Chapter 9

Intraoperative Imaging for Verification of the Correct Level During Spinal Surgery

Claudio Irace

Additional information is available at the end of the chapter

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1. Introduction

One of main problems in current medical practice is the rocketing conflict patient *vs* physician, generally popularized with the term malpractice; this is particularly true in the field of surgical activity. When dealing with errors occurring in different specialties one of the first and embarrassing event is to deliver surgery at the incorrect (not affected!?) side or level; as the wrong-side in most cases may be prevented by means of strict application of a protocol consisting of vocal identification, cross-check with clinical chart and unequivocal skin marking before incision, avoiding the wrong-level in spinal surgery requires some additional in-depth measures.

When performing a lumbar microdiscectomy or a one-level decompression (even endoscopically assisted), the exploration of a wrong disc space may be not considered a relevant error; nevertheless it can become a true ordeal for the patient in terms of acute or late-occurring complications [1]. Medico-legal implications are easily understood, although such a matter is ill-defined. Some authors have identified the wrong-level as the second most common reason for reoperation for lumbar disc herniation [2]; and this grim event has been recognized as one of the starting-points of the cascade of symptoms leading to the well-known failed back surgery syndrome (FBSS); nevertheless many surgeons deem wrong-disc surgery as inconsequential [3] and not necessarily involving a worsening of patient's symptoms.

Concerning the anterior approach to the cervical spine it's mandatory to have an intraoperative x-ray confirmation of the disc space before performing discectomy; indeed no anatomical bony points may lead the surgeon to the correct disc space undoubtedly. When operating upon the thoracic spine via a posterior approach the problem of level identification is more complex and several x-ray images could be required; in these cases surgical incisions and approaches are longer and it's rare to mistake the spinal level. The

posterior approach to the lumbar spine involves the highest risk of level-error if the surgeon does not perform routinely an intraoperative x-ray. As you can see, at any spinal level plain x-ray study or standard fluoroscopy done intraoperatively are the pivotal step to avoid a wrong-level operation.

2. Verification of the correct level

2.1. Surgical localization in the cervical spine

If one considers medico-legal reports about malpractice for wrong level in spinal surgery, two main groups may be recognized: cervical and lumbar. Concerning anterior cervical spine surgery, cases referred for malpractice due to level error are few; this is quite easy to explain, because standard surgical strategy includes mandatorily a x-ray control before violating the disc space. The following is what we perform in this kind of surgery.

A preliminary x-ray image is obtained after having applied a metallic tool on the lateral area of the neck; this mark will serve as a better indication of the skin fold in which the horizontal skin incision will be done [Figure 1]. After having performed surgical dissection along the carotido-oesophageal plane a fluoroscopic control will be delivered before making disc incision [Figure 2]. These two steps allow the surgeon to explore the correct disc space in almost every case.

The only true problem may arise when operating at a lower cervical level in a patient with a short neck and/or prominent shoulders. In such cases, before skin incision, it's helpful to pull patient's shoulders down to try obtaining a better visualization of the lower cervical spine on lateral x-ray view. It must be remembered that prolonged and excessive cranio-caudal pulling of the shoulders may cause injury of the spinal accessory nerve entering the trapetius muscle fibers; so, it is safe to remove shoulder traction as soon as having obtained x-ray confirmation of the disc space to be explored, without waiting the surgical procedure be completed. If even such a measure does not allow to visualize the disc space to be explored – which is usually is the C6-C7 or C7-Th1 one – nothing remains that to identify the lowest disc space, by placing a wire in the disc space and obtaining a fluoroscopic check; then, the surgeon will perform the planned discectomy at the one or two more caudal segment. It goes without saying that a postoperative computed tomography (CT) scan must be obtained as soon as possible at the end of surgery, to confirm the correctness of the disc space operated just before.

Although rare another cause of wrong-level in anterior cervical spine surgery may be related to error in compilation or interpretation of patient's clinical charts. When compiling the medical chart the physician may not clearly identify the pathological level to be operated, and this is due to hasty transcription and observation (if done!) of magnetic resonance (MR) and/or CT scans. Or it frequently occurs that neuroimaging studies report cervical disc herniations or foraminal stenosis at two or more levels, and these findings are then reported in clinical charts without specifying the level to be operated; in the operating room the surgeon starting the planned cervical discectomy will approach that level which is

not the one correlated to patient's symptoms and signs. Therefore we recommend that before skin incision patient's neuroimaging reports and medical charts be matched one another as first, and then compared with neurodiagnostic images, so to have an unequivocal confirmation of the disc space to be explored.

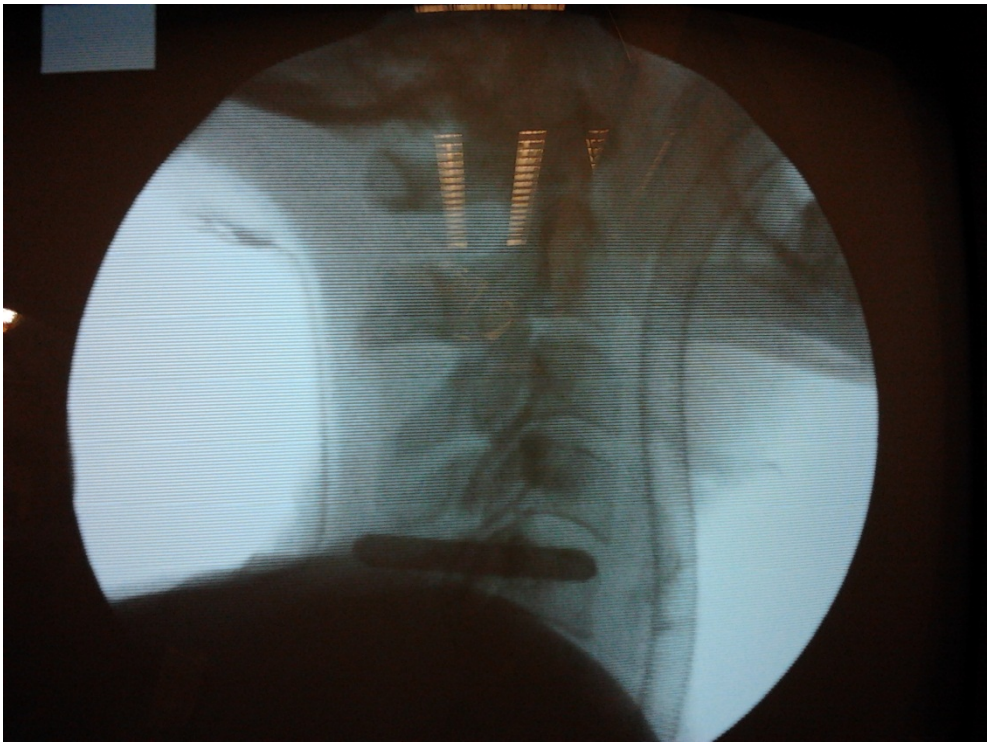


Figure 1. Intraoperative lateral cervical fluoroscopy. A metallic tool applied over the skin points the C4-C5 disc space. As you can see patient's prominent shoulders do not allow an optimal visualization of the lower cervical spine.

2.2. Global introduction to lumbar spine microsurgery

The scenario becomes dangerously grey when the wrong-level occurs at lumbar spine surgery: the rate of this kind of error sadly increases and medical and medico-legal consequences become potentially dramatic. Well keeping in mind this complication when performing microsurgery at the lumbar spine, one of the most important principles in microsurgery must be here remembered: the surgical scar formation, which is considered the main cause of the FBSS, is less extended when a more reduced approach is used. Following this principle, the skin incision for a one-level lumbar spine microsurgical procedure is 2.5 to 4.0 cm: **no external landmarks may convoy the surgeon to the correct level through such a narrow corridor**. Nevertheless some surgeons perform operations at the L5-S1 level making no intraoperative x-ray control [4], only by recognizing anatomical

features of sacrum; and in the same way they operate upon upper lumbar levels simply 'counting' from L5-S1. Such an attitude has to be rejected. First, one cannot approach a lumbar upper level (for example, L3-L4) simply 'counting' from L5-S1, without making a long skin incision and extended skeletonization of paravertebral muscles. Second, anatomical variations (*e.g.*, a transitional vertebra) may contribute to miss the interspace to be explored. As a final point, even an L5-S1 disc space in a hyperlordotic spine may be missed if the superficial dissection and the operative microscopy are not oriented in an oblique enough direction [1].

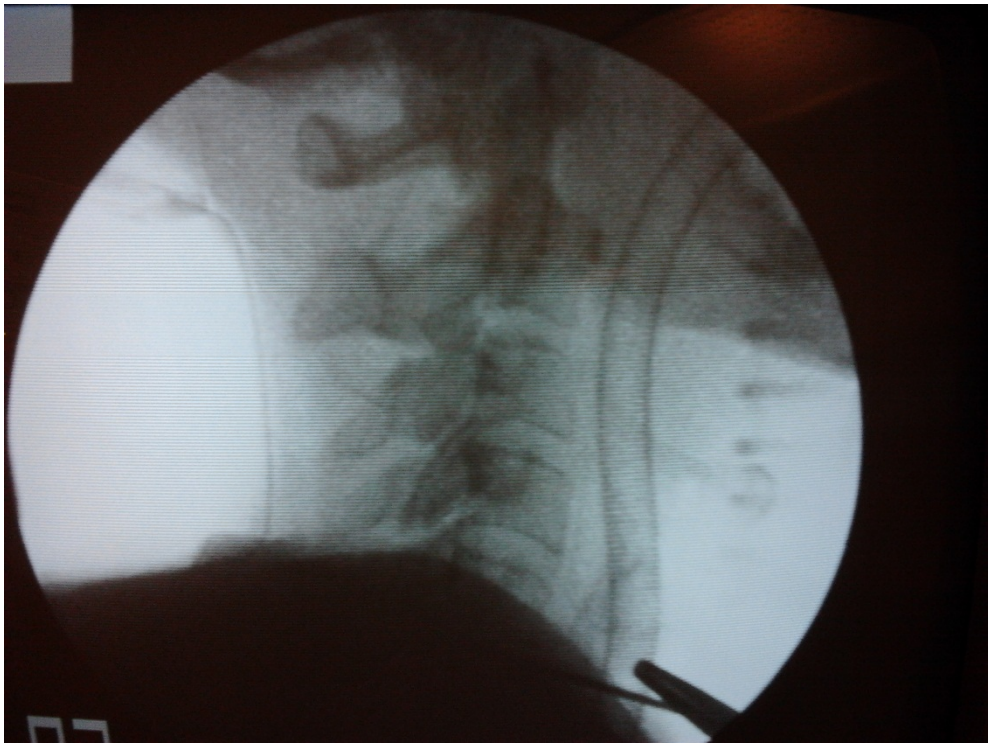


Figure 2. Intraoperative lateral cervical fluoroscopy. Before disc incision a wire is inserted in the correct disc space C5-C6, which may be seen even if partially obscured by superimposing shoulders.

Therefore the basic rule to perform a microsurgical one-level operation at the correct lumbar interspace is to obtain a good-quality x-ray intraoperative confirmation; a lateral view provided by a C-arm fluoroscopic machine, well placed over the patient lying prone and with a metallic tool applied to a bony marker (*e.g.*, the spinous process), allows the surgeon to direct the dissection toward the correct space to be explored, even if working in a tubular-like surgical corridor.

2.3. Surgical localization in the lumbar spine

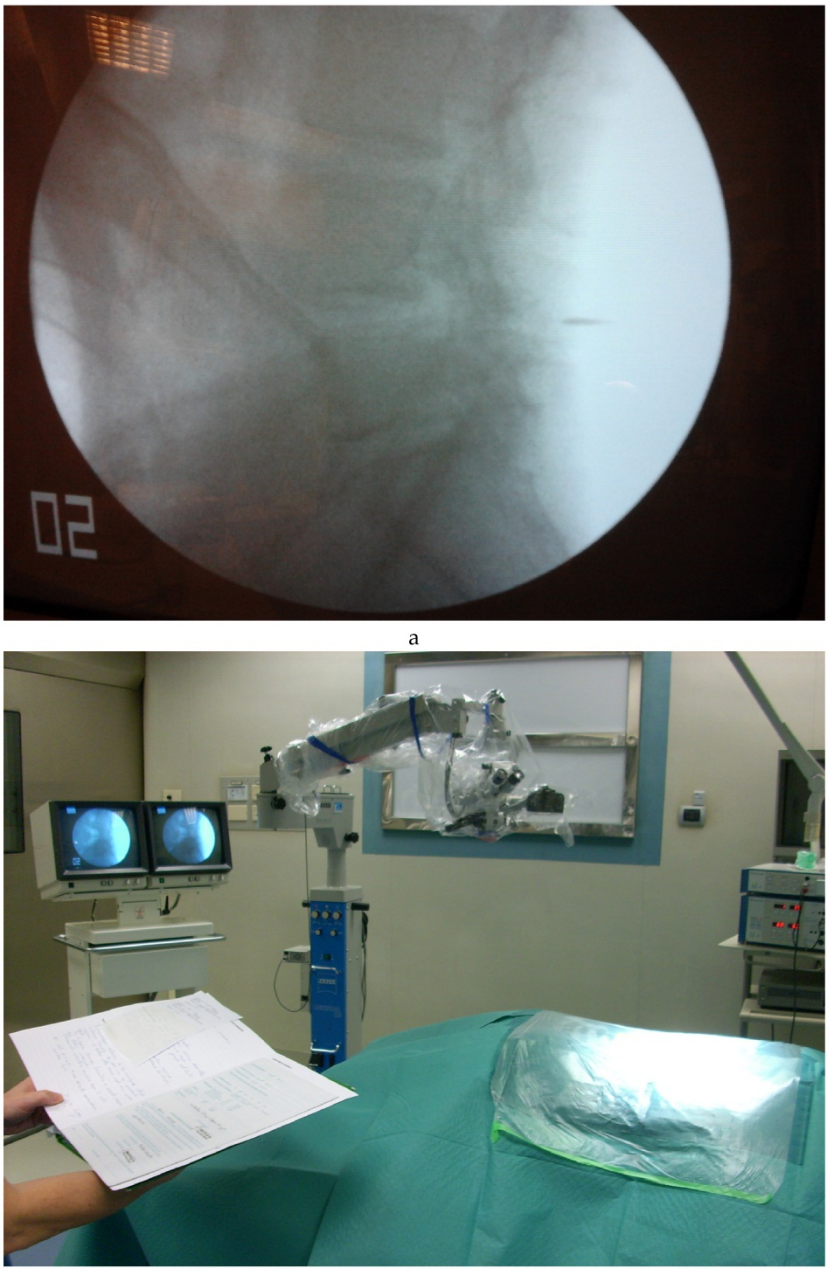
The strategy of utilizing a lumbar radiopaque tool on a bony landmark to indicate the level to be explored, checked by fluoroscopy before and, if required, after skin incision has been adopting by our School for about forty years. Moreover we have identified three further 'crucial aspects': global strategy, attention, precision in level identification; and the corresponding starring are: the surgeon, the circulating nurse, the (neuro)radiologist.

Basing upon this background we have designed a 3-step method to avoid the level (but the wrong-side too!) error in lumbar spine surgery; this method was called IRACE, meaning Intraoperative Radiograph And Confirming Exclamation [1]. (**Step 1**) In the operating room, with the patient in the prone position, a wire is applied to the cranial spinous process of the level to be explored and a fluoroscopic control is delivered [Figure 3a]; if the level is confirmed by the radiologist, the superficial part of the wire is cut away. (**Step 2**) Before skin incision the surgeon asks out loud for level confirmation; the circulating nurse reads aloud the level and side reported on the patient's medical chart [Figure 3b]. (**Step 3**) Additional fluoroscopy is utilized when anatomical landmarks appear confounding or when subtotal arthrectomy (for foraminal or extraforaminal disc herniations) is planned, and the articular process to be drilled is marked for further confirmation. Before skin closure the scrub nurse reminds the surgeon to remove the wire if not already done; he pulls it out saying 'Tip!', meaning that the wire has been removed as a whole.

The ISO system defines the rules ensuring the delivery of a elevated standard of care; our Department received an official certificate attesting our accomplishment of the requirements of the ISO 9001:2000 standards [Figure 4]. This ISO system requires several procedures describing core activities of each function; about lumbar disc surgery a specific procedure was designed to avoid level error and this procedure is the pivot of the 3-step IRACE method we have just described.

2.4. Field of application of the IRACE method

The IRACE method may be mainly used in four kinds of operation at the lumbar spine. Of course the first and most frequent and important procedure is microdiscectomy; in this procedure we think that the wire placed in the spinous process of the cranial vertebra, previously confirmed fluoroscopically, is a valuable guide to perform all subsequent surgical steps in a tubular-like corridor. Another surgical intervention in which our method can help the surgeon is the one-level uni- or bilateral foraminotomy or decompression for spinal stenosis; in these cases bone spurs, osteophytes and thickening of ligamentum flavum make the skeletonization and bone decompression at the correct level difficult; if a scoliosis or a degree of obesity coexist, hence an intraoperative radiograph interpreted by a neuroradiologist becomes fundamental. A third context in which we suggest using this method is the endoscopic foraminotomy; in this procedure the correct localization is a critical point and posteroanterior and lateral fluoroscopies are performed before, during and after surgery [5]. At last a fourth procedure is the interspinous stabilization; even in this case a level error may occur [Figure 5] and therefore our method is advisable too.



a

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Figure 3. (a) Intraoperative lateral fluoroscopy obtained before skin incision; the wire placed in the spinous process of L-4 is demonstrated. (b) Before skin incision the circulating nurse reads patient's medical chart aloud to remember level and side of lumbar disc to be explored.

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Figure 4. Reproduction of the renewal of certification ISO 9001:2000, issued to the Unit of Neurosurgery, Casa di Cura Igea, Milan, Italy

a

b

Figure 5. (a) Preoperative sagittal reconstruction CT scan. This patient came to our attention after having performed a "interspinous stabilization L4-L5" elsewhere, as reported in medical discharging chart; soon after this surgery her bilateral claudicatio radicolaris started to worsen; the CT scan clearly shows the DIAM interspinous device applied at the L3-L4 interspinous space (wrong). (b) Postoperative CT scan. The COFLEX device correctly inserted at L4-L5 is well visualized; the DIAM at L3-L4 was intentionally left in place to avoid late compromise of segmental stability.

2.5. Other strategies to avoid the wrong-level operation

Different methods and protocols have been suggested to avoid wrong-level or wrong-side errors, aiming to identify and correct the potential causes of this problem. Three main methods adopted to avoid the error of level are currently used. 1) The '**Sign, Mark and Xray (or SMaX) Program**'. It has designed by the North American Spine Society and it is included

in a wider checklist addressing the problem of performing the right operation in the right patient at the right site. This program consists of signing the level and side before surgery, marking the level in the operating room using a metallic instrument on a bony landmark, performing a lumbar radiograph with the marker in place [6]. 2) The Joint Commission on the Accreditation oh Healthcare Organizations **'JCAHO Protocol'**. It articulates a 3-step process: preoperative verification involving the patient, marking the operative site, a time-out before starting surgery [7]. 3) The **'ABCD pause'**. It's basically a preincision step during with the surgical team re-analyzes the operative schedule and diagnostic imaging [8].

If we compare the above strategies with the IRACE method, we can observe that concerning the SMaX Program, our method seems more detailed and integrated because of the subsequent oral confirmation. The JCAHO Protocol appears effective when applied to other fields of surgery, but it is less specific than the IRACE method when utilized in lumbar spine surgery. The ABCD pause does not identify the single person dedicated to the oral check; moreover the time-out *per se* does not address the problem of level error which may derive from incorrect direction of dissection during microsurgery [1].

3. What we feel about the matter of wrong level

Going back to the 'crucial aspects' involved in level error lumbar spine surgery, the first to be matched is surgical strategy. An elective microsurgical procedure in lumbar spine region starts well before disc space exploration and refers to what we have called as the "atmosphere" of the operation. This means that the surgeon starting a lumbar microdiscectomy (or another one-level procedure) must participate in the positioning of the patient and personally choose the diagnostic neuroimages deemed necessary for a correct surgery; we strongly feel that the habit of the surgeon of coming into the surgical suite once the patient has already been positioned and draped must be abandoned [1].

The second point is attention. Loss of concentration, fatigue, sense of inferiority, or a mix of these aspects, can lower the degree of attention, particularly in those steps of the operative procedure which are considered less important, for example the initial exposure of the interlaminar space and the lamino-arthrotomy. In the operative theatre we have identified the circulating (or assistant) nurse as the one who is able to better remember to the surgeon the level to be explored just before skin incision. Indeed the assistant nurse is not directly engaged in the procedure (as the scrub nurse really is), moves freely all around so having easy access to neurodiagnostic images and medical charts.

The third and perhaps central point is the precision in lumbar spine identification and, hence, the importance of the (neuro)radiologist. All spine surgeons well know how regional anatomy sometimes may be difficult to interpret, due to congenital anomalies or local abnormalities induced by previous surgeries. Surgeon's skill is a *conditio sine qua non*, but the correct lane to engage may be correctly indicated only by a lateral x-ray image obtained intraoperatively. The (neuro)radiologist will also be able to provide a correct interpretation of a poor quality x-ray image, for example due to obesity of the patient; last he will provide

a decisive correlation between the intraoperative fluoroscopy and the preoperative neurodiagnostic images; the typical example is the presence of a transitional vertebra, which may be called in MR or CT report differently from what reported on medical charts.

4. 360°-considerations

We feel the problem of wrong level or side still exists and it is far to be eliminated; it's hard to admit but many spine surgeons are reluctant to face this issue and such an attitude does not contribute to its solution. It's difficult to quantify the true dimension of the wrong-level, but it may be assumed that this error rate ranges from 0.14 to 5.3 percent [1]. Several studies demonstrated that most of wrong-level spinal operations occur at the lumbar level.

A lot of conditions has been identified as potentially leading to a wrong-level operation; when dealing with spinal surgery it must be remembered that these condition have been amplified by the fast increasing number of "spinal" procedures. Currently we think that the use of an intraoperative neuroimaging study should be mandatory. We have to remember here once again that this matter mainly addresses one-level microsurgical procedures (indeed the most frequent one) and endoscopic operations, which involve short skin incisions and tubular-like surgical corridors, directed only to the disc space or the neural foramen to be explored.

Fatigue, often coupled with external forces which press all the surgical team to complete a crowded operative session quickly, represent an explosive cocktail. In current spinal surgical activity it is not difficult to encounter repeat lumbar discectomies, scheduled on the same day; cases involving same-level, different-side disc herniations or vice versa strongly ressemble an assembly line, which involves an increased potential gross error [9]; the surgeon is in a hurry and the first step he disregards to spare time is fluoroscopic control for level identification.

From philosophical and practical points of view the microsurgical approach constitutes another potential cause of error. It has been demonstrated that the wider the surgical approach the more extended the scar formation [10]; basing upon the finding that scar formation is perhaps the main cause of the FBSS, hence it appears clear that the microsurgical approach is to be preferred strongly to standard 'opener sky' surgery (further multiple advantages of lumbar spine microsurgery go beyond the scope of this chapter). But, this having said, it must be stressed that the attitude to work in a finger-like often deep surgical field, which is indeed the microsurgical field, constitutes a peculiar ability, that needs a long-lasting learning curve. In lumbar spine microsurgery, even if performed by experienced 'good hands', the error of level is always behind the corner, mainly because the fatigued surgeon trusts of his 'dissecting' finger too much; and once the self-retractor is being in place, subsequent surgical steps progress forcedly toward a single disc space, which may be correct or not. How to avoid such a highly undesired event?

5. The neuroradiologist

Our experience using the IRACE method in over 1000 lumbar spine microsurgical procedures has showed that the better way to start a lumbar spine one-level microsurgical operation is performing an intraoperative radiography with a wire placed in the cranial spinous process of the level to be explored. This lateral x-ray image will be easily read by the surgeon himself, but in most of cases the presence or the remote interpretation by the neuroradiologist is fundamental.

First, the reading of a radiograph is really his own job, and, at least in the Italian code, a radiological report can be signed exclusively by a medical doctor who obtained the specialization in Radiology (and medico-legal consequences are obviously understood).

Second, local conditions such as scoliosis, obesity, coexistence of internal metallic instrumentation easily obscure the radiographic appearance; the neuroradiologist is the one who can correctly extricate among all different 'greys', appearing close to the wire applied to the spinous process.

Third, the neuroradiologist is free from surgery's stressing pulse, as on the contrary is the surgeon; therefore he can provide a correct, shining and ultimate interpretation of the intraoperative radiographic image (or ask for repeating it, if required) stressless.

6. Lessons learned

As a final consideration we can state that the attention we paid to the matter of wrong-level is so strong, that our strategy starting with a fluoroscopy performed after having placed a wire in the spinous process has become the starting point of any one-level lumbar spine surgical procedure.

Keeping in mind the somewhat abandoned "ancient doctor-patient relationship" [11], we wish to point out the current surgical activity of academic institutions and large hospitals, in which many patients are globally managed by multiple treating physicians and nurses; it means that, in the global process of assistance to the patient, cardinal steps of indication for surgery, compilation of medical charts and elucidation of the informed consent, and the operation itself are performed by different physicians [12]. If all this is true, hence **strict cooperation between neuroradiologist and spine surgeon, to have a useful x-ray study performed and interpreted intraoperatively in a short time, is one of the clues for a successful spinal operation.**

7. The future

If we assume that in lumbar spine microsurgery a localizing intraoperative image before skin incision is essential, two ways may be anticipated at the moment. On one side we can expect a technological advancement of radiological equipment, in order to deliver better spine images utilizing very low radiations. On the other side, different neurodiagnostic

techniques are to be adopted and in this light intraoperative CT scan seems to be the most promising. It is currently used in stabilization surgical procedures and since its introduction a substantial decrease of the rate of pedicle screw malpositioning has been reported. The next obvious step could be its implementation in the routine daily spine surgical activity, although high costs and additional radiation exposure to the patient markedly limit its diffusion.

Author details

Claudio Irace *
Department of Neurosurgery, Hospital "IGEA", Milan, Italy

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* Corresponding Author

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