

Study of the mechanical properties of rachianesthesia needles as part of materiovigilance

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ABSTRACT — OBJECTIVE: *Spinal anesthesia needles are sterile medical devices used during cesarean procedures such as lumbar punctures with the administration of a local anesthetic in the cerebrospinal fluid. It is a simple and reliable anesthesia technique. However, it can be complicated by difficult needle removal. This complication is an event estimated to have an incidence between one in 20,000 and one in 30,000. Difficult removal can sometimes be due to a broken needle. This rupture can be manifested by a break in the needle tube, but also by a dislocation of the connection between the hub and the needle tube.*

MATERIALS AND METHODS: *Following complaints from healthcare establishments relating to difficulties in removing spinal anesthesia needles due to a dislocation of the connection between the base and the tube, we evaluated the breaking force of the base / tube connection of the implicated needles. Thus, we compared the breaking strengths of two different lots of spinal anesthesia needles (test lot and reference lot) using ISO standard 7864 as a technical reference. This standard requires a minimum breaking force of the needles of dimension 25G equal to 22 Newtons.*

RESULTS: *Regarding the test batch, more than 50% of the samples tested did not comply with the specifications of the standard. On the other hand, concerning the reference lot, all the samples tested showed values of the breaking force higher than the minimum breaking force required by the standard. Compared to the needles from the reference lot, we can say that the needles from the test lot have an increased risk of rupture of the connection between the hub and the tube when the needle is withdrawn at the end of the procedure medical.*

CONCLUSIONS: *Thus, a systematic control of the breaking force, as carried out in our study, should be carried out on all lots of spinal needles in particular and on lots of single-use, non-reusable needles in general, in accordance with the standard. ISO 7864. This is in order to avoid exposing patients to severe risks which can go as far as neurological complications and financial losses for the patients.*

KEYWORDS

Mechanical property, Needle, Rachianesthesia, Materiovigilance.

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INTRODUCTION

Spinal anesthesia is a form of regional anesthesia where a local anesthetic is injected into the intrathecal space. It performs a chemical section or block of the motor, sensory and sympathetic spinal roots of the spinal cord. Spinal anesthesia is performed during lower limb surgeries, but also during abdominal and subumbilical surgeries (cesarean sections, etc.). The sterile equipment required for spinal anesthesia includes (Figure 1):

- Quincke 22 G (0.8 mm) needles are perforated at their bevelled end.
- Sprotte and Whitacre 25G needles have a blunt tip (pencil point) and the hole is located very close to the tip. The 25G needle is very flexible and twists easily, often requiring the use of a 19G introducer 40 mm in length.

Spinal anesthesia needles are sterile medical devices used during cesarean procedures such as lumbar punctures with the administration of a local anesthetic in the cerebrospinal fluid. It is a simple and reliable anesthesia technique. However, it can be complicated by difficult needle removal. This complication is an event estimated to have an incidence of between one in 20,000 and one in 30,000^{1,2}. Difficult removal can sometimes be due to a broken needle³. This rupture can be manifested by a break in the needle tube, but also by a dislocation of the connection between the hub and the needle tube.

The shape of the bevel of the needle, as well as its diameter are important parameters in the achievement of spinal anesthesia. Indeed, these characteristics play a non-negligible role in the occurrence of Post-Dural Puncture Headaches (PDPH), which are non-exceptional and disabling iatrogenic complications. It has been noticed that the needles, which have a pencil point at the end, spread more than they cut the fibers of the dura mater, giving less headaches.

Thus, using small diameter spinal needles results in a significant decrease in the incidence of PDPH⁴. Another study also shows that the use of 22G needles promotes a higher incidence of headache compared to 25G needles⁵.

In addition to the risk of headache following spinal anesthesia, there are also risks associated with misuse of the anesthetic act (insertion or removal) or a manufacturing defect in the medical device used. Thus, one can be confronted with a fractured or sheared needle in connection, most often, with improper handling of the needle during insertion or removal^{6,7}. You may also experience a rupture of the connection between the hub and the needle tube when removing the needle. Therefore, it is recommended that spinal needles, in general, should be examined for manufacturing defects before use⁸.

The objective of our study is to try to provide answers to complaints from health establishments, relating to the difficulties of withdrawing spinal anesthesia needles due to a dislocation of the connection between the base and the tube during procedures of spinal anesthesia. To do this, we will assess the breaking force of the base / tube connection of the needles concerned by the study in order to be able to rule if the problem raised is related to a problem of inadequate handling of the medical device in question by the medical staff or if it is a problem linked to a manufacturing defect in the medical device in question.

ISSUE

Various practitioners at the health center level have claimed incidents during the use of a medical device in spinal anesthesia: spinal trocar 25g x 90 mm, bevelled tip, with introducer, sterile.

Below we present the various complaints related to this subject:

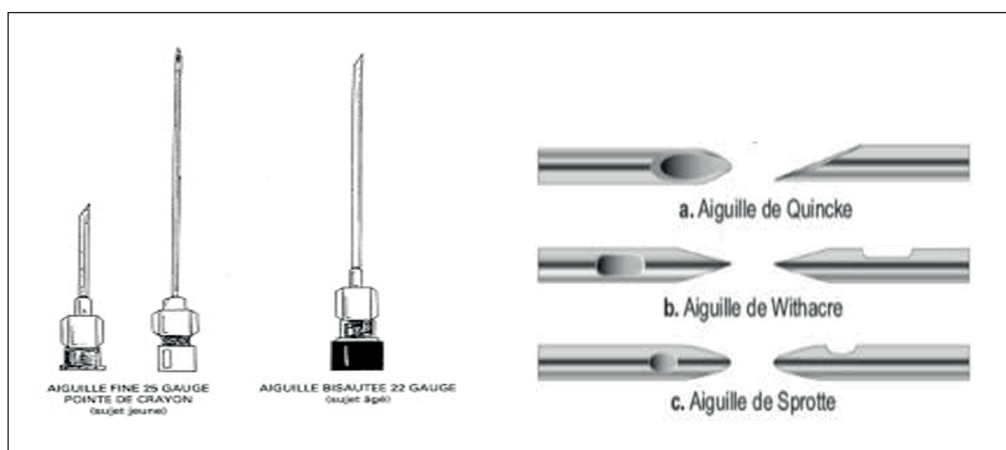


Figure 1. Different types of spinal anesthesia needles with the shape of the bevel.

- Complaint 1: The National Pharmacovigilance Center of Morocco has received several notifications of materiovigilance concerning the trocar incriminated by spinal anesthesia mentioned above. One of the complaints comes from the Almansour Provincial Hospital Center in Casablanca (Morocco) in which the notifier claims: “At the time of use, the medical device broke twice and that just the metal end which remains stuck on the patient’s back with impossibility of practicing the gesture. The stuck end is difficult to recover with a sterile glove. This problem arose with two devices from the same batch and with two different manipulators”.
- Complaint 2: Another complaint concerning the same incriminated trocar was received from Provincial Hospital Center Mohammed V in Sefrou (Morocco), through which the notifier claims: “when performing the spinal anesthesia, there is detachment of the needle from the plastic part of the trocar. This means that the needle remains attached to the patient’s back with a great risk of migration”.
- Complaint 3: The Supply Division reports a complaint from the Regional Directorate of the Ministry of Health, Casablanca-Settat region (Morocco) for the same offending trocar. The incident encountered by the resuscitators and anesthetists is: “Spinal trocar broken during introduction to the patient’s back”.

MATERIALS AND METHODS

To constitute the elements necessary for the analysis, we carried out a homogeneous and representative sampling of the batch of implicated medical devices. A sample was taken directly from the Provincial Hospital Center Almansour in Casablanca (Morocco), the other through incriminated samples received from the Supply Division in Rabat (Morocco).

A fully automated Lloyd LF plus® material testing machine (Figure 2) (Lloyd, Southampton, UK), computer controlled with “Nexygen plus” software is used as analytical equipment. The tensile test uses suitable accessories in pneumatic mode allowing the measurement of the force necessary to break the bond between the base and the tube of the trocars.

With the help of this machine, it is possible to perform a wide range of tests, namely: tensile, compressive, flexural tests, determination of adhesive and tear strength. But also cyclic tests between load or deformation limits equivalent to tests with application of a constant load or tests with ramp of programmed force increment with variation of the test time. The measurement sensors used are interchangeable load cells. Each machine can, among

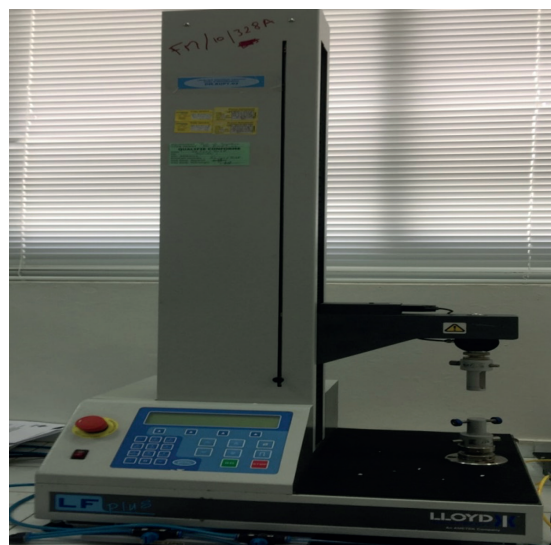


Figure 2. The Lloyd LF plus® tensile strength measuring machine

other things, be equipped with a wide range of accessories, in particular: pneumatic jaws, grippers, handles, compression plates or planes and strain gauges. The “Nexygen plus” software provides an instant and graphical reading of the progress of the test with a great capacity for interpreting and processing the results obtained.

The purpose of the test is to determine the force at break of the connection between the hub and the tube of the spinal needle. The interpretation of the obtained results was evaluated based on the requirement of the minimum force necessary to break the assembly between the hub and the needle tube⁹. During this investigation, a study was carried out to evaluate the results obtained with the incriminated trocart constituting our test object in comparison with a spinal anesthesia trocar used by practitioners and deemed to present no incident, named below trocart de reference: spinal anesthesia needle 25g x 90 mm, bevelled tip, with introducer, sterile.

To attest to the reproducibility and the credibility of the results obtained, the tests were carried out by two different operators on different days.

The breaking force of the connection between the base and the tube of the anesthesia needle was measured by operator 1 out of 10 samples (from Provincial Hospital Center Almansour in Casablanca, Morocco). The measurement of 10 other forces at the rupture of the connection between the base and the tube of the anesthesia needle was carried out by operator 2 on samples (from the Supply Division in Rabat, Morocco). The breaking force of the connection between the hub and the anesthesia needle tube was measured by operator 1 on 08 reference samples.

All needles were conditioned in the same way prior to testing the breaking force between the hub and the anesthesia needle tube.

Table I. Force required to test the hub and needle tube assembly⁹.

Nominal outer diameter of the needle in (mm)	Minimum breaking force in (Newton)
0.3	22
0.33	22
0.36	22
0.4	22
0.45	22
0.5	22
0.55	34
0.6	34
0.7	40
0.8	44
0.9	54
1.1	69
1.2	69

pT1bN0: FIGO Tumour Classification – p(pathological) T1b (Tumour > 5 mm but ≤ 10 mm in greatest dimension) N0 (No regional lymph node metastases); pT1bNX: FIGO Tumour Classification – p(pathological) T1b (Tumour > 5 mm but ≤ 10 mm in greatest dimension) NX (Regional lymph nodes cannot be assessed (for example, previously removed); CBRT: Control group; SuBRT: Treated group.

To simulate the laboratory test with the clinical situation, we have set a set of parameters as follows:

- a maximum force of 500 N.
- The load is of the controlled displacement type and the travel speed is 50 mm / min.
- The test proceeded as follows for each trocar:
- We raise the force capture to 500N
- Adequate accessories are attached
- We connect the pneumatic system with the air compressor
- We start the software “Nexygen plus”
- We configure the tensile test method
- We launch the test
- One recovers the results and their corresponding graphs: Force at break (Newtons) as a function of Time (Seconds).
- The results obtained for the spinal anesthesia and the reference trocar are interpreted and evaluated.

Using ISO 7864 as a reference standard, the value of the measured breaking force was compared

with that required in this standard. The standard specifies that the assembly between the base and the needle tube must not be broken by a force exceeding the minimum force indicated in Table I, applied either in traction or in compression along the axis of the needle⁹.

RESULTS

The results obtained by the two operators for the offending trocar and by the first operator for the reference trocar are shown in Table II and Figures 3-5.

Table II shows the high rate of failures obtained with the implicated trocar: Either 50% by operator 1 and 70% by operator 2. On the contrary, the reference trocar did not detect any failure. This clear reproducibility of results further justifies the non-compliance of the trocar in question and also confirms the incidents encountered by practitioners with this trocar. Among other things, the non-failure proven by the Laboratory is a signifying preference for the use of the reference trocar by practitioners.

DISCUSSION

Several types of spinal anesthesia needles are available for clinical use and their physical and mechanical properties vary considerably. These properties become more important in the event of complications related to the trocars, such as damage to the catheter during insertion, difficulty in removal or rupture during removal¹⁰. Thus, data on the mechanical properties of the trocars can be used to study the complications encountered in the clinical use of the different types of trocars. In this study, we compared the breaking strengths of two different lots of spinal anesthesia needles (test lot and reference lot) using ISO standard 7864 as a technical reference. This standard requires a minimum breaking force needles of dimension 25G equal to 22 Newtons. With regard to this specification, we can deduce that:

Table II. Results obtained for the implicated trocar and the reference trocar.

	Samples		Total samples tested	% of defective samples
	force _{measured} < force _{minimum}	force _{measured} > force _{minimum}		
Trocar involved operator 1	5	5	10	50%
Trocar involved operator 2	7	3	10	70%
Reference trocar	0	8	08	0%

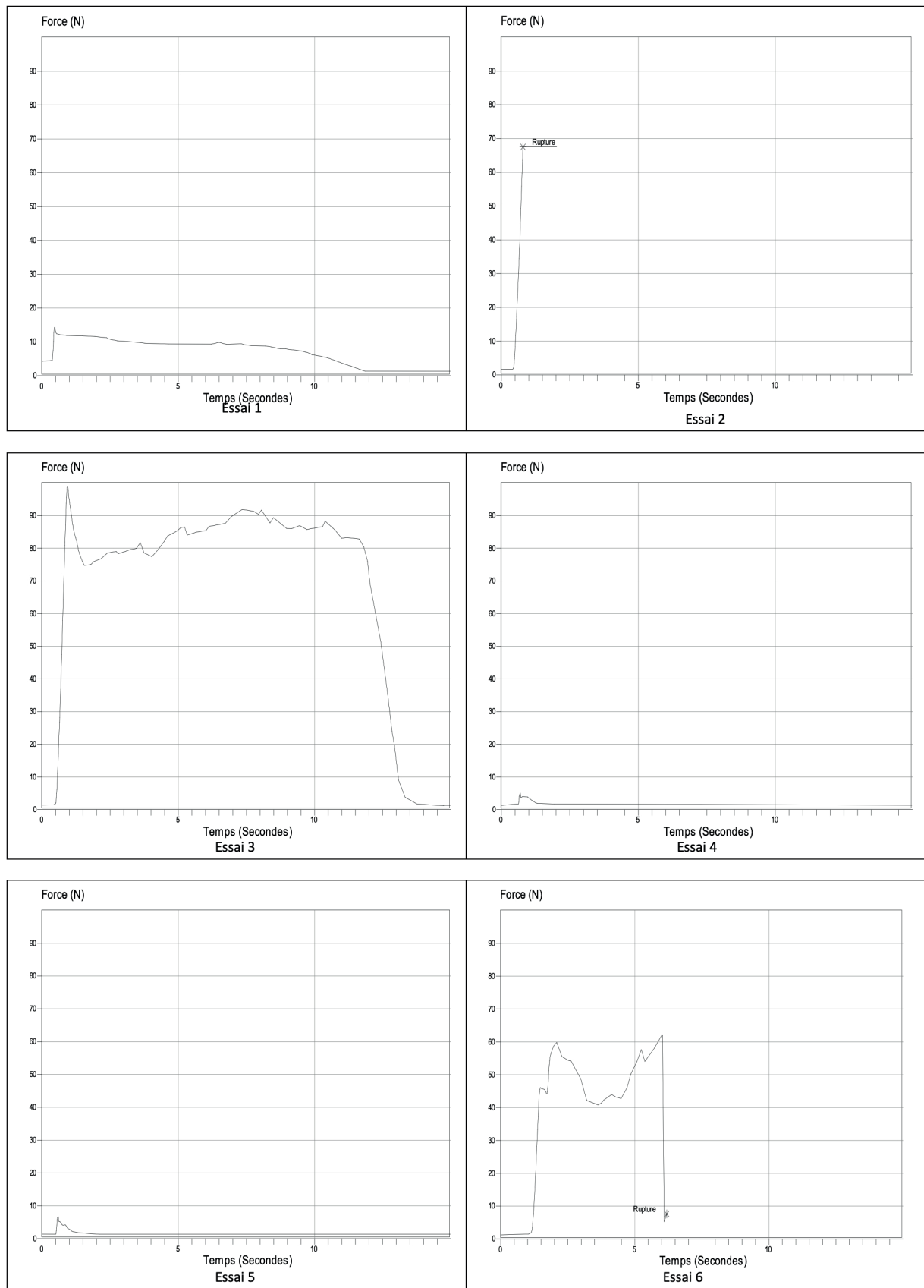


Figure 3. Results of the traction test on the incriminated spinal needles of the operator N ° 1.

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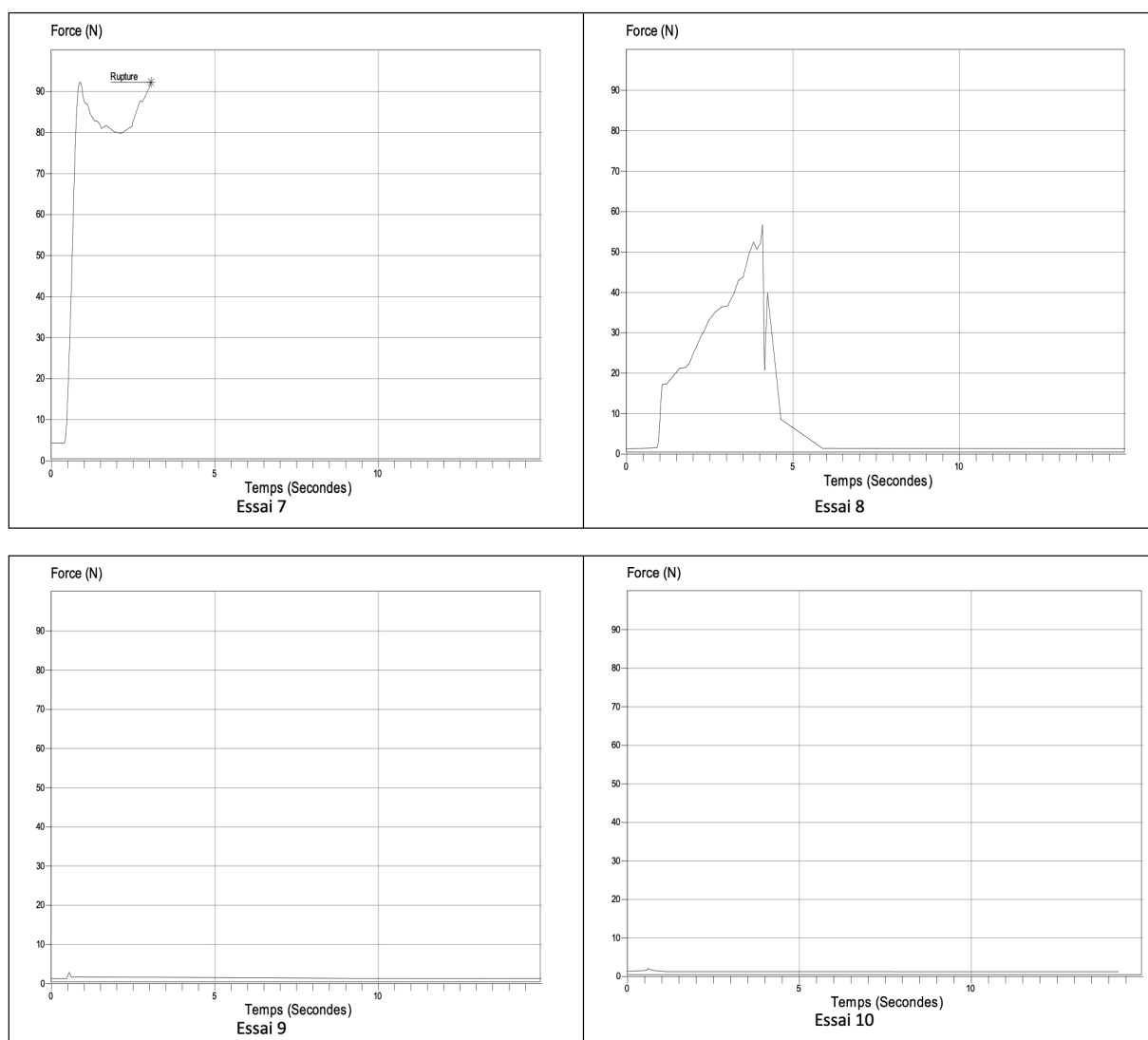


Figure 3 (Continued). Results of the traction test on the incriminated spinal needles of the operator N ° 1.

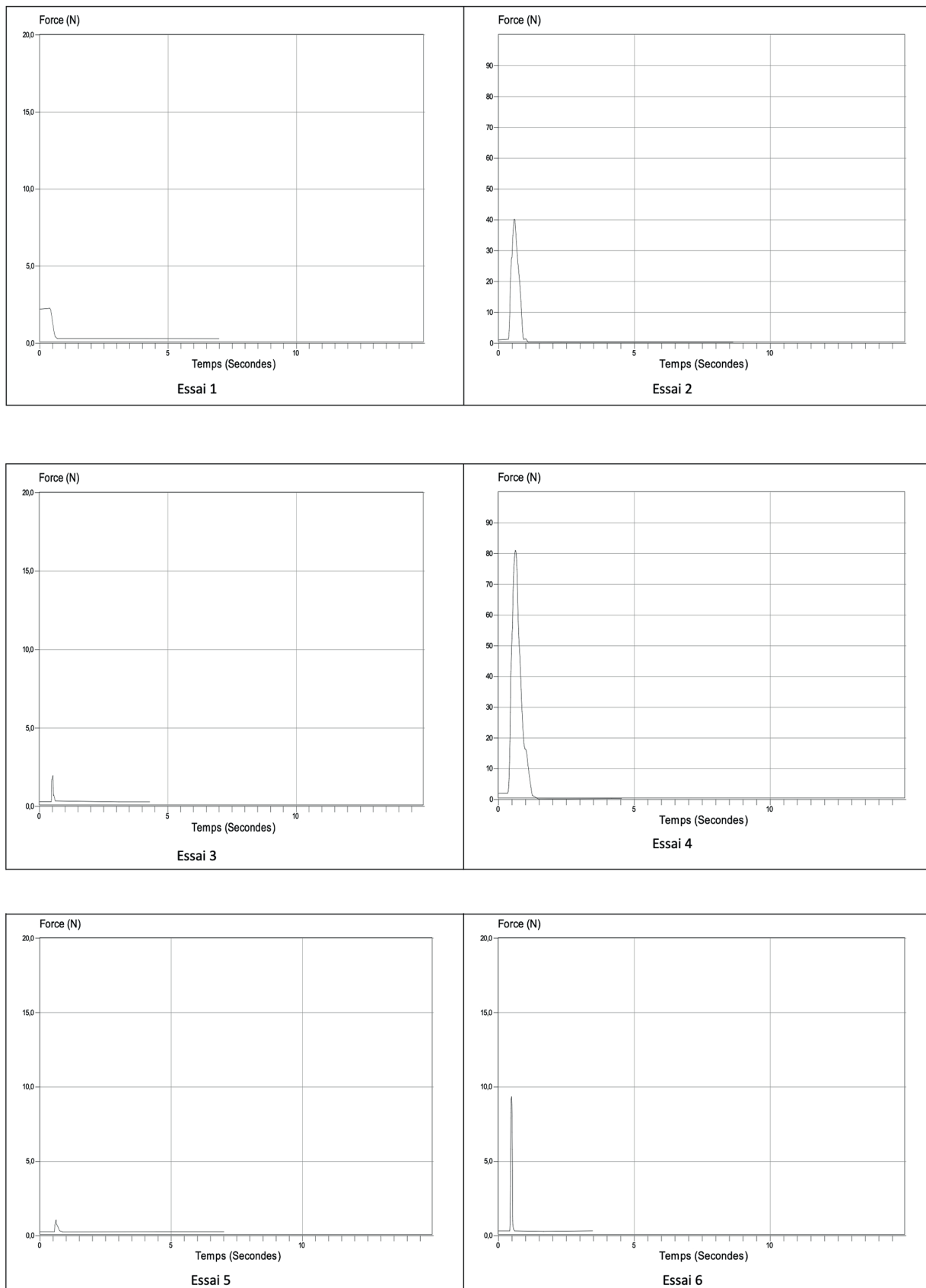
Concerning the test batch comprising the spinal anesthesia needles which have been the subject of several complaints, 12 needles out of 20 tested (operator 1 + operator 2) have a breaking force lower than the limit value required by the ISO 7864 standard. This is equivalent to a rate of more than 50% of the samples tested do not comply with the specifications of the standard, concerning the breaking force of the connection between the hub and the needle tube (Table II). Added to this is the fact that the values of the breaking force of the needles of the test batch are randomly dispersed from each other (Figure 3 and Figure 4). This shows the heterogeneous nature of this incriminated batch and an uncontrolled stability of its manufacturing process and control of mechanical properties. Thus, there are needles with a very high breaking force and others with a very low value of this breaking force.

Concerning the reference batch, comprising the needles used by the practitioners and having not

been the subject of any complaint, all (8 samples) tested showed values of the breaking force greater than the breaking force minimum required by ISO 7864. Therefore, these needles meet the specifications of the standard.

Compared to the needles from the reference lot, we can say that the needles from the test lot have an increased risk of rupture of the connection between the hub and the tube when the needle is withdrawn at the end of the procedure. medical. This easy and recurring breaking of the base / needle tube connection can be the result of:

- An unsuitable flow of the connection.
- Inadequate drying.
- A possible heterogeneity of the material constituting the base.
- Insufficient insertion of the needle tube into the hub.



(Continued)

Figure 4. Results of the traction test of the incriminated spinal needles by operator N °2.

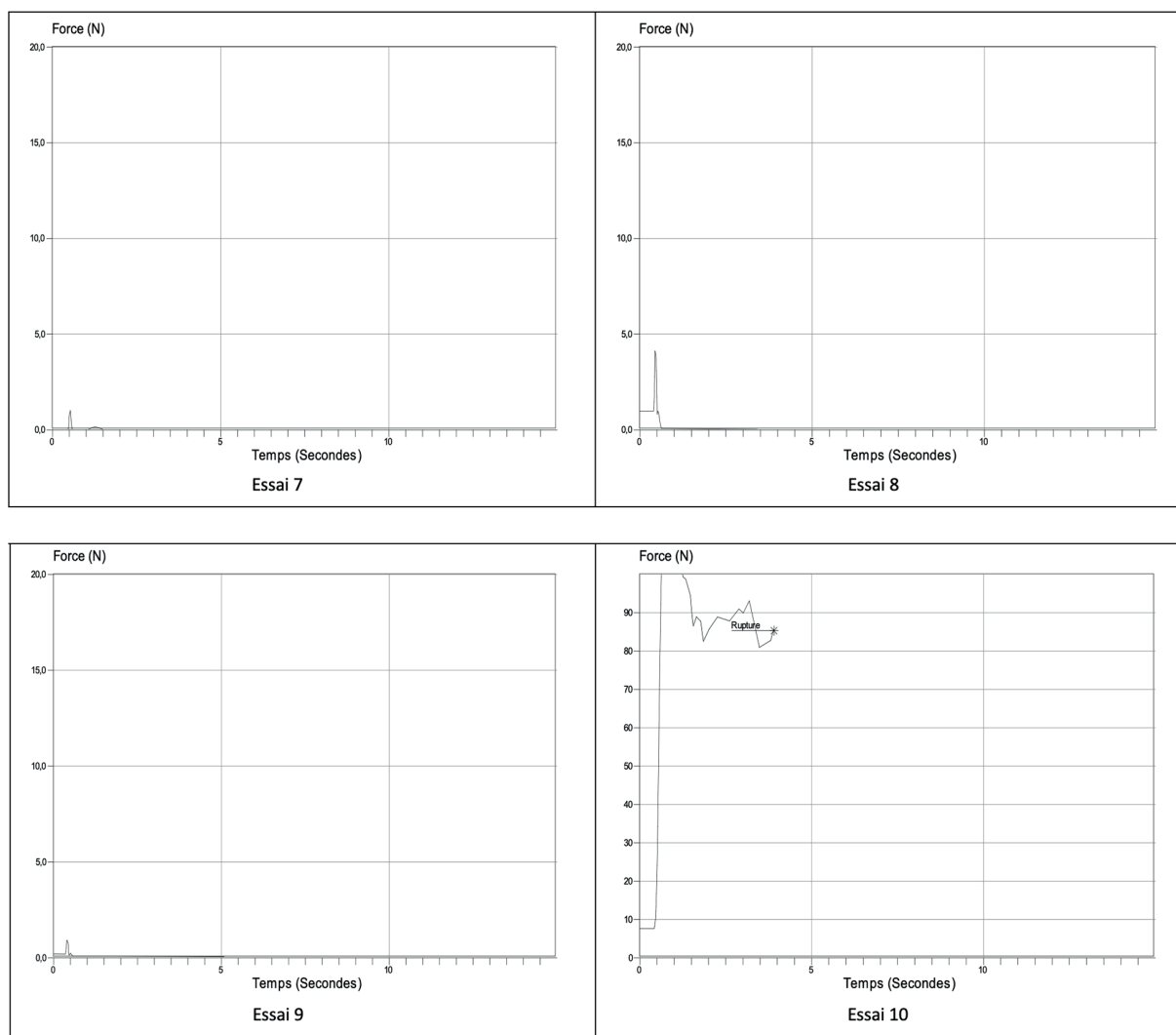


Figure 4 (Continued). Results of the traction test of the incriminated spinal needles by operator N °2.

This probable manufacturing defect could be at the origin of the heterogeneous and random behavior of the mechanical properties measured on the needles of the incriminated batch. This results in a risk for the patient and a financial loss for the consumer.

Faced with this risk, a physical check to assess the mechanical properties of batches of spinal needles, regardless of the purpose of lumbar puncture or spinal anesthesia, is required before they are placed on the market. This systematic control would certainly prevent the severe complications related to incorrect use or manufacture of spinal needles¹⁰.

Several studies have been carried out on ruptures of the spinal needles linked to misuse⁶⁻⁸. However, few studies have examined spinal needle ruptures related to manufacturing defects. Nishio et al¹¹, to elucidate the possible causes of needle breakage related to the manufacturing process, evaluated the characteristics inherent in epidural catheter materi-

als likely to predispose their breakage. The tensile strength of these materials was evaluated and they concluded that nylon or polyurethane catheters were stronger than Teflon or polyethylene catheters. Ates et al¹² concluded that polyurethane catheters were more resistant than radiopaque catheters. However, none of these studies specifically assessed the breaking force of the connection between the hub and the needle tube as performed in our study. The studies by Nishio et al¹¹ were limited only to a comparison of the mechanical properties of three types of epidural catheters (nylon, polyurethane, radiopaque) in order to predict their resistance to rupture.

The danger with this kind of problem is that the rest of the needle that is stuck in the patient's spinal space cannot be removed. As mentioned in the complaints, the metal tube of the needle is difficult to recover with sterile gloves by the medical profession. Like the majority of cases reported in the literature¹³⁻¹⁵, the remainder of the needle could be imme-

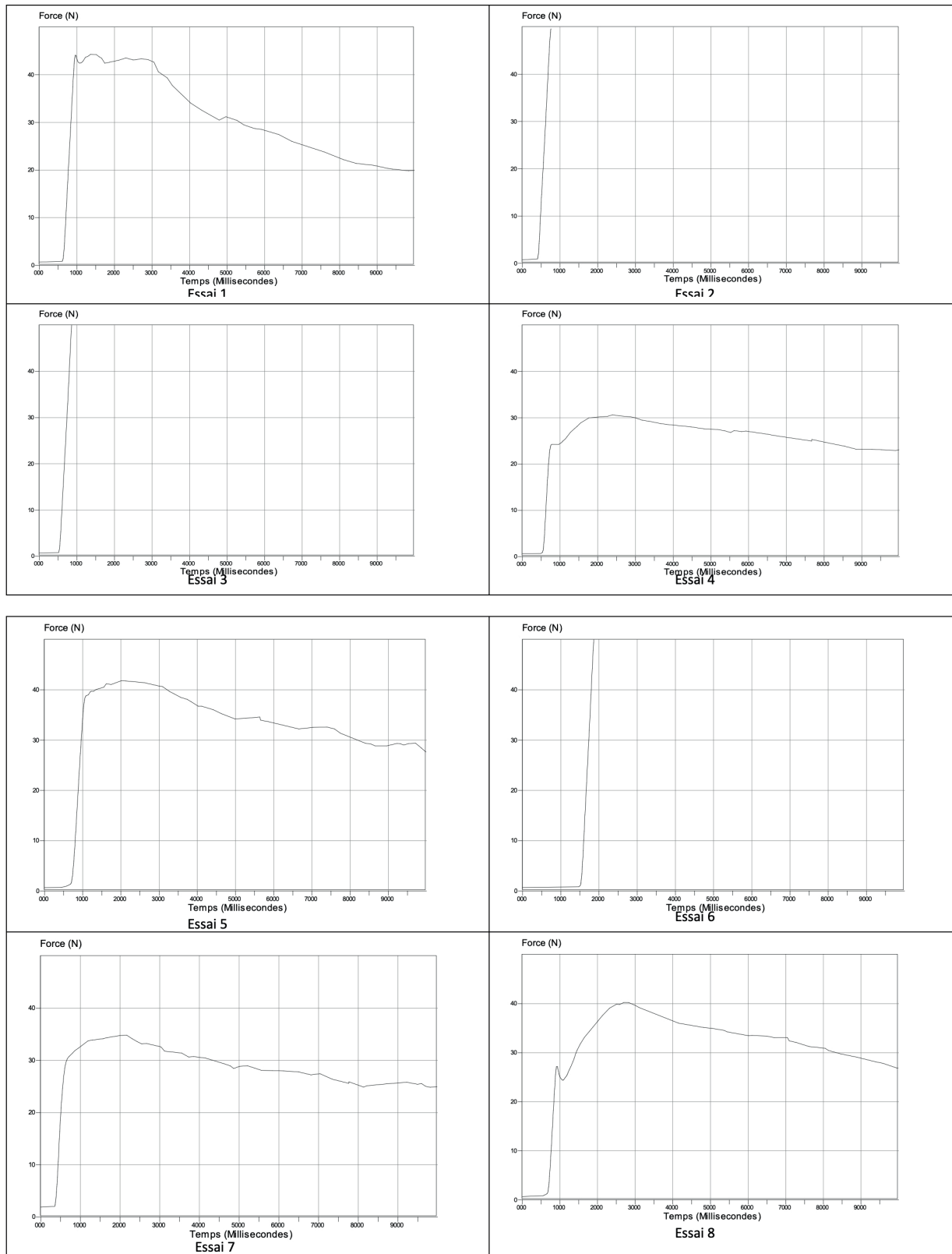


Figure 5. Results of the traction test of the spinal needles of the reference lot.

diately withdrawn after its rupture without sequelae, since the level of the rupture was outside the patient's body. As the rupture occurred at the connection between the hub and the needle tube, the distal end of

the needle tube could be grasped and served as a support for the needle removal. In cases where the level of the rupture is *in situ* i.e. inside the patient's body, the problem is much more delicate and the removal is

often difficult sometimes requiring X-ray images and surgery¹³. Thus, several studies report the occurrence of neurological complications following a rupture of the spinal needle *in situ*^{16,17}. These different scenarios indicate that the early removal of a broken needle should perhaps be recommended, especially when the onset of symptoms that can lead to neurological trauma may occur over time.

CONCLUSIONS

The rupture of a spinal anesthesia needle during its use is certainly a rare phenomenon but can occur either as a result of an error in handling the needle during the medical procedure or as a result of a manufacturing defect. The key to reducing needle breakages due to mishandling is training medical personnel. However, to avoid needle breakages linked to manufacturing defects, the solution lies in checking medical devices before they are placed on the market. Thus, a systematic control of the breaking force, as carried out in our study, should be carried out on all lots of spinal needles in particular and on lots of single-use, non-reusable needles in general, in accordance with the standard. ISO 7864. This is in order to avoid exposing patients to severe risks which can go as far as neurological complications and financial losses for the patients.

CONFLICTS OF INTEREST:

The authors declare no conflict of interest

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