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ARTICLE

Authors Info :
* Pathological Anatomy, University Polyclinic Foundation Campus Bio-Medico of Rome
*° UniCamillus Saint Camillus International University of Health and Medical Sciences
**^ Diapath S.p.A.

Author's correspondence
Roberto Virgili
r.virgili@policlinicocampus.it

§ The Authors contributed to the paper equally.

Valentina Bartolucci *§, *Arianna Costantini* *§, *Martina D'Angelo* *§, *Maria Chiara Giangarè* **^, *Fabrizio De Angelis* **^, *Clara Pecorella* **^, *Carmelo Lupo* **^, *Roberto Virgili* *°

USE OF A NEW DEVICE TO IMPROVE THE PERFORMANCE OF THE TECHNICAL PREPARATION OF HISTOLOGICAL SECTIONS.

EFFECTIVENESS MEASUREMENT THROUGH THE LEAN SIX-SIGMA METHODOLOGY (OVERALL EQUIPMENT EFFECTIVENESS - OEE)

SUMMARY

INTRODUCTION:

By applying the Lean Six Sigma methodology to the processes of technical preparation of paraffin sections in the Pathological Anatomy laboratory, we used its tools to measure the possible benefits linked to the introduction of new technologies aimed at improving process performance.

OBJECTIVES:

The aim of the study is to make use of the Lean methodology tools to prove how it is possible to 'measure' the impact and the possible benefits of a new technology introduced in the Pathological Anatomy laboratory.

METHODS:

By applying the tools of the 'Lean thinking' methodology, we have used a new technology and measured its effectiveness in order to achieve an improvement in performance, therefore reducing the time frames of technical preparation.

RESULTS:

The application of the Lean methodology and its tools to measure the effectiveness of a new technological solution applied to the technical preparation process of histological specimens has made it possible to ascertain a reduction in the preparation time of 5.7 minutes every 30 slides cut.

DISCUSSIONS:

The changes made to the process by using this new technological device made it possible to increase production in the same time unit, reducing set up and changeover time frames, with a 5.39% increase in the performance percentage.

CONCLUSIONS:

The option of using the Lean methodology tools to measure the effectiveness of technological innovations for the technical preparation stage of histological sections made available by the industrial world in Pathological Anatomy processes, has a positive impact on laboratory performance in terms of efficiency, with increased productivity, as well as in terms of lower clinical risk, with a lower risk of tissue loss due to operations for orientation of the embedded sections closer to the cutting plane.

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INTRODUCTION

In the previously published article (see "Lean techniques and their application in Pathological Anatomy-Parallels between industry and healthcare- Impact on processes – IJPDTM vol.5 no.1 2022) we applied the Lean methodology to the process of technical preparation of histological specimens in the most time consuming step, i.e. embedding and cutting. The results of the application of the lean methodology led to increased process efficiency (PCE process cycle efficiency from 18.18 to 35.17) with a decrease in daily WIP (*work in process*). In addition to these results, the analysed data made it possible to establish objective workloads, for both embedding and cutting, with mean production values.

The measurements of the cutting activity led to an average value of 30 embeddings/ hour per technician with an assumed production of 180 embeddings in the 6 hours of their work shift.
A subsequent check identified a discrepancy between the measured values and actual production, with a decrease from 180 embeddings/6 hours to 150/6 hours, which was the subject of subsequent analysis.

The Toyota Production System (TPS) uses a number of tools to continuously improve the processes and manage any abnormalities. In this work, we used the OEE tool.

We therefore analysed the process applying the OEE lean tool (*Overall Equipment Effectiveness*) to ascertain whether the cause of lower production compared to the expected levels was due to unavailability of the instrumentation, its efficiency and product quality. We identified a loss of performance between the step "embedding grossing" and the subsequent one "embedding alignment and cutting ".

OEE (*Overall Equipment Effectiveness*) is a lean tool to analyse and improve production processes assessing losses due to their availability,to performance and to *quality*.

Down time losses due to availability in a process include all events that stop the scheduled production, such as instrumentation faults, lack of materials and set-up and changeover time.

Losses due to performance (*speed losses*) include those factors that affect the speed of a process and reduce it compared to its maximum potential.

Quality losses mean that production does not comply with the expected quality standards and therefore requires reprocessing, reducing the actual net production.
We may therefore identify the main loss categories by type as shown in **fig. 1**
The relationship between the percentages of availability, of performance and of product quality is the actual productivity index of the process.
In this paper we have limited ourselves to the analysis of the measured timing with regard to the production steps only (embedding and cutting), omitting any measured loss of performance/availability due to other factors such as breaks, lack of materials, temporary equipment failure, etc. as they have little impact on the analysis.

We therefore measured this value, with and without using Galileo Pro, and obtained the relevant OEE (*Overall Equipment Effectiveness*) and the delta of production.

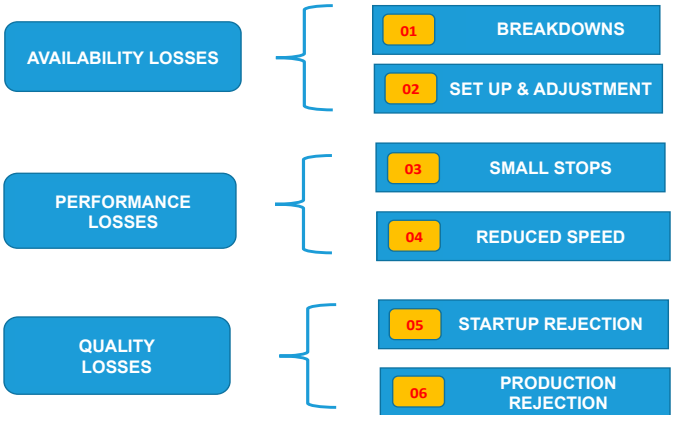

FIGURE 1

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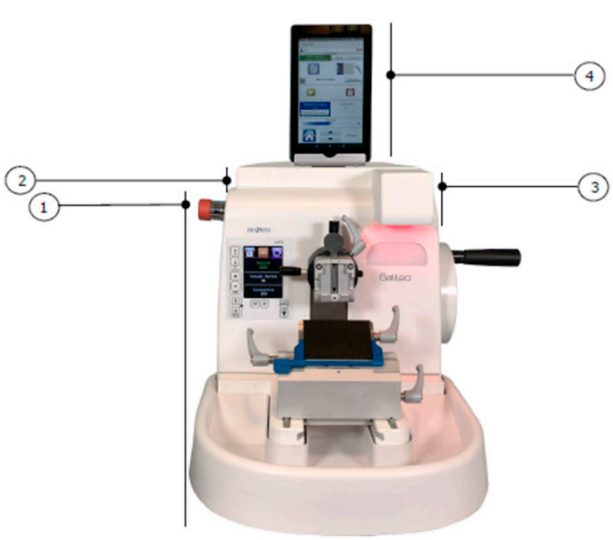
Having identified that the main process losses are due to set-up and adjustments, in this step of the process (grossing and cutting) we used a new device that enables position recognition of the grossed embedded sections and avoids the need for the operator to progressively move the embedded section close to the blade, to test its advantages in terms of time savings and quality.

Let us describe the **Diapath Galileo series 2 PRO** system that we assessed.
The PRO system applied to the Galileo Microtome Series 2, is an innovative system that supports and streamlines the specimen cutting steps: it makes it possible to store and save the grossing position of all histological samples and recall this position whenever necessary, at the time of cutting, therefore without requiring manual alignment. The system recognises any type of barcode used.

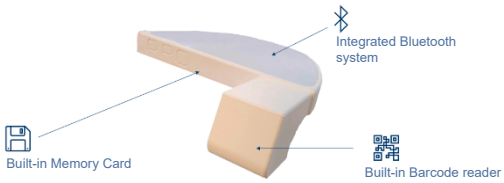
Thanks to the built-in, continuous mode **barcode reader**, the Pro System stores the block position at the end of grossing, before being placed on the cold plate for cooling, thereby pairing the last position of the specimen with respect to the blade holder, with the scanned embedded section ID.
At the time of cutting, the previously grossed embedded section is scanned again by the built-in barcode reader. In this way, the PRO System automatically positions the specimen clamp of the microtome in the last position stored for that specimen with respect to the blade holder, and it will be possible to perform the cut quickly, with the highest precision and with no need to modify the cutting settings or correct the specimen position, therefore also with complete safety for the operator.

Furthermore, to make the best use of the ever narrowing spaces of cutting stations, the workstation has been redesigned to make it more functional and compact. The Microtome is equipped with a **tablet** connected wirelessly to the Pro System, which make sit possible to have complete control over the basic functions of the microtome, replacing the Remote Control device conventionally used, as well as over the PRO System, in addition to storing the data related to operator, sample, date and time of use.



1. Galileo AUTO Series 2 automatic rotary microtome
2. PRO System with Bluetooth and built-in internal Storage
3. Built-in barcode reader Tablet with PRO App
4. Tablet with integrated PRO App

galileo series 2 microtome with pro system



The PRO System - detail

OBJECTIVES

In the routine of a Pathological Anatomy laboratory for the step of grossing and cutting embedded specimens, instruments are used (microtomes) which, regardless of aesthetic and functional upgrades, are essentially built on a well-established technology, and which as such cannot be defined as 'innovative' as it does not significantly affect process efficiency.

The purpose of this paper is to assess, by measuring the results with the lean methodology, the advantages derived from the use of a new accessory for a type of rotary microtome (Galileo Pro) in order to assess its impact on the cutting process performance, from the point of view of the quantity of embedded specimens cut in the unit of measure, as well as in terms of solving the clinical risk of loss of material due to the setting required after grossing the embedded specimen or in the event of needing to perform a second cut.

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METHODS

We carried out comparative tests with three different technicians on 1576 embedded specimens: 1006 embedded surgical samples and 570 embedded biopsy samples. The embedded samples were grossed and cut by each technician with the standard method and using the "Pro" system. The data are set out in the following tables (**tab. 1 and tab. 2**):

TABLE 1
MICROTOME WITHOUT PRO

BLOCK TYPE	NUMBER OF BLOCKS	GROSSING TIME	CUTTING TIME	MIN GROSSING/EMB	MIN CUTTING/EMB
Biopsies	60	28	42	0.47	0.70
Biopsies	60	27	41	0.45	0.68
Operators	60	30	39	0.50	0.65
Operators	60	29	40	0.48	0.67
Operators - Cuti	30	12	30	0.40	1.00
Miscellaneous	30	8	25	0.27	0.83
Miscellaneous	30	10	24	0.33	0.80
Operators - Cuti	30	11	30	0.37	1.00
Operators	34	20	35	0.59	1.03
Operators	30	18	30	0.60	1.00
Operators	40	25	39	0.63	0.98
Operators	30	20	25	0.67	0.83
Biopsies	30	15	25	0.50	0.83
Operators	30	18	30	0.60	1.00
Biopsies	30	16	23	0.53	0.77
Operators	30	17	27	0.57	0.90
Biopsies	30	18	26	0.60	0.87
Operators	30	16	25	0.53	0.83
Biopsies	30	15	25	0.50	0.83
Operators	30	18	30	0.60	1.00
Biopsies	30	16	24	0.53	0.80
Tot biopsies	**240**		**average bio.**	**0.51**	**0.78**
Tot operators	**460**		**average oper.**	**0.54**	**0.89**
Tot mix	**60**		**average mix**	**0.51**	**0.86**
TOTAL	**760**		**average tot**	**0.51**	**0.86**
				30.6 seconds	**51.6 seconds**

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TABLE 2
MICROTOME WITH PRO

BLOCK TYPE	NUMBER OF BLOCKS	GROSSING TIME	CUTTING TIME	MIN GROSSING/EMB	MIN CUTTING/EMB
Biopsies	60	28	24	0.47	0.40
Biopsies	60	28	37	0.47	0.62
Biopsies	60	27	35	0.45	0.58
Operators	60	28	24	0.47	0.40
Operators	60	30	36	0.50	0.60
Operators	60	40	37	0.67	0.62
Operators - Cuti	30	12	20	0.40	0.67
Miscellaneous	30	12	23	0.40	0.77
Miscellaneous	30	8	21	0.27	0.70
Operators - Cuti	30	12	20	0.40	0.67
Operators	30	20	18	0.67	0.60
Operators	32	19	22	0.59	0.69
Operators	31	18	20	0.58	0.65
Operators	33	21	22	0.64	0.67
Biopsies	30	16	22	0.53	0.73
Operators	30	17	28	0.57	0.93
Biopsies	30	15	20	0.50	0.67
Operators	30	18	25	0.60	0.83
Biopsies	30	15	22	0.50	0.73
Operators	30	17	21	0.57	0.70
Biopsies	30	18	20	0.60	0.67
Operators	30	16	25	0.53	0.83
Biopsies	30	15	21	0.50	0.70
Tot biopsies	**270**		**average bio.**	**0.50**	**0.64**
Tot operators	**486**		**average oper.**	**0.55**	**0.68**
Tot mix	**60**		**average mix**	**0.33**	**0.73**
TOTAL	**816**		**average tot.**	**0.52**	**0.67**
				31.2 seconds	**40.2 seconds**

ANALYSIS OF DATA AND RESULTS

The results obtained and summarised in the following tables are representative of the advantages in terms of total time savings and by type of sample (biopsies, operators). While there is no gain margin in the grossing stage, although there is no loss of performance either, considerable time savings are observed in the cutting stage.

The result is an advantage in productivity equal to cutting 1 rack more per technician every 6 racks of cut slides in the same time unit. Therefore, in the same time interval taken for cutting, production will go from 5 to 6 racks of slides.

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Δ total grossing= 0.6 seconds per embedded specimen

Δ total cut = 11.4 seconds at each embedded specimen

40.2 seconds cutting per embedded specimen* 30 slides = 20.1 minutes cutting for one rack with PRO
51.6 seconds cutting per embedded specimen* 30 slides = 25.8 minutes cutting for one rack without PRO

11.4 * 30 = 5.7 minutes saved per rack (30 slides)

Δ biopsy grossing= 0.6 seconds per embedded specimen

Δ biopsy cutting= 8.4 seconds per embedded specimen

38.4 seconds cutting per embedded specimen* 30 slides = 19.2 minutes cutting for one rack with PRO
46.8 seconds cutting per embedded specimen* 30 slides = 23.4 minutes cutting for one rack without PRO

8.4 * 30 = 4.2 minutes saved per rack (30 slides)

Δ operator grossing= 0.6 sec per embedded specimen

Δ operator cutting= 12.6 seconds per embedded specimen

40.8 seconds cutting per embedded specimen* 30 slides = 20.4 minutes cutting per rack with PRO
53.4 seconds cutting per embedded specimen* 30 slides = 26.7 minutes cutting per rack without PRO

12.6 * 30 = 6.3 minutes saved per rack (30 slides)

We then calculated the OEE (Overall Equipment Effectiveness) both when using the Galileo Pro system and without using it.
The 'big losses' that most affect the results are above all the losses due to setup and adjustment which also affect the overall performance. The measured data are summarised in the following tables (**tab. 3 and 4**).

TABLE 3

OEE FACTOR WITHOUT PRO	WORLD CLASS
Availability	68.50%
Performance	53%
Quality	99%
OEE	35.94%

TABLE 4

OEE FACTOR WITH PRO	WORLD CLASS
Availability	59.50%
Performance	70%
Quality	99%
OEE	41.23%

The overall OEE delta is therefore 5.39% better thanks to the use of Galileo Pro.

DISCUSSIONS

As evidenced by the data and their analysis, using a system that recognises the grossing position at the time of cutting the embedded specimens affords considerable time savings. The advantage in terms of clinical risk is also far from negligible, that is, less waste of the embedded specimen in activities for finding the cutting plane.
The fact of using a methodology ('OEE' tool by Lean Six Sigma) to measure the advantages achieved in terms of efficiency and effectiveness makes the results objective and repeatable.
Using a well-established methodology focused on continuous improvement and the elimination of waste also makes it possible to validate a new technology in analytical terms and be able to prove real advantages before it is introduced into the routine.
In the use of the Galileo Pro system we have also been able to find opportunities for improvement that would increase the effectiveness of the device, and specifically:

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1. Possibility to interface several microtomes in order to share data concerning the cutting position detected in a cutting station and achieve realignment of the others.
2. Possibility to interface the 'Pro' system with the laboratory's operating system for specimen traceability.
3. Possibility to simultaneously print out the slide with barcode reader with position recognition.

CONCLUSIONS

In this study we have been able to ascertain the option of using the Lean methodology tools to measure the effectiveness of technological tools made available by the industrial world in Pathological Anatomy processes, and measure the positive impact on laboratory performance in terms of efficiency, with increased productivity, as well as in terms of lower clinical risk, with a lower risk of tissue loss due to operations for orientation of the embedded sections closer to the cutting plane.

Before making changes to a laboratory routine, it is important to be able to measure and validate the results that may be achieved, especially when they follow the introduction of a new technology.

Through its tools, the lean methodology allows us to carry out these validations ex ante in order to decide whether to implement the processes with new technologies and/or changes thereto.

It also allows professionals to carry out the necessary assessment and ascertain the benefits, adapting to the change made to the processes.

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