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Kaizen: Engineering tools for development, evaluation, certification and continuous improvement of microsurgical abilities and procedures

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ABSTRACT
Introduction: microsurgical procedures are multi-variable situations, difficult to objectively analyse. Procedures evaluation-improvement-certification is a strong and developed science for engineers. Kaizen is a renamed methodology in this area. This study aims to use Kaizen tools and politics to design a protocol for hand-skills training at a microsurgical scenario, with continuous improvement ability and objective evaluation capabilities.
Materials and methods: a step-by-step hand-skills training protocol was designed using Kaizen method and an experienced microvascular team opinion. It was performed by one surgeon, using a biological sample (placenta) as a surgical simulator. PDCA Kaizen protocol helped to define variables (time elapsed and mistake committed while performing a precise task) and a mistakes-score building to evaluate every single step of the procedure. The scenario was fully controlled to avoid bias. Results were statistically analysed.
Results: twelve placentas were used to achieve the goals. Total working time was 13h47m03s. Longest attempt was the first one (1h49m05s/2mistakes). Shorter attempt was the fourth one (53m29sec/3mistakes). Average time was 1h15m11sec. After 7 attempts, learning curve achieves a plateau. After 12 attempts, no mistakes level was achieved, (57min37sec).
Conclusion: Kaizen application to microsurgery results in a training programme that shows significant impact reducing time-needed and mistake-committed levels. Kaizen helped to use an experienced team expertise, identify useful variables, evaluate a complex procedure, data processing, and continuous-improvement-politic inclusion. Learning curves were precisely built, and teaching progress objectively measured. This method could also be applied to analyse and evaluate surgical procedures.

Keywords: Microscopic surgery, Kaizen method, Evaluation protocols, Hand-skill training.

1 INTRODUCTION

This scientific paper intends to introduce the Kaizen PDCA method as a powerful instrument to identify (within a microsurgical procedure) improvement situations and to initiate a continuous improvement pathway. This will be done by selecting a specific situation (hand-skill training), applying the PDCA tools to design a protocol, measure variables, evaluate results, and identify how to start improvements on it.

In the following paragraphs, the topic will be approached by presenting the main background chapters and describing each one of them. Those chapters will be described in the following order: A- the Kaizen method, B- the microsurgery evolution, C- the role of technology and visual aid systems, and D- the use of microsurgical simulators for hand-skill training.

In general terms, a microsurgical procedure could be proposed as:

a) *treatment method* (aiming for a disease resolution; with a patient as surgical scenario)

b) *training method* (aiming to evaluate the operator skills; the scenario should optimally be a surgical simulator).

Both situations could be Kaizen-evaluated and (after choosing the training modality) will be conducting every step of this study to serve as a demonstration of its versatility. Besides, the novelty of this work is based on the application of Kaizen in the microsurgical field, validating once again this continuous improvement tool in the health sector. To perform tissue manipulation at high magnification levels, represents a meaningful gain at hand-skill in microsurgery.

1.1 THE KAIZEN METHOD

After World War II, industries were challenged by a new productivity paradigm. The Kaizen method, a new point of view for procedures analysis and evaluation, was focusing on operator's accumulative experience and its application to a procedure under strict scientific/logical rules. This theory was presented to the scientific community with the publication of "Kaizen: The Key to Japan's Competitive Success", by Masaaki Imai (1986). This book is the germinal contribution in the field of continual improvement literature and provides valuable insights into the principles and tools of Kaizen. Although the focus was on production management methods, soon Kaizen showed successful application in quite different fields. Imai (1986: 4) considered that Kaizen is a kind of umbrella that includes most of the uniquely Japanese management practices [37].

The core of this new perspective, oriented to properly diagnose and accurately solve problems, is known as the PDCA (acronym for Planning, Doing, Checking, Acting) cycle (Figure1). Sometimes, as mentioned by Gabran and Swartz (2012: 9), "Acting" is replaced currently by "Adjusting" [36]. By using this cycle, data and practical experience are processed, allowing to standardize procedures in a dynamic way, always aiming to a fundamental concept: continuous improvement.

Kaizen PDCA paradigm [16] and its specific tools were followed for every step, thus, becoming the method and the rules of this study itself. Those PDCA tools could be listed as:

- Planning basics (will be represented in the Material and Methods section)

a. Detecting improvement situations (using a group of experts counselling)

b. Precise problem definition

c. Problem main causes detection (Brainstorming, Ishikawa cause-effect diagram)

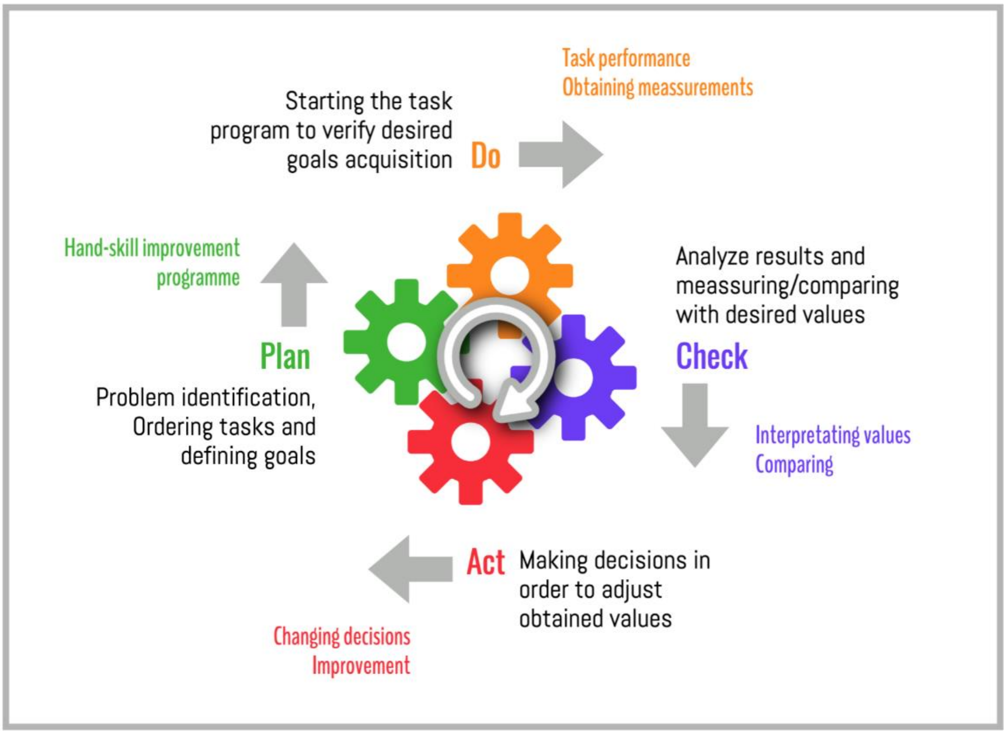
d. Causes weighing (Pareto's diagram)

e. Action Plan (5W1H technique).

f. Goals, variables and KPI's (Key Performance Indicators)

- Doing (will be represented by the Task Performance and shown in the Results section)
- Checking (will be represented at the Discussion and Conclusion section)
- Acting (standardization of the programme and taking actions after results and new improvement detection; will be also outlined at the Conclusion section)

Figure 1: Kaizen PDCA cycle is shown in a diagram. Stages of this paper are enounced with coloured letters at every step of the cycle.



Source: own elaboration.

This Japanese evidence of effectivity in many areas using Kaizen [24, 25, 26], promoted this method to start being used in western countries. Mainly, the industrial area was the first to adopt it, but the health care system and practitioners were not an exception. The first documented applications of Kaizen in the healthcare sector were reported in the 1990's [34, 35]. Particularly, private hospitals in the USA introduced the tool for improving healthcare processes and services, mainly as a productivity tool for saving money. The approach is widely used now by numerous hospitals around the world, with new goals like staff's involvement or motivation, humanization of workplace, standardization or quality improvements [36]. Some of the current applications are enumerated (with their correspondent academic references) in the following lines:

- In surgical activities: identify areas for improvement and make small changes that lead to significant steps forward in efficiency, quality, safety, and workplace culture [30].
- Improving equipment utilization: such as by reducing downtime or improving maintenance practices. This can lead to increased efficiency and reduced costs [29].
- Implementation of Kaizen in a surgical equipment manufacturing industry: the study showed that the application of Kaizen about manufacturing medical equipment, led to significant improvements in efficiency, quality, safety, and workplace culture [31].
- Improving healthcare from the bottom up: involving hospital staff in the improvement process. This can lead to a sense of ownership and motivation to participate in the improvement process [27].
- Limited focus on sociotechnical aspects and the partial compliance to Kaizen templates may indicate an incomplete understanding of the entire Kaizen process and of how it relates to the overall organizational goals. This can hamper the sustainability of Kaizen practices and results [28].

On the other hand, implementing Kaizen in the healthcare sector can be very challenging. A summary of such challenges can be synthetized as [27, 38, 39]:

- Lack of a process focus: nursing leadership is often focused on programs, while front-line staff are focused on tasks, which can lead to a lack of process focus.
- Resistance to change: professional staff may be resistant to change, particularly if they have been practicing a certain way for a long time.
- Time constraints: hospital personnel are often busy and may not have the time to participate in Kaizen activities.
- Lack of training: professionals may not have the necessary training or knowledge to participate in Kaizen activities.
- Inadequate communication: there are breakdowns between different departments or levels of the organization that can hinder the implementation of Kaizen.
- Limited resources: it can make it difficult to implement Kaizen activities, with limited funding or staff.

For overcoming these challenges, healthcare organizations need to provide adequate training and support to staff, establish effective communication channels, and allocate sufficient resources to

Kaizen activities [27, 39]. Additionally, healthcare professionals need to be engaged and empowered to participate in continuous improvement activities to drive change and improve healthcare outcomes [36].

In contrast with this evidence, there are no official registries for Kaizen being used by surgeons or surgical processes itself in the literature. Even so, it is not difficult to correlate a surgical procedure with those that Kaizen method propose to analyse. Both, surgical and Kaizen, share some strategical points:

a) Operators accumulative experience.
b) Thorough process analysis.
c) Scientific methodology to apply rules.
d) Objectively select and measure variables which defines a procedure.
e) Procedures and processes developed on a time base.
f) Planning and developing changes to gain effectiveness and better results.
g) Acting (adjusting) and checking in a continuous improvement manner.
h) The possibility of changing, deleting and adding steps and/or tools to the procedure

1.2 THE MICROSURGERY EVOLUTION

The surgical field has been evolving since the very beginning of the microscope era. For neurosurgeons, five decades ago, professor Yasargil [22], among others, sets some of the main concepts of microsurgery.

By the present time, microsurgery is the gold standard for a wide range of pathologies, but also with the addition of significant technological and academic changes that have come to the scene recently. Visual aid systems, such as hybrid microscopes, endoscopic assistance, laser ultra-fine-built instruments, artificial intelligence modules, image fusion, and many other tools should be properly understood and handled by surgeons working in this microscopic anatomical universe.

Building objectives evaluations about the real value of these advances, is not always an easy task. This is even more difficult due to the high speed of this evolution, and the remarkable amount of time that quality evidence requires to be generated and then work as technology inseparable companion.

This evolved microsurgery is nowadays being practiced by many specialties: neurosurgery (e.g., aneurysm clipping, artery bypass, cistern ostomy for brain trauma), orthopaedics (limbs reconstruction), vascular surgery (re-perfusion techniques using bypass), organ transplant surgery (portal pedicle reconstruction after ablation-donation procedures), and many other examples.

This context sets the main actor in the centre role again: the surgeon, with their capability to stay alert to changes, to co-exist within this evolution, to constantly look for new knowledge, and to train their skills.

Those skills are now in the challenging situation of being tested by powerful levels of visual magnification, taking hands-eye coordination to its very limits. Thus, improvement in this area can be transformed into surgical results.

The way this microsurgical universe is explored is not less important. As a matter of facts, it is mandatory to perform this exploration not only in a scientific manner, but also under an effective, continuously sharing and improving modality. The Kaizen method enlighten this situation.

1.3 THE ROLE FOR TECHNOLOGY AND VISUAL AID SYSTEMS

Microscopic surgery refers directly to microscopic anatomic structures that have to be properly visualized and manipulated. The door for the microscopic universe is represented by the optical system used to upgrade vision capabilities, and finally reach this micrometric level at a good definition.

A visual aid system is defined as any kind of element used to upgrade normal physiological sight. They mix illumination and positioning structures, integrated into more complex systems such as the binocular microscope, hybrid technologies as ARveo (Leica ®), Kinevo (Zeiss ®), or fully digital and robotized system like the AEOS Exoscope (Aesculap ®) or the ORBYE (Olympus ®).

All of them show benefits and limitations. The chosen visual aid system has a direct impact while evaluating microsurgery (and microscopic techniques in general) [1,13,14] and that is why they are particularly mentioned here. Some basic information about those systems should be mentioned, but any further information exceeds the scope of this paper.

1.4 THE USE OF PLACENTA MODEL SIMULATORS FOR MICROSURGICAL TRAINING

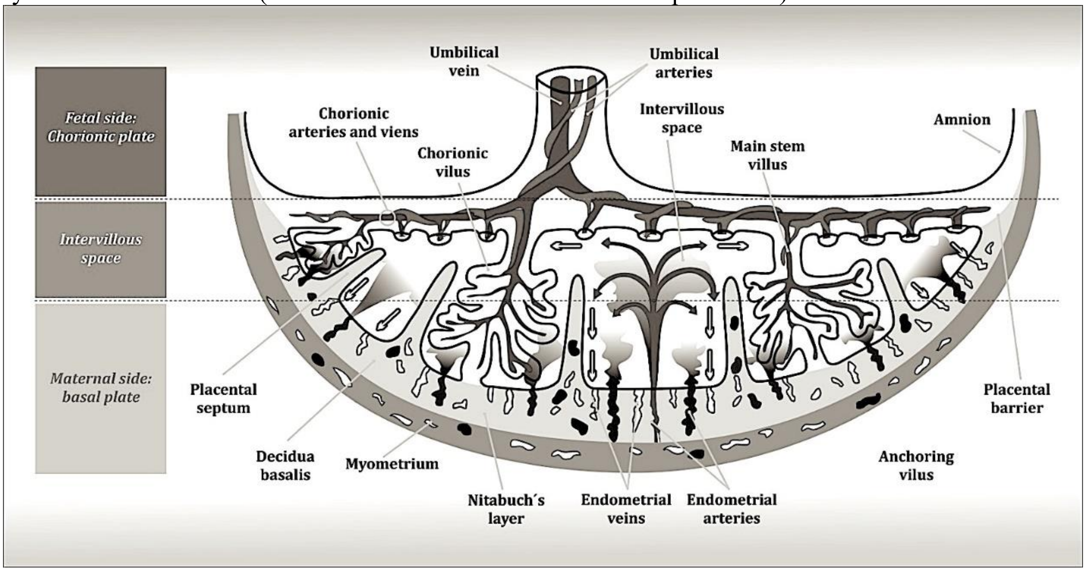
Among others, placenta simulators could be an excellent option for a surgeon´s hand-skill development.

This human tissue has some particular properties [11,8,3,5,9] that make it interesting for vascular surgeons and even more so for neurosurgeons (Figure 2): placenta vessels have a remarkably similitude to brain cortical vessels and their surrounding tissue. Previous and strong academic experiences [20,15,4,19,3] can be found at this respect.

Direct extrapolation from training fields to the real surgical field is not an easy task, but it is well known that a thoroughly conceived and structured training plan can solve this issue if some criteria are respected.

The reviewed literature shown some lack of precise information in this topic. Multiple variables should be precisely measured in a well-controlled scenario, avoiding bias and bringing order to good data management and evaluation.

Figure 2: this placenta diagram shows each vessel coming from the umbilical cord (grade I vessel) covered superficially by the maternal side of the amniotic layer (that mimics the arachnoid surface). Vessels will divide into two branches (dichotomy splitting) being half diameter (grade II vessel) compared to the parental one. This division will take place once more (generating grade III vessel) before reaching the deep chorion and richly vascularized basal decidua, which is covered by a thin layer of laminar chorion (that mimics arachnoid trabeculae and pia matter).



Source: modified from Gray, H. (2013 edition) [40].

2 MATERIALS AND METHODS

As mentioned above, Kaizen PDCA methodology will be leading the analysis of a complex scenario (hand skill surgical training) and the building of a logical and ordered procedure.

- Planning Basics

a. *Improvement situation:* a group of experts at microsurgical interventions (members of the Neurosurgical department at KIMS Karad University) discussed the topic and selected "continuous improvement of microsurgical skills at high levels of magnification". This choice was made because of the logical relation between hand-skills and surgical results. There was also evidences of the need about gaining excellence at this specific scenario for many reasons (new more precise instruments available, new visual aid devices, new challenging surgical situations to solve). The surgeon performance depends not only in acquiring a certain level, but also to keep training and adapting to new features available; that was the main reason to look for a continuous improvement protocol.

b. *Precise problem definition:* no specific microsurgical programme available to improve hand-skills and instruments/devices handling, with the possibility of measuring progress and start a continuous improvement situation. [It is advisable to make a differentiation: hand-skill level is an ability which will be helpful for any microsurgical procedure. Even when specific tasks and goals are given as a protocol, the evaluation **is not** about the effectivity of the manoeuvre (e.g.: "safe vessel dissection" or "stable vessel suture"), but about the dexterity needed to perform it in a better way].

c. *Problem main causes:* this situation was also analysed by the same group of experts in the field.

- *Brainstorming:* no proper surgeon's training/evaluation to perform microsurgery manoeuvres; low amounts of time working at high levels of magnification; microsurgical simulators high costs; no teachers to upgrade techniques; no training programs available/affordable; no specific visual devices handling instructions; not using adequate instruments; no optimal visual aid device available.
- *Ishikawa cause-effect diagram*: after debate by the same team, all causes of problems were grouped in four areas.

- Problems about the scenario: to evaluate real surgical cases as hand-skill markers, do not appear adequate (**ethics**) and suboptimal for objective interpretation (**variability**). Surgical simulators allow more control of the scene but are expensive (**costs**) and not easy to obtain (**availability**).
- Problems about the expertise acquisition: there is no easy/affordable ways to assist to training courses (**affordability**); nor to specific teachers for microsurgical techniques and microsurgical instruments/devices using (**accessibility**). There are no specific protocols to measure, evaluate and certify microsurgical dexterity (**un-specificity**).
- Technical problems: high skill level needed to perform quality procedures under microscope view (**training time**); lack of parameters to identify problems in the technical area (**variables selection**); multiple sources of information about technical matters (**diversity**), with difficulties to compare/choose between them (**interpretation**).
- Miscellaneous: inadequate visual aid system (**visualization**); lack of parameters to choose magnification level (**zooming**); inadequate instruments to perform each task (**instrument**); inadequate sutures and/or suturing strategy (**suture**); impossibility to assess progression and detect problems (**protocol**).

d. *Causes weighing:* A Pareto's diagram was developed to prioritize causes using four criteria (direct incidence over hand skill development, possibility to generate an objective protocol, using available resources, affordability), to identify the most important variables to focus on.

e. *Action Plan:* by using 5W1H technique (What, Why, Where, Who, When, How, for every principal causes) an action plan was generated using the following main decisions:

- To use a surgical simulator.
- To build a precise step by step protocol.
- To identify variables to properly evaluate dexterity (hand-skills).
- To select the most precise measuring system possible for the selected variables.

- To choose progressive difficulty level tasks, in order to help skill acquisition.
- To start using this protocol as a scientific field to evaluate microsurgical dexterity.
- To objectively define related terms as “magnification level” and “quality procedure”.
- To evidence general results and submit them to statistical analysis.
- To verify effectiveness of the proposed method.
- To evaluate the use of Kaizen method while evaluating surgical procedures.

f. *Goals:* once this analysis is made completely, the process to define a main goal is a logical consequence: **to introduce “surgical hand-skills at a microsurgical environment” in a continuous improvement modality of training**. Jointly with this main goal, there are other associated topics (secondary goals) being observed with this programme:

- Mastering the visual aid system handling and exploit their capabilities
- Choosing appropriate zoom level for different tasks
- Selecting and using microsurgical instruments to better perform tasks
- Validating the proposed protocol to certify microsurgical dexterity
- Validating Kaizen as a surgical procedure evaluating and continuous improvement method
- Evaluate the adaptability of this method to real surgery scenario and to other related topics (devices comparison, instruments precision, techniques variations, etc.).

2.1 TASK PROTOCOL

Once the planning stage offered a main structure and a books/papers review on different related topics was made (“surgical training”, “surgical learning curves”, microsurgical techniques” and “microsurgical devices”), a new interview with experienced neurovascular surgeons of the institution were conducted to design a programme with specific tasks and thoroughly descripted stages. A step-by-step progressive complexity protocol was then built to better achieve the above-mentioned goals.

Placenta was selected as a biological simulator. Care was taken to handle it during the trial: the sample will be properly preserved, transported, and conserved for up to 48 hours at an appropriate temperature. After that period, the placenta will be discarded due to loss of connective tissue properties [10,12].

Variables to be measured will be:

1. **time elapsed**: clock will be started at the beginning and stopped when each task goal is achieved.
2. **mistakes made**: mistakes made scoring system is proposed for all of the tasks

Time should be understood not as an absolute value, but for its stretch-inverse relationship with performance dexterity (better skill, less time used). The elapsed time will be measured. No stops for any reason are allowed.

Mistakes will be classified as a minor mistake (registered with an "m" letter) or a major mistake (registered with an "M" capital letter), then registered during task performances. Different combinations of those major and minor mistakes will be used to define each task mistake-limits.

To establish a numeric correlation, major mistakes will account 4 points and minor mistakes 1 point (arbitrary). Descriptions of major and minor mistakes are given (Table 1). The intention to use this rule is to prioritizes the quality of the procedure.

Table 1 - Mistakes classification

Major	Selected parental vessel is damaged (bleeding from wall break)
	Selected vessel appears as non-permeable after suture (verification method does not allow flux along the sutured vessel).
Minor	Small branches coming from parental vessel are cut (intentionally) or damaged (unintentionally)
	Deepest layer of laminar chorion is damaged and chorion/decidua level is reached (bleeding from background or direct view of decidua tissue)
	Sutured vessel shows a leak point after suture (verification method reveals extra vascular flux out of the vessel or through pseudo-lumen at adventitia level)
	Stitches failure (verification method shows a stitch with not enough tension, coming out or misplaced)

Source: own elaboration

Tasks were planned based on two aspects: complexity and magnification level. The magnification level should be reached as a balance between comfort and proper handling of tissues. This level will be mentioned as low-level magnification (LLM), mid-level magnification (MLM), or high-level magnification (HLM) following descriptions in Table 2.

Table 2 - Standard levels of magnification

LLM Low level of magnification	from simple-sight vision to loupes level vision (10x magnification level).
MDL Mid level of magnification	special aid will be needed and options are available to get at 10x – 25x magnification level (e.g. microscope, cameras, exoscope)
HLM High level of magnification	special aid should reach 25x or higher level at proper light conditions and angles (e.g. microscope, cameras, exoscope).

Source: own elaboration

In order to set the working scenario in the same conditions for all the samples (so the evaluation focus can be placed on hand-skills only), there is just one surgeon performing all the trial. The placenta was placed on a flat surface to achieve optimal lighting condition and avoid any possible bias related to angle or position.

Registers were made by handwriting while performing the corresponding task. Then, registries will be transferred to a Google Sheet ® platform for immediate automatic analysis, corroboration, and further database building.

The instrument set was provided by a local provider, following international standards for microvascular surgery (2 straight forceps, 1 curved forceps with non-traumatic tips, 1 straight scissor, 1 up-curved scissor, 1 side-curved scissor, 1 micro needle holder). The instrument set was always the same during the whole programme, in order to avoid any kind of bias during data evaluation. Suture was mono-nylon 10/0.

2.2 PROGRESSIVE DIFFICULTY TASK PROGRAM

A programme of five tasks will be performed. Each task will be detailed in the following paragraphs. Every task should be repeated as many times as necessary to complete it without any mistakes before progressing to the next difficulty level.

Task 1 to 4 were planned to serve as initial training about: being comfortable while working with the anatomy and special properties of the surgical simulator, being familiar with this particular set of rules, and having a smooth interaction with the proposed tools (microscope features, instrument set). Registries were taken but not accounted to build results database.

Just Task 5 was used to build a database for analysis, evaluation, and results exposition.

2.2.1 Task N1

Difficulty level: basic / Visual magnification: LLM

Main goal: basic set up, instruments handling, visual aid system handling

Mistakes limit: no mistakes limit

Stop clock: no clock registries

Description:

1. Instruments and microscope set up. Placenta proper positioning.
2. General navigation at 6x magnification level to recognize anatomic landmarks: umbilical cord, grade I – II and III vessels, vessels "cross roads" (arteries are always going over the vein).
3. Select a grade I vessel and perform a complete inspection, proximal to distal, and both sides of the vessel.

4. As a final step, this selected vessel can be manipulated in a free manner. Deep chorion/decidua levels should also be recognized.

2.2.2 Task N2

Difficulty level: basic / Visual magnification: LLM

Main goals: instruments handling, basic tissue manipulation

Mistakes limit: 2Major + 4minor

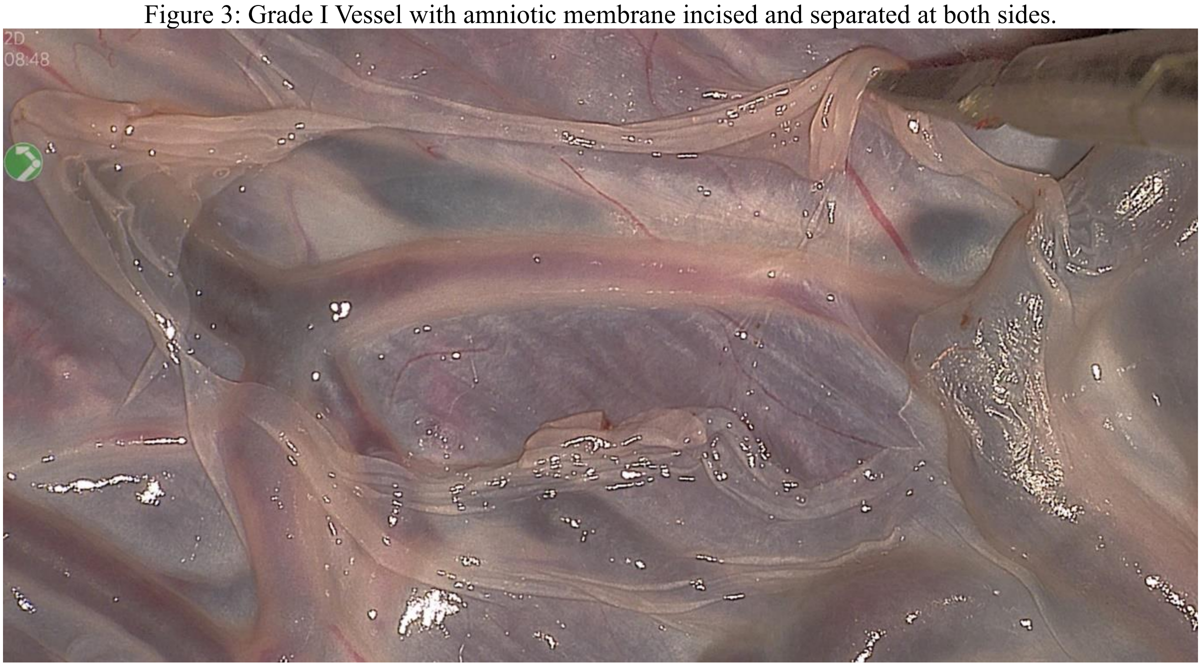
Stop clock: when amnions membrane over a vessel dissection is achieved

Description:

1. Select a grade I arterial vessel (Figure 3). Measure 20mm of it (Figure 4).
2. Dissect superficial layer (amnions) from it. Amnions could be easily separated and mobilized after a longitudinal incision on the layer over the vessel.
3. Mobilize the opened membrane to both sides of the vessel.

NOTE: the amniotic membrane could be absent in cases where it was disrupted during labour or during manipulation and preservation.

Figure 3: Grade I Vessel with amniotic membrane incised and separated at both sides.



Source: own elaboration

2.2.3 Task N3

Difficulty level: basic-mid level / Visual magnification: LLM-MLM

Main goals: partial vessel dissection

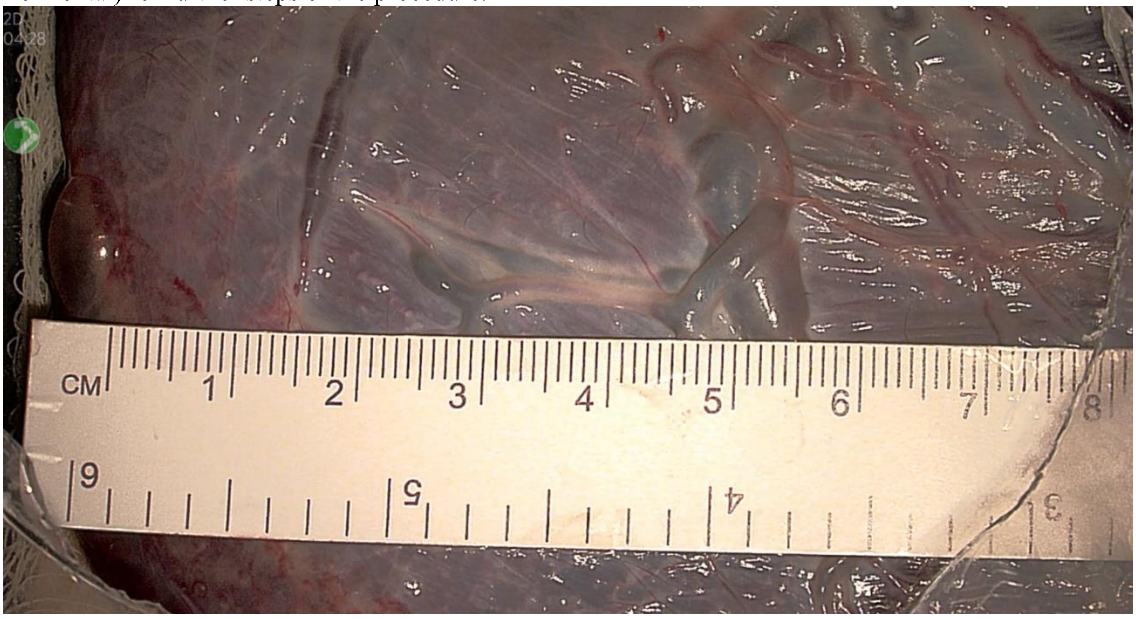
Mistakes limit 1Major + 3minor

Stop clock: when the vessel dissection is achieved

Description:

1. Select a grade II vessel (vein). Measure 15mm of it.
2. Dissect superficial layer (amnions) from it. Amnions could be easily separated and mobilised after a longitudinal incision over the vessel.
3. Partially dissect the intermediate layer (laminar chorion) at both sides of the vessel, without dissecting it from the bottom face of the vessel. This layer is partially fused with the adventitious layer of the vessel. Care must be taken not to damage the vessel wall.
4. Mobilize both opened membranes to both sides of the vessel. The vessel, once freed, should be only attached to deep-bottom layers only.

Figure 4: Vessel proper measurement and selection. Note that placenta was positioned in a convenient manner (vessel is straight horizontal) for further steps of the procedure.



Source: own elaboration

2.2.4 Task N4

Difficulty level: mid-level / Visual magnification: MLM-HLM

Main goals: complete vessel dissection

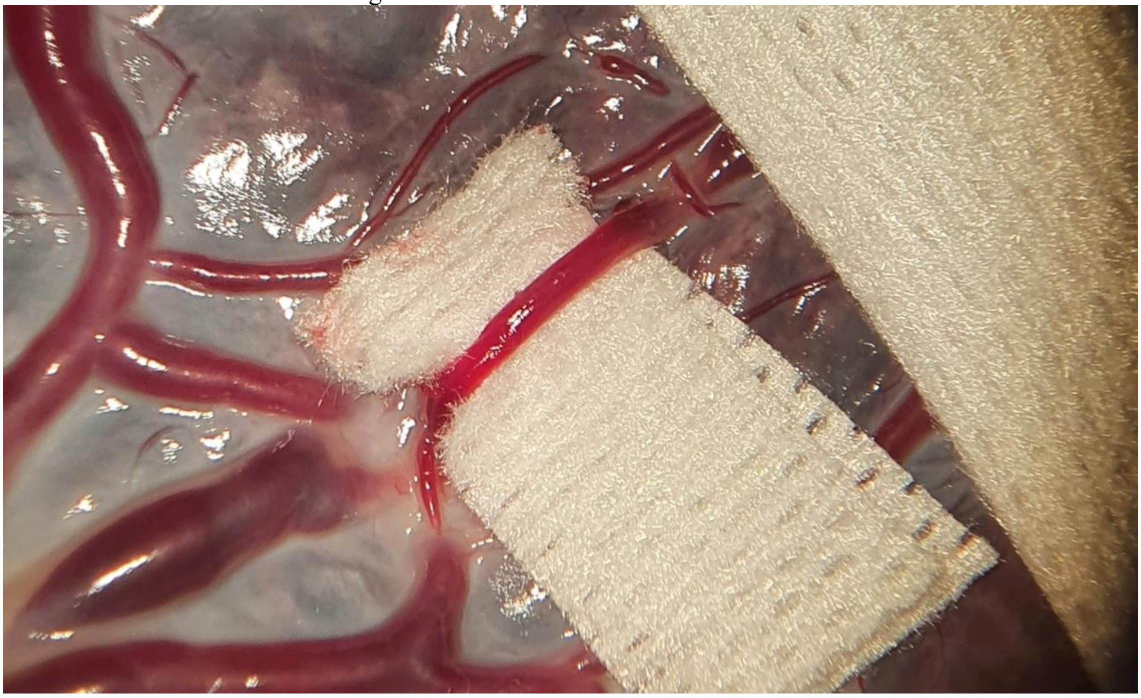
Mistakes limit 1Major + 3minor

Stop clock: when vessel dissection is achieved

Description:

1. Select a grade III vessel (artery). Measure 15mm of it.
2. Perform a complete 360 degree around-vessel dissection.
3. Rubber sheet should be able to pass below the vessel (Figure 5).

Figure 5: Grade II Vessel - 360 dissection.



Source: own elaboration.

2.2.5 Task N5

Difficulty level: high-level / Visual magnification: HLM

Main goals: vessel complete dissection and suture

Mistakes limit: 1Major + 2minor (6pts) / or / 4 minor (4pts)

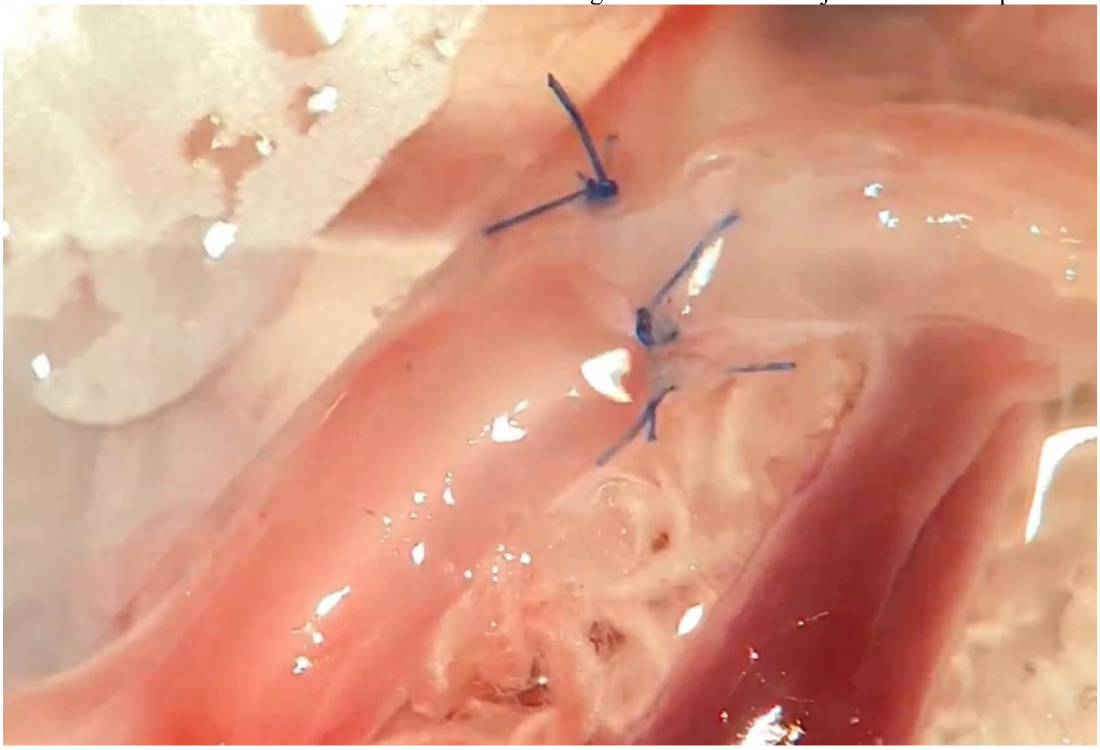
Stop clock: when an all-around suture is complete (7 stitches, Figure 6). Vessel verification proof should be performed after clock stops.

Description:

1. Select a grade II vessel (vein). Measure 15mm of it and fully 360 dissect it.
2. Rubber sheet should be able to pass below the vein.
3. Select a grade II vessel (artery1). Measure 15mm of it.
4. Perform a complete 360 degree around-vessel dissection.
5. Rubber sheet should be able to pass below artery1.
6. Select a new grade II vessel (artery2). This new vessel should be near enough to engage a termino-terminal contact between artery1 and artery2. Measure 15mm of it.
7. Perform a complete 360 degree around-vessel dissection.
8. Rubber sheet should be able to pass below artery2.
9. Prepare both vessels for suture. This should include removing all soft tissue around the vessel which could cause a flap effect in the suture line. Also, both free extremities should be non-tense and reach easily the other extremity.

10. Sharp-cut both vessels, preferably with a one-movement scissors cut. Irrigation and even clipping could be necessary to create a good working condition for further steps.
11. Identifying vessel walls thickness by using blue biological ink, could be necessary.
12. Suture starts. Planning the sequence properly is mandatory. Technique includes separated stitches all around the vessel. For this diameter, 7 stitches will be necessary. Suture should always be 10/0.
13. After suture, one of the vessels is selected, and verification proof is done (proximal canalization of one of the vessels and direct visualization of the suture line at the maximum magnification level, while injecting saline solution).

Figure 6: Grade II Vessel termino-terminal 10/0 suture being tested with saline injection from the proximal end.



Source: own elaboration.

NOTE: specially in this last task, care must be taken to not move the placenta. All changes in sight, angle and illumination required to accomplish the task, must be solved by microscope handling.

A special registration form was proposed for this task (Table 3):

Table 3 – Data records model			
Task 5 - Time and mistakes records			
Date		Placenta number:	
Step name	**Time elapsed**	**Mistakes**	
Vein dissection			
Artery1 dissection			

Artery2 dissection		
Suture		

Source: own elaboration

After the full programme was completed, data from this table was collected in a digital online spreadsheet, as planned.

3 RESULTS

Full raw data registers were collected and can be seen in Table 4.

Table 4 – Raw data records																						
	Placenta 1		Placenta 2		Placenta 3		Placenta 4		Placenta 5		Placenta 6		Placenta 7		Placenta 8		Placenta 9		Placenta 10		Placenta 11	
	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk	time	ms tk
Vein dissection	0:43:29	1	0:33:29	0	0:27:37	0	0:10:27	1 M	00:32:01	0	00:23:40	1	00:23:26	1	00:23:28	0	00:14:00	0	00:15:30	1	00:15:37	0
Artery 1 dissection	0:19:19	1	0:24:15	0	0:16:18	0	0:10:31	0	0:13:30	0	0:12:35	0	0:13:07	1 M	0:10:53	0	0:13:16	0	0:08:05	0	0:09:56	0
Artery 2 dissection	0:16:01	0	0:17:18	0	0:06:26	0	0:10:27	0	0:13:05	0	0:12:19	0	0:10:52	0	0:07:14	0	0:10:55	0	0:06:40	0	0:04:50	0
Suture	0:30:15	2	0:25:25	2	0:38:38	2	0:22:04	2	0:26:12	2	0:33:15	2	0:25:54	1	0:18:23	2	0:23:37	1	0:25:30	2	0:27:14	0
Total	**1:49:04**	**4**	**1:40:27**	**2**	**1:28:59**	**2**	**0:53:29**	**6**	**1:24:48**	**2**	**1:21:49**	**3**	**1:13:19**	**5**	**0:59:58**	**2**	**1:01:48**	**1**	**0:55:45**	**3**	**0:57:37**	**0**

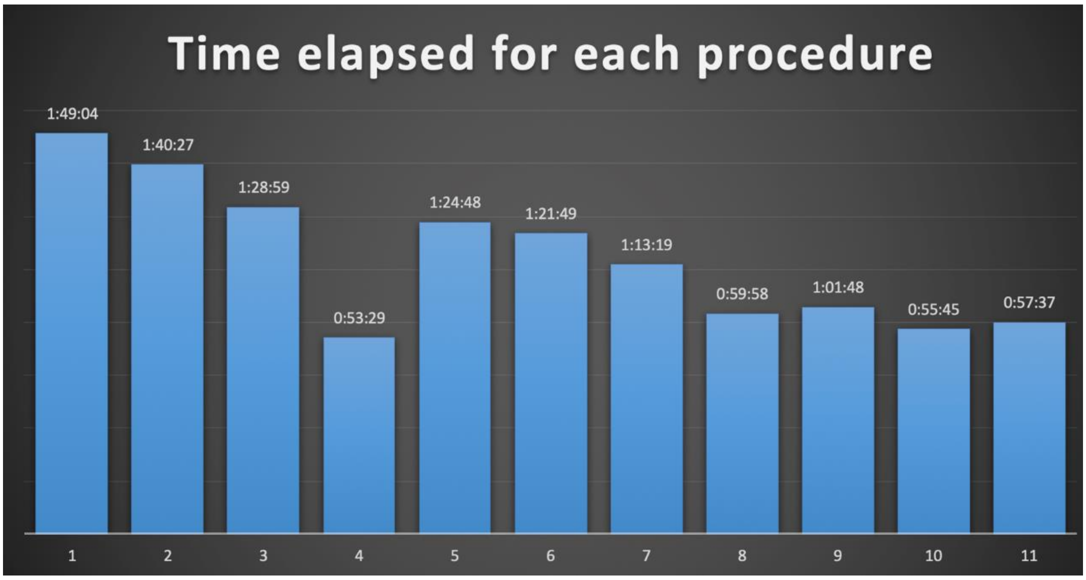
Source: own elaboration

Twelve placentas/procedures were necessary to perform Task 5 without any mistakes. One of those procedures was excluded (between placenta 4 and 5) for meeting exclusion criteria, mentioned at this task description.

Each placenta sample was used for just one procedure. So, different attempts correspond to different placentas.

The total number of samples meeting all inclusion criteria (n=11) were used to represent the evolution about "time elapsed" variable during this trial (Figure 7):

Figure 7: blue bars are marking the total time registered for each task attempt. Total time for each procedure appears at the top of the bar.



Source: own elaboration.

The longest attempt was the first one, accounting 1h49m05sec; by the other hand shorter time was 53m29sec (accounting 3 mistakes, at the 4th attempt of this task).

The time needed to perform this task with no mistakes was 57m37sec (last attempt).

Total time working with task 5 was 13h47min03sec (12 placentas, 1 excluded for mistakes criteria).

The average time for this task was 1h15min11sec.

Among all stages needed to accomplish Task 5, vein dissection appears to be the one accounting more errors.

Vessel suture was the most time demanding step.

With a base in Figure 7, mistakes committed levels were added to show how time and mistake variables interacted (Figure 8). It can be noted at this latter figure that after 3 attempts, time decreased significantly (shortest time appear at placenta number 4), but also mistakes show a big peak at this same point.

Figure 8: blue bars reveal the total time registered for each task attempt; red line is showing mistakes made in each attempt.

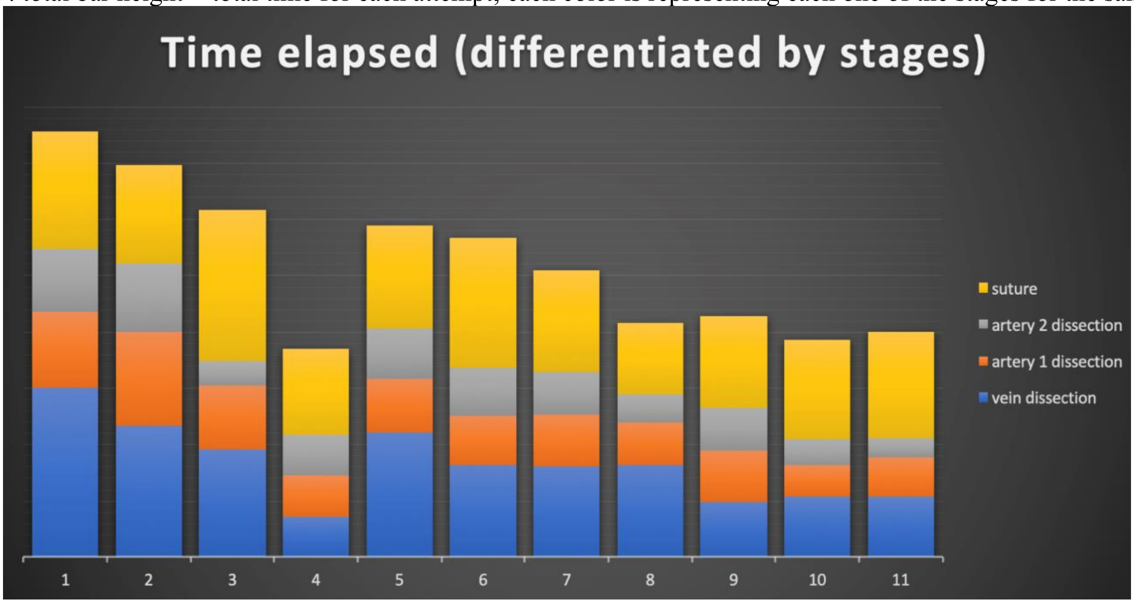
Source: own elaboration.

This mistake peak was followed by one attempt with even more mistakes, then being discarded for meeting exclusion criteria (between placenta numbers 4 and 5).

Technique was revised and extra care taken to solve this issue in further attempts. After this technique revision, time rose again, but mistakes reach significant lower level.

Evaluating each step of this same Task 5, similar proportions can be seen for each attempt (Figure 9).

Figure 9: total bar height = total time for each attempt; each color is representing each one of the stages for the same task.

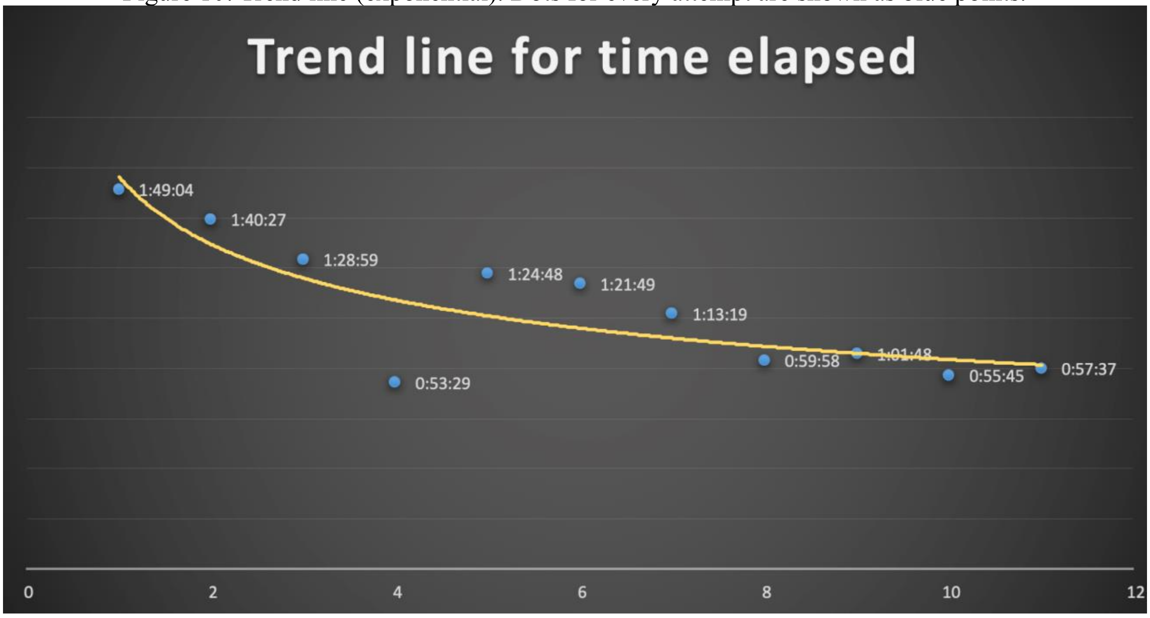


Source: own elaboration.

Vein dissection (blue) and suture stages (yellow) take the most of the time. Artery dissection shows similar levels for artery1 (orange) vs artery2 (grey), but the later was always shorter in time.

Interesting differences were found among attempts, even after a plateau level (after placenta 7) was reached. To better appreciate those events, a trend line was built (Figure 10).

Figure 10: Trend line (exponential). Dots for every attempt are shown as blue points.



Source: own elaboration.

The line itself is showing a "learning-curve" [17,18,23] pattern, with a final plateau level after exponential changes in the beginning.

Dots above or below the line represents differences from expected situations (trend line). These changes are meaning significant facts, as well. They will be explained in the following paragraphs.

3.1 STATISTICAL ANALYSIS

Taking all steps of the task together, there is no direct relationship between the time needed and mistakes committed.

This could be probably caused for differences between stages, all of them related to skills and experience (a larger sample could clarify this effect). It is not possible to exclude other type of external causes.

To enlighten this situation, different stages of the task are grouped-on and analysed separately, because **Variance** (VAR) and **Standard Deviation** (SD) shown a clear difference among "dissecting" vs "suturing" steps.

The vascular suture was the most time-demanding and unsettled (this fact could be showing suture step as the most difficult step in this task (or less expertise level from the operator), and also needing more time to be trained. Even so, VAR decreased notably in the lasts samples (Initial SD 327,61 to final SD 73,54).

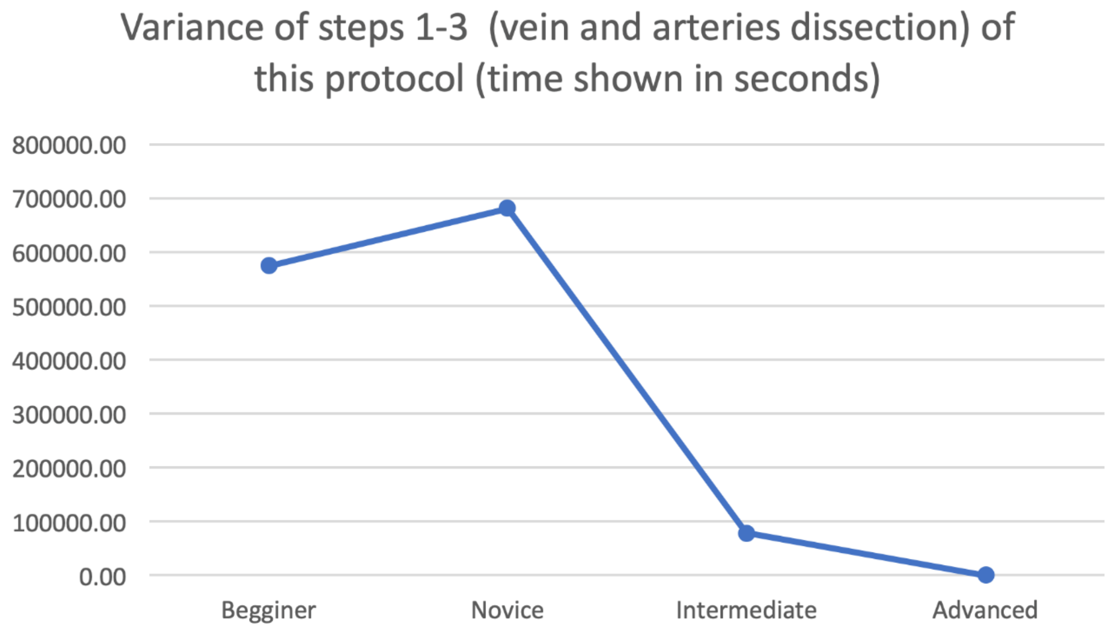
This same VAR and SD decrease is also present and more evident for dissection stages (stage 1 to 3, vein and arteries dissection). The SD value was initially 757,35, with a final value of 5,66. The **Coefficient of Determination** (CD) for these dissection steps reached a value of 0,92 (interpreted as a good model to predict the changes).

The decreasing values of VAR and SD show the effect of training and, thus, support the learning curve's final expected results.

To better show these statistical differences, samples will be also grouped by the level of expertise or experience in this protocol.

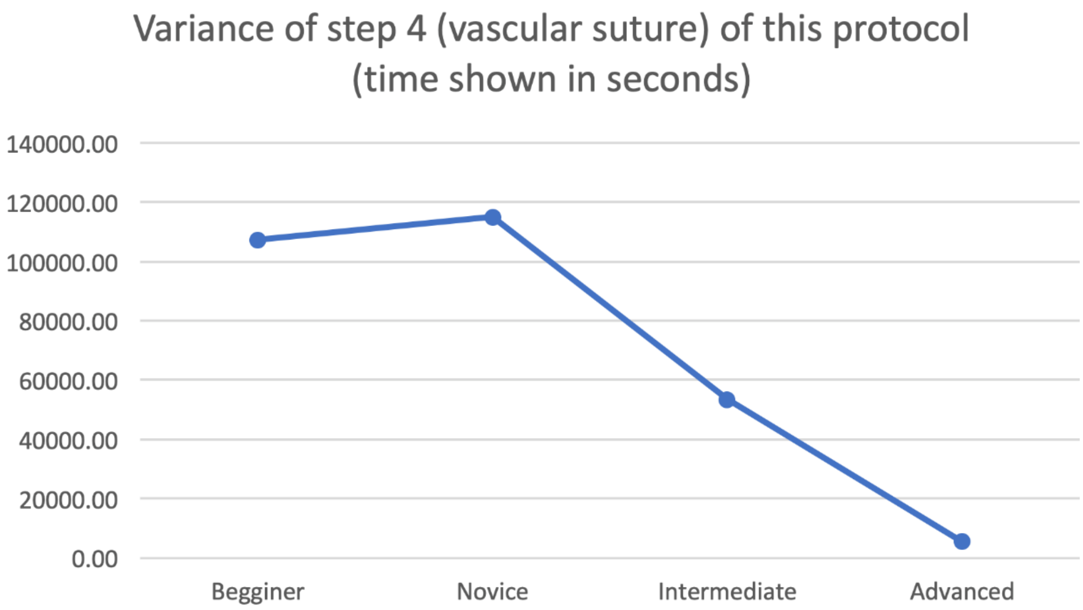
The samples 1 to 3 will be named "Beginner." Samples 4 to 6, "Novice". Sample 6 to 9 as "Intermediate" and, finally, Sample 10 and 11 will be named as "Advanced" (Figures 11, 12, and 13).

Figure 11: Variance in time to perform step 1 to 3, for grouped categories: Beginner (samples 1 to 3); Novice (samples 4 to 6); Intermediate (7 to 9); Advanced (10 and 11). Time is shown in seconds.



Source: own elaboration.

Figure 12: Variance in time to perform step 4, for grouped categories: Beginner (samples 1 to 3); Novice (samples 4 to 6); Intermediate (7 to 9); Advanced (10 and 11). Time is shown in seconds.

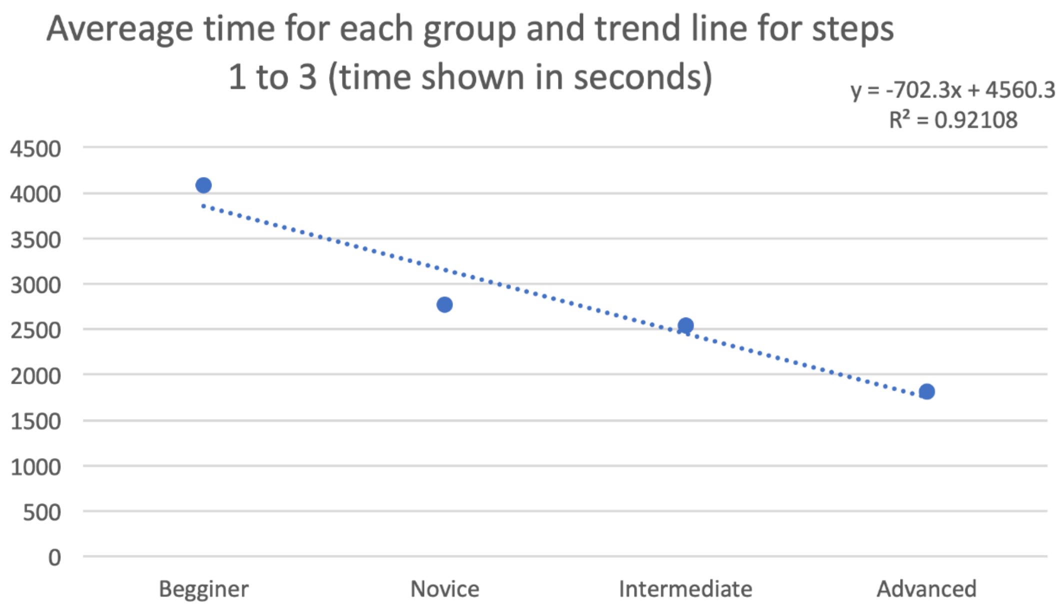


Source: own elaboration.

In these figures (Figure 11 for steps 1 to 3, and Figure 12 for step 4) is interesting to see how the "Novice" took more average time than "Beginner", but it could be corresponding the upper quality level reached after the strategy revision (less mistakes). This situation, rather than negative, could be interpreted as a good sensitivity to "strategical changes" during the performance.

In Figure 13, the trend line for step 1 to 3 is built. Dots for each average time are shown, with small dispersion (SD 5,66; CD 0,92).

Figure 13: Average time for grouped categories. Beginner (samples 1 to 3); Novice (samples 4 to 6); Intermediate (7 to 9); Advanced (10 and 11). Time is shown in seconds. Trend line is also shown as a dotted line. ($R^2 = 0.92$).



Source: own elaboration.

4 DISCUSSION

Surgical procedures and surgical training have always been a challenging topic in medical science. The operation room is cross-roads for multiple variables like patient anatomy, different approaches, surgical plan, techniques options, available medical evidence, tools/instruments availability, disease particularities and many other parameters should be taken in count to properly decide at every step of a surgery.

The surgeon skills and learning process (represented by learning curves) [23,17,18,2] are also crucial features to analyse and evaluate. Awarded of this situation, many health-care centres have become highly specialized in certain areas to gain experience and particularly train professionals in a particular field.

Start evaluating and protocolling surgical procedures in an accurate manner (with specific variables, step by step definition, objective results and even certification capabilities) could lead to improve the way that surgical information and experience is managed.

By using Kaizen methodology, the main goal and the most important variables to focus in, were logically found. Even the topic "hand skill training" was also selected among others, using this methodology. A more detailed view for these initial steps are available at the SAMECO and INTI databases [33].

The specific and thoroughly designed protocol (to train surgical dexterities when performing a microscopic procedure) was directly related to benefits about data acquisition, analysis, sharing and using. Also, statistical ascertainment shows the efficiency and adaptability of the proposed method.

While building the procedure, the method itself was demanding new tools (like a "mistake score") and to clarify concepts previously used but with poor definition (like "magnification level"). It was remarkable useful working under a controlled system and how it helped to maintain objectiveness and precision.

The method also noted flexibility to be changed, allowing the inclusion of those mentioned new tools/concepts. This adaptability is a strong point about why to use Kaizen method: it is prepared to evolve on the go, to serve as a continuous improvement base.

It is also clear that without using a method with all of these possibilities, data analysis becomes un-specific and/or difficult to manage. Controlled scenarios and defined variables also allows to include a process (a surgical procedure, a defined manoeuvre or a part of them) in a diminished-bias environment, and also set them ready to continue an improvement pathway.

It is also important to understand the mathematics within this process and to give the proper importance to each measure. If this math work is done in a right way and data is built confident and reliable, using different methods (statistics formulas, cross-linked databases, artificial intelligence modules) can also bring the possibility of making prognosis and projections when evaluating skills, or to choose between options when performing a surgery.

The Kaizen method is already being used at many in-hospital instances [6,7,21] but no records of Kaizen method usage for surgical procedures could be found by the authors at this time.

5 CONCLUSIONS

Being the biological sample, instruments, surgeon and visual aid system the same for all the samples; the decrease in **time** and **mistake level** could be interpreted as an improvement in **hand-skill level** (dexterity) acquired at a particular scenario.

This initial data interpretation, reveals the effect of training (intending "training" as repeated attempts of a particular task, at a controlled scenario) over the selected variables. Evidence was found as significant time decreasing and controlled mistake level, after less than 14h of training, for this proposed task.

Structured variables identification and precise data acquisition gives us the possibility to evaluate a process and each one of its stages (Figure 9).

At Figure 10, a trend line was built, narrowly corresponding to a "learning curve" effect. The latter has been previously studied in the surgical field with good correlations for one-person progression [2,23].

Interesting differences about the time/mistakes interpretation were also noticed at a couple of dots (placenta 4 and 5) of this figure: the dots were distanced from the trend line.

The former could be due to a "loss in quality," represented by the shortest time but a greater number of mistakes. The latter could be due to a "change of strategy," represented by a longer time but minimal mistake level. These kinds of observations are useful to evidence de sensitivity of the method to technical changes.

Even being under a subjective subtract, this could be of great value when evaluating modifications and suspecting/discovering unknown variables.

Re-grouping data was useful to define 4 stages for the trainee's **expertise**: *beginner, novice, advance* and *expert*. This stratification depends on the number of procedures performed under a same protocol and scenario. The time elapsed and mistake level for each expertise level denoted a good correlation and utility as an evaluation method (Figure 11 and 12).

This same data segmentation also allowed to differentiate two situations:

a) The three initial steps (dissecting vessels) showed a different evolution. The reasons for this result could be because: the operator selected different level of magnification; dissections steps were less difficult than the suture stage; unclear reasons (placenta differences, different strategies used).

b) The last step (suturing the vessels) was the most time demanding and also a big mistake generator. It could be due because of the high difficulty level or some other causes (incorrect technique, inadequate proof testing, etc.). It is also possible that extending the number of procedures performed, better results were achieved.

For all of the above mentioned, it was possible to confirm that the main goal was achieved: the present protocol was useful (and generated evidence) about dexterity evolution (hand-skill improvement) for the 3 initial stages (dissecting vessels stages).

Similar situation occurred with the last stage (suturing vessels), but further investigation is needed in order to obtain the same strong evidence.

During this experience, expected secondary goals were also reached (further testing should be taken to confirm them):

- Visual aid system handling was improved.
- Task and magnification levels were synchronized more accurately.
- Microsurgical instruments were tested and selected with more confidence.
- Microsurgical dexterity (dissecting stages) learning curve can be built and then used to make modifications to the learning experience of the trainee.
- Microsurgical dexterity (suturing stages) was able to be identified as a different situation and more investigation is needed to better understand the findings.
- Kaizen method allowed to design and evaluate a surgical procedure.
- Kaizen method showed flexibility to add modifications and maintain confidence.
- Kaizen method showed sensitivity to detect on-the-go variations.
- Kaizen method showed ability to detect unknown variables and new improvement situations.
- Kaizen method could be allowing new applications (re-designing tasks, adding variables to refine precision, compare different techniques or devices, test new instruments, etc.).
- Teaching goals (prognosis, projections and certifications) are reachable with similar methods.

Data acquisition and managing were one of the most valuables findings during this trial. This feature can make the information to be available at multiple centres and databases will have the opportunity to be fed by multiple contributors using the same protocol and parameters. Applying new technology (like artificial intelligence or deep learning) to such databases, could lead not only to surgical but to research improvements too.

This method achieved good results even with minimal requirements and an easy-to-access biological simulator. It is especially important in places where a training centre is difficult to access (high costs, lack of cadaveric samples, lack of bio-laboratories, absence of facilities, low income environments, etc.).

While performing tasks, new tools can be applied to gain in specificity and control over variables (Operative Instructions, using key-steps and key-reasons tools). This stage could be of great value while selecting strategies during a surgical procedure, mixing teachers advices and evidence available at this respect.

CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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