroscopy. In pulsed mode, the x-ray beam is not constantly delivered to maintain images but is delivered intermittently, the most recent image being displayed until the next one becomes available. Use of variable-rate pulse fluoroscopy can significantly reduce the x-ray dose. For example, at 7.5 pulses/s, there is 75% reduction in radiation dose with pulsed compared with continuous fluoroscopy; at 3 pulses/s there is 90% dose reduction. Slower pulse settings, however, are associated with substantial noise on the fluoroscopic images[9]

Reducing the risk of C-arm overheating

The buildup of heat is a major limitation in fluoroscopy time and x-ray tube longevity. The importance of this issue increases if C-arm equipment is used for imaging during more complex procedures as EVAR. During extended x-ray tube operation, heat energy accumulates and ultimately limits x-ray production if insufficient cooling time is allowed. [4]

Heat energy accumulation is more rapid during long periods of continuous x-ray use and is intensified by factors as steeply angled projections, image magnification modes and high body mass index (BMI). The surgeon cannot alter the size of the patient, but imaging strategies using pulsed fluoroscopy, surgical table iso-roll and low attenuation are factors than can help to enable the decrease of heat energy accumulation and prevention of equipment shutdown.

Mobile solutions prove lower dose vs. fixed systems

Radiation dose in EVAR has been proven to be substantially less by using modern portable C-arms than fixed dedicated angiographic systems.[10]

In a Swedish study from 2005 the research team performed clinical procedures in an operating room using a mobile C-arm unit with low-dose functionality and the Stille imagiQ surgical table. The study concluded that if the procedures had been performed using a dedicated angiographic equipment with its factory settings, the dose-area product (DAP) values would be about eight times as high.[4]

In a French retrospective study11 published in 2011, the radiation exposure during an aortic endovascular aneurysm repair was evaluated using a mobile C-arm with low dose and pulse mode together with the Stille imagiQ table. The study proved that radiation exposure during endovascular

treatment of simple or complex aortic aneurysm with a mobile C-arm can be considerably minimized by applying the ALARA principle.

Regulations and guidelines in place

Every C-arm sold in the USA since mid 2006 measures, displays and records reference dose. Guidelines stipulate that radiation dose should be monitored during fluoroscopically guided procedures, either by the operator or by a designated individual in the procedure room. Patient radiation dose should be recorded appropriately in the medical record. Patients who have received a sufficiently large radiation dose should have follow-up at 10-14 days and at 1 month after the procedure for possible deterministic effects.

The imaging guidelines[7] from 2009 stipulate that "Equipment should be operated at the lowest fluoroscopic dose rate that yields adequate images". The Endovascular Surgery reference book by Moore & Ahn, stipulates that the use of a floating surgical table helps to reduce dose exposure as it simplifies positional changes and the need to adjust the fluoroscope constantly[12]. In general, the operator shall always adhere to the principles of ALARA[13].

Because radiation exposure during fluoroscopy is directly proportional to the length of time the fluoroscopy equipment is activated, additional dose reductions can be realized with various maneuvers.[5]

Quantifying selected relative effects of dose reduction

A 20% reduction in dose during a fluoroscopic procedure as EVAR can reduce the mean effective dose up to more than 5 mSv. This corresponds to the same radiation exposure as more than 250 PA chest radiographs.

Conclusions

The comparative study proved that the Stille imagiQ2 table required 20% lower exposure than the Stille imagiQ table holding all else factors constant. We conclude that the new Stille imagiQ2 table helps to reduce harmful radiation exposure and can be a key contributor of keeping dose rates ALARA. A 20% reduction in dose during EVAR could lead to a radiation reduction in excess of 5 mSv.

Reducing radiation is strongly supported by clinical and governmental guidelines, and is paramount in the ensuring patient and caregiver safety. Reduced table top attenuation aligns with these regulations and may lead to reduced C-arm overheating issues and increased utilization of low-dose mode. Modern mobile C-arm solutions have also proven to generate reduced dose which supports the use.

Vascular surgical procedures*	Mean effective dose (mSv)	Equivalent number of PA chest radiographs (each 0.02 mSv)	Corresponding number with 20% dose reduction	Reduction in PA chest radiographs
EVAR	8.7-27	435-1350	348-1080	87-270
Venous access procedures	1.2	60	48	12
Renal/visceral angioplasty	54	2 700	2 160	540
Iliac angioplasty	58	2 900	2 320	580

* Mean effective doses from different vascular surgical procedures as described by International Atomic Energy Agency14

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Stille imagiQ2

Stille - Surgical perfection. For life.

Stille is one of the oldest medical device companies in the world. We develop, manufacture and sell proprietary high-quality surgical instruments and specialty tables to leading surgeons worldwide. We have done so for more than 170 years.

Stille's offering consists of a strong brand and products renowned for their superior quality. We manage our business in two distinct business areas: surgical business and the patient positioning business.

Surgical business
We offer a complete line of handcrafted, forged surgical instruments featuring delicate design, industry-leading durability and a unique feel, which has made Stille a well-known and highly respected supplier by surgeons throughout the world.

Patient positioning
We offer two main groups of procedure-specific tables for cardiovascular surgery, gynecology, urology and urodynamic examinations. These tables feature a high level of functionality and ergonomics, and appealing aesthetic design.

Stille has been developing medical devices since 1841 and has always been committed to providing the safest and highest performing solutions that live up to our motto: Surgical perfection. For life.

STILLE

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