THE 5TH INTERNATIONAL WORKSHOP ON INNOVATIVE SIMULATION FOR HEALTH CARE

SEPTEMBER, 26-28 2016
CYPRUS

EDITED BY

AGOSTINO BRUZZONE
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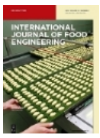

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WELCOME TO IWISH 2016!

On behalf of the Organization Committee of the International Workshop on Innovative Simulation for Healthcare (I-WISH 2016) we are pleased to welcome all the delegates.

The scope of IWISH is very broad; indeed, a holistic view of healthcare necessarily leads to an interdisciplinary research approach ranging from life-science to management disciplines. Furthermore, this interdisciplinary nature of IWISH is also supported by the continuous growth of computational power that foster a very tight integration between natural and computational sciences also opening the doors to new paradigms in life science research. Furthermore, in terms of methodologies, the huge complexity of biological systems let deterministic and deductive methods reach their limitations, thus simulations together with advanced methods of modelling are new tools to get insight into the huge diversity of healthcare.

The IWISH workshop, part of the I3M Multi-conference, aims to bring together scientists from engineering, natural and life sciences to stimulate discussion on new methods and topics in the emerging field of healthcare. The papers included in the IWISH 2016 proceedings range from new design procedures for healthcare prostheses to re-habilitation monitoring and bio-signals identification, from health care facilities management to operators' training. The scientific quality of the articles has been assured by the work done by the International Program Committee members and reviewers (each paper has received a double blind review). Nevertheless, we are also proud to say that most of the articles came directly in the form of full draft papers and therefore it was easy to recognize the valuable work already done by the authors.

IWISH 2016 is held in Larnaca, where you are all welcome to enjoy this fantastic venue and have a great, fruitful and interesting conference.

Marco Frascio
University of Genoa
Italy

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The IWISH 2016 International Program Committee (IPC) has selected the papers for the Conference among many submissions; therefore, based on this effort, a very successful event is expected. The IWISH 2016 IPC would like to thank all the authors as well as the reviewers for their invaluable work.
A special thank goes to Professor Loucas S. Louca from University of Cyprus as local organizer and to all the organizations, institutions and societies that have supported and technically sponsored the event.

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Index

Construction and Validation of a Low-Cost Laparoscopic Simulator

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ABSTRACT

INTRODUCTION. To present the University of Genoa Advanced Simulation Center (ASC) and the design a trainer (eLap4D) that would achieve the equivalent goals of the fundamentals of laparoscopic surgery trainer at an economical cost. The validation process is going to be shown too. METHODS. The laparoscopic trainer is a physical low-cost laparoscopic training platform that reproduces the tactile feedback (eLaparo4d) integrated with a software for virtual anatomical realistic scenarios (Unity3D V 4.1). A sample of 20 students was selected, divided into 2 homogeneous groups with respect to the level of confidence with the use of video games, consolles, smartphones (this has been possible thanks to the use of a questionnaire, administered before the practical phase of training).
The groups participated in a training program based on 5 basic laparoscopic skills (laparoscopic focusing and navigation, hand – eye – coordination and grasp coordination). So, a second and third study sample was chosen, consisting of 20 post graduate students (intermediate group) and 20 experienced surgeons; for theese groups was provided a training program identical to the previous group as well as their subdivision into 2 group.
The face validity was used for an ergonomic analysis of the simulator, the construct to test the system's ability to differentiate potential expert users (experienced surgeons) from non-experts (student without experience in laparoscopic surgery).

RESULTS. We analyzed the results of the three samples obtained by comparing variables such as:

score
% of fullfillment
panality
time

At the same time, the students' improvements have been monitored, developing a customized learning curve for each user.
To evaluate the structural characteristics of the simulator a specific questionnaire has been used.
The results encouraged us. The simulator is ergonomically satisfactory and its structural features are adapted to the training. The system was able to differentiate the level of experience and also has therefore met the requirements of "construct validity".
CONCLUSION. Valid laparoscopic simulators can be constructed at an economical cost.

Keywords: low cost simulation, face validity, construct validity, training, laerning curve

1. Background

The mission of a simulation center in medical reality is to improve patient safety and clinical outcomes by integrating medical simulation based teaching methodologies into the educational curriculum for all students, residents, attending physicians, nurses and other ancillary health care staff.
The main goal of the Simulation Center is to improve safety within patient care. Current and future health care professionals "practice on plastic" honing their skills, refining advanced techniques and learning valuable social interactive tools for delivering important news to patients. This translational research becomes vital for creating the gold-standard in patient safety and medical teaching. One of the most interesting expericnce is about a completely original laparoscopic trainer.
Nowadays laparoscopic surgery is considered the gold standard to treat a lot of diseases, but not all surgeons have acquired the skills necessary for laparoscopic procedures, for example such as proficiency in ambidextrous maneuvers with new tools, enhanced

hand-eye coordination, depth perception and compensation for the camera angle, the need to repeat the same exercises to improve these laparoscopic skills has made basic laparoscopy amenable to simulator based training. The continually increasing demand of more complex laparoscopic simulators has led to a rise in prices of these tools and has inspired us the creation of a 4d simulator which is a physical low-cost laparoscopic training platform that reproduces the tactile feedback (eLaparo4d) integrated with a software for virtual anatomical realistic scenarios (Unity3D V 4.1). The School of Medicine of Genoa and the Biomedical Engineering and robotic department (DIBRIS) have cooperated to create a low-cost model based on existing and brand new software. The simulator allows the team work: two surgeons can work together like in reality and the system allows the use of real operative instruments, all equipped with tactile feedback. But before using this simulator to assess skills and competencies it needs to be seriously and thoroughly validated: among the five validities Recognized (content, face, construct, concurrent and predictive) we has decided to employ the face validity and the construct validity: the first is usually used informally to define the realism of the simulator or whether the simulator represents what it is supposed to represent and the second because mandatory in distinguishing the experts from inexperienced operators based on a performance score. In this paper we are going to describe the platform validation results using these two types of validities: face and construct validity.

2. Materials and methods

2.1 The Advanced Simulation Centre

The ASC has been introduced in October 2011 from the need to offer students and graduate students of the School of Medical Sciences and Pharmaceutical more adequate professional training to the health needs.
The strongest motivations for the use of simulation for the training of future health professionals are:

need to train to perform safety maneuvers increasingly complex and invasive;
need to reduce the learning time curves of innovative procedures;
increase in the medical-legal litigation and the carrying out of clinical maneuvers on the part of students must take place after an appropriate training that allows to learn from mistakes;
introduction on the market of more sophisticated devices for the simulation that allow to reproduce more and more realistic clinical scenarios.

The ASC has been designed on the model of the Simulation Centre in Montreal at McGill University and is organized into sections:

- Macrosimulation: using mannequins to the whole person or body parts that, depending on the technological complexity of the dummies and the complexity of clinical scenarios to be played, it is divided into high- medium-low fidelity.
- Microsimulation: consists of computer workstations for the solution of interactive clinical cases in order to train students and make clinical decisions correct in the right time.
- Relational simulation: using clinical environments realistically reproduced in which, using the technique of the game of roles and the use of "standard patients" students are trained to report the relationship with patients and working in a team.
- Virtual Reality: consists of devices with different technological complexity, from box trainers in computerized tools that can restore the sense of touch, by which you acquire manual skills such as basic surgical techniques or performing complex laparoscopic procedures.

The ASC is divided into two wings involving an area of about 400 sq.
The curricular courses offered are as follows:

Bachelor of Science in School of Medicine

- First Aid (first year): 270 students divided into 14 groups for 8 hours at group
- Biophysical and Clinical methodology (III year): 280 students divided into 32 groups for 20 hours in group
- Gynecology and Obstetrics (V year): 240 students divided into 8 groups for 8 hours at group
- Radiology (IV year): 240 students divided into 12 groups for 20 hours in group
- Pediatrics (V year): 240 students divided into 8 groups for 8 hours at group
- Emergencies (VI year): 240 students divided into 32 groups for 44 hours in group
- Vocational training medical-surgical (VI year): 240 students divided into 32 groups for 20 hours in the group.

Bachelor of Science in Nursing

- Vocational training (II, III): relational workshops for 80 students of the pole S. Martino divided into 4 groups for a total of eight hours per group.
- Check certification service according to the method OSCE (Objective Structured Clinical Evaluation) for 470 students of all regional poles (8 hours for 20 days)

- Bachelor in Physiotherapy
- Aesthetics of passive mobilization (II and III year): 40 students divided into 4 groups for 4 hours in group

Bachelor of Science in Dental Hygiene

- Relational Laboratory (III year): 40 students divided into 4 groups for 4 hours in group

Bachelor of Science in Dietetics

- Relational Laboratory (III year): 20 students divided into 2 groups for 4 hours in group

Specialization schools

- Anesthesiology and Intensive Care
- Emergency Medicine
- Internal Medicine
- Cardiology
- Nephrology
- Gynecology
- General and Digestive Surgery

We can estimate a commitment to teaching between 50 and 20 hours/year for each school.

The total number of students trained annually at the center has been estimated at around 2800 for a total of about 2500 hours of teaching imparted.
Students, on request, may attend the center individually or in small groups to self-study in the free zones of the programmed teaching.
At the end of each course, every student receives a quality assessment questionnaire perceived.
The ASC also hosts and organizes courses aimed at external users, health professionals for their continuing education or categories of citizens who for various reasons are related to health issues. It is, therefore, offered to BLSD Courses (Basic Life Support and Defibrillation), ATLS (Advanced Trauma Life Support), First Aid, CRM (Crisis Resource Management), etc.
According to the ARS (Regional Health Agency), the Coordination of Rare Diseases and ATM Rare Diseases of IRCCS Gaslini pediatric hospital, at the Centre are held free courses for caregivers, family, or household employees of patients, especially children, suffering from chronic diseases disabling, in order to reduce the Hospitals and ensure a more safe and comfortable home care. These courses have a semi-annual basis and to date have been over 150 Caregivers formats.
For each type of training activity in the simulation it uses the teaching methodology derived from the training of flight personnel, now adopted by decades by the Aeronautical Companies. In particular, each procedure is broken down into a check-list of actions that learners construct with the guidance of the tutors in order to acquire the necessary automatism in critical or emergency conditions.
The evaluation of 'learning takes place using the method OSCE (Objective Structured Clinical Examination), consisting of a "stations" exam where the student must perform the procedures using the check-list he built.

It's already on a successful attendance of the center by the students of Biomedical Engineering courses and Bioengineering of the Polytechnic School. The center offers these students the opportunity to make contact with simulators of the latest generation and to study the materials they are made of is the software that govern them, the video-recording system and audio connection between systems of the center and between the center environments and operating rooms IRCCS San Martino, in the simulation devices for measuring air quality and dispersion of medical gases and fumes of which are equipped the rooms of Macrosimulation to high-fidelity.
Currently, in collaboration with the center, they are being developed some degree thesis in Bioengineering.
The ongoing collaboration with the Polytechnic School has also resulted in the implementation by the DIBRIS a prototype augmented reality for video-laparoscopy with haptic properties, being validated by doctors in specialist training of the surgical field schools.

2.2 The simulator system

The development of a laparoscopic surgery simulator is nowadays one of the most important subjects in the field of MIS. There are many important aspects that need to be considered when designing such a kind of simulator. Surgical simulators are very complex systems, mainly because MIS techniques are characterized by a very high level of visuo-motor coordination and multi- user cooperation within reduced operating spaces. Moreover, the implied technologies are sophisticated and expensive. Laparoscopy simulators are a powerful way to improve the skill gamut for the medical doctors to master such systems at a very low cost. Developing a simulator with this kind of purpose is not easy and has many concerns to take into account. For instance, other than having a well structured visualization environment, aspects such as information communication, feedback capabilities, human factors, operative constraints, ergonomics and training aspects need great attention. Although at the current state not all of them has been fully developed yet, the whole design process of the project, including the choice of hardware and software technologies, has been specifically approached to reach the introduced goals.
The system is based on a nodejs application server that manages the visualization system, the communication with hardware interfaces and the database where users' data are stored. The server technology is indeed a sort of data gateway between the several different elements,

regardless they are hardware or software. Figure 1 shows how communication data are exchanged from the very low part of the system (Hardware Interfaces, bottom) to the user interface (HTML Client,top).

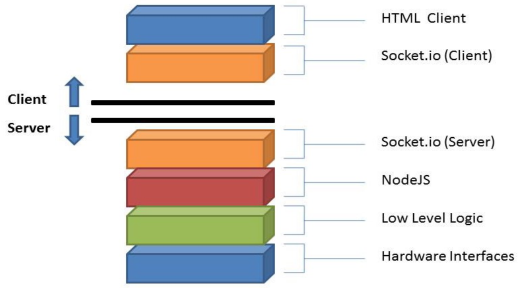

Figure 1. part of the system simulation

The user interface is a simple HTML5 web page running a Unity3D engine 2 plugin. We run several performance tests to compare Unity3D and native WebGL, getting same results. We finally decided to adopt Unity3D engine due to its rapid development time. WebGL is a great technology but still too young to allow us working on a powerful and robust framework. The use of web pages as the main user interface allows us to be more versatile and in the future will give us the possibility, thanks to HTML5 powerful characteristics, to easily share contents in a live way with other systems. An interesting feature is, for example, having the possibility to be guided by an external supervisor, who is monitoring the training phase, while data are quickly exchanged via internet.

A. Visual and Physical Modeling

As previously introduced, visual modeling is a very important aspect of the entire project. A laparoscopic surgery simulator needs a detailed representation of the organs and the tissues inside of the human abdomen. The meshes included in eLaparo4D are developed in Blender 3D Modeling software3, and then imported in Unity3D, including textures and UV maps. Eventually, in Unity3D render shader materials are added to the raw meshes, to simulate the specific surface of each of the modeled tissues. In Figure 2, a screenshot of the current virtual environment is shown.

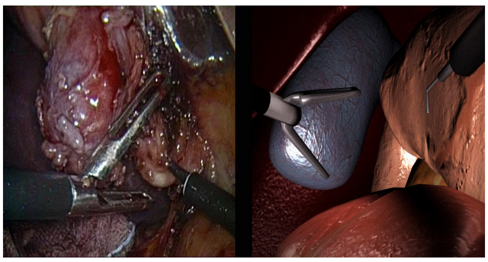

Figure 2: a screenshot from the current aspect of the virtual environment compared to a screenshot of the camera view of a real surgical operation

A great effort has been made to realistically simulate physics avoiding system overloads (excessive computational loads, affecting usability). As remarked by our colleagues of the Laparoscopy Unit of the Department of Clinical Surgery, highly specific training sessions are required to help the operator achieving a proper skill set. In an ideal scenario, medical students should have access to a complete simulator composed of several training scenes, as part of a modular and step-based training process. While the main components and controls of the simulator should be in common, each scene should focus on a very specific surgery operation, differentiating in: the zone and the organs physically manipulated (the target), the particular surgical maneuvers per- formed (the task), and the type of manipuli used (the means). This implies that, according to these 3 components, not all the elements included in a training scene need the same level of realism, especially in terms of physical behavior. In general, the targets of the operation are supposed to have a more accurate physical behavior with respect to an organ in background; but also among the targets the level of accuracy can vary. Even in the same scene the physical simulation of the targets can change over time, according to the manoeuvre the operator is currently performing with the manipuli (e.g. a simple grasping vs. a precise carving). Furthermore, the learning of a complex task - carried out with complex means - should be achieved subdividing the task itself into several simpler steps, preparatory to a complete simulation; so, often, the global complexity of the physical simulation of the same set of organs can vary from scene to scene.

Considering these remarks, we developed a dynamic parametric physical simulation approach, arbitrary applicable to the rendered meshes in every scene and able to avoid system overloads. Such an approach permits the creation of different scenes starting from the same set of models and interaction algorithms, easily supporting a step-based training. In detail, each 3D object in the scene carries a selectable 3 layer collider component, driving a vertex deformation script. The first layer is a simple box collider; the second one is a combination of simple shape colliders which cover, with good approximation, nearly all the volume of the object; the third is a precise mesh collider which exactly coincides with the vertex disposition of the object's mesh. In Figure 3 it is possible to see the 3 different collider layer for a gallbladder model. According to the relevance the 3D object has in the scene (depending on target, task and means of the currently simulated operation), one of the 3 layer is activated, modifying the physics behavior defined in the vertex deformation script. When the box collider layer is active, the script handles collisions, allowing motion but not modifying the aspect of the colliding objects. This configuration is proper for background objects, far from the target. The second, composite, layer supports a more precise collision detection and introduces a script-based rough surface deformation when simple collisions occur (e.g. two organs collide while one is grasped and moved by the operator). This configuration provides a level of

realism suited for the organs that surround the actual target of the operation, or for the targets undergoing simple manipulations (simple tasks like flipping, pushing, lifting, etc.). Finally, the mesh collider layer allows the deformation script to perform a precise local vertex deformation, whenever a collision is detected. Such a detailed behavior supports inward surface deformation caused by pressure, as well as tissue stretching, folding and cutting, typical of manipuli-based surgical manoeuvres. Indeed, this configuration fulfills the strong needs for realism of the targets of the surgical operation, especially when the task is demanding and complex manipuli are the main means.
The use of each layer is characterized by a different computational load: light for the first layer, intermediate for the second one and heavy for the third one. The load, obviously, depends also on the level of detail of the modelled meshes. In addition, the chosen layer can be switched dynamically. This means that the same organ can have a more or less accurate physical response to manipulation, according to the evolution of the system (e.g. the operator’s activity, the currently interacting manipulus), limiting as much as possible the CPU load while preserving realism. Moreover the real-time setting of the layer, coupled with the monitoring of the operator’s performance, offers the intriguing possibility to dynamically adjust the complexity of the task, automatically choosing a level of realism that fits or challenges the operator’s skill.
Using a Unity stereoscopic plugin, we are able to visualize the scenes in stereoscopic 3D. The possibility to train operating with a stereoscopic visual feedback engaged our colleagues of the Laparoscopy Unit of Clinical Surgery Dept., since stereo cameras for real laparoscopy have been accurately assessed in biomedical engineering research, and are quickly spreading in the medical industry.

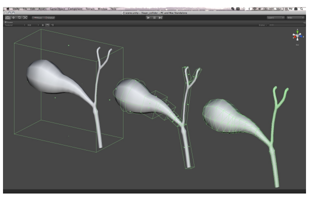

Figure 3. different collider layer for a gallbladder model

2.2.1 Haptic Feedback

Haptic feedback is implemented thanks to the use of three Phantom Omni devices from Sensable. The first two are used as manipuli (grasper, hook or scissors) and the third one is used to move the camera within the virtual abdomen, as it happens in a real scenario. The system generates a resultant force when the user puts a manipulus in contact with a mesh, according to the executed task. Phantom devices have been chosen because reasonably low cost although precise enough for the needed level of realism. Furthermore, their stylus-like shape will permit a complete merging of the devices with the physical environment reconstruction; in particular, each stylus will be easily connected to real manipuli. Thanks to an Arduino board connected to a vibrating motor we have also included a vibration feedback. Vibration is used to enhance the realism of operations like tissue shearing (hook) and cutting (scissors).
The current feedback solution, coupled with the web-based structure of the application, makes available a haptic- based remote guidance, during which a supervisor, even if not physically present in the same room, can haptically guide the hands and the manipuli of the trainee to show him/her the proper way to execute a critical task.
At the moment we are using a very basic force feedback calculation algorithm, based on compliant contact. Although a much more detailed force feedback solution is needed, at the current state eLaparo4D allows a first comparison with real laparoscopy systems and permits the collection of feedback from medical doctors.

2.2.2 The training interface

Training is a key aspect in the eLaparo4D system as already outlined. The user has his/her own profile, is tracked over time and has is/her own history.
Every exercise has its own allowed/not allowed actions letting the user earn or loose points. The scale and points assigned have been decided with the consultancy of several medical doctors, giving us feedback about what are the needs of a well skilled surgeon. The possibilities given by a HTML5 user interface allow us to be very versatile in the user profile management.

2.3 The validation process

A valid simulator measures what it is intended to measure.
There are a variety of aspects to validate; subjective approaches are the simplest.
In this sense, we have chosen 2 different kind of validation:

1. The Face Validity
2. The Construct Validity

Face validity usually is assessed informally by no experts and relates to the realism of the simulator; that is, does the simulator represent what it is supposed to represent.
This kind of validity relates to the realism of the simulator.
A questionnaire validation was created.
In this document 12 closed-ended questions were selected about the following topics:

- ergonomics
- structure

- realism
- tactile feedback
- quality

For each question must be given a score according to the rating scale "Likert" (Highly inadequate, Insufficient, Sufficient, Good, very good).

Concurrent validity: is the extent to which the simulator, as an assessment tool, correlates with the "gold standard."

This testing can be achieved by evaluating 3 groups of subjects, with a different professional experience, with the simulator, comparing different variables. This necessitates establishing an objective structured assessment of technical skills (OSATS) evaluation by which the model or "gold standard" performance can be assessed reliably for comparison.(Max V. Wohlauer et al. , 2013)

About this, the simulator must be able to distinguish the experienced from inexperienced surgeons. This is best determined by testing a large number of surgeons with various degrees of training, experience, and frequency of performance of a specific surgical skill or procedure.

For competency assessment, the performance of an individual on a simulator should ideally predict, or at least correlate with, that individual's performance in the real environment of the operating room. As such, a valid and reliable measure of operating-room performance must be established. This allows differentiation between surgeons assumed to be clinically competent (experienced or expert clinicians) and non competent (junior or inexperienced residents).

2.3.1 Sample and inclusion criteria

We have involved a total of 60 subjects to the validation program. This entire group is divided into 3 categories: cluster A is composed by 20 students of Medical and Pharmaceutic Sciences of the University of Genoa without any experience in laparoscopic surgery, cluster B by 20 general surgery residents with moderate experience in surgical skills and Cluster C by 20 experienced surgeons but not peculiarly in laparoscopy.

About "Selection criteria" we have chosen the number of laparoscopic surgical procedure as first operator as parameter.

- Group A: novices (NO experience in laparoscopic surgery)
- Group B: 20 intermediate (at least 10 total laparoscopic operations in the last year)
- Group C: 20 experienced (more than 10 total laparoscopic operations in the last year)

Each group has been divided into two smaller homogeneous groups based on the questionnaire about the personal level of confidence in the use of videogames, virtual platforms, etc:

- Subgroup A1, B1: little/absolutely not confident
- Subgroup A2, B2: confident/very confident

The questionnaire has been administered to each subject before the beginning the test.

2.3.2 Testing mode and setting

To guarantee a correct statistic analysis, we have adopted a closed testing system where the subjects had a limited number of attempts (an open testing system might show bias like weakness, time delays or methodological limits).

When finished the test, the beginner and intermediate groups have been completed the "Face validity" questionnaire to explore the ergonomic adequacy of the system.

Each subject had max two attempts for every examination (2 attempts for exercise 1 level easy, 2 attempts for exercise 1 level intermediate, 2 attempts for exercise 1 level difficult).

Each participant has finalized 6 examinations for a total of 30 at the end of the process.

The setting has been the same during all the parts of the process. To increase the subject 's perception of the scenario in which it will operate, every subject had to dress surgical gloves, coat, mask and headdress.

Similarly, the platform has been prepared with the virtual utilities present on the surgical field to make the hand pieces movements more adherent to reality.

2.4 Basic skills

For the platform validation, 5 tasks have been selected. These exercises are related to the acquisition of tasks which allow students to reach basic gestures competences. They could practice using probes that simulate the haptic feedback according to the kind of action.

The 5 selected tasks are:

1. *laparoscopic - focusing - navigation*: This task aims to evaluate the ability to navigate a laparoscopic camera with a 30º optic. This is done by measuring the ability to identify 14 different targets placed at different sites

   Two different exercises were chosen:

   Exercise 1: the student, working with a 30° ptic, have to focus different solid targets in a static scenario. This task evaluates the macro – focusing.

   Exercise 2: the student working with a 30° ptic, have to focus a lot of hidden micro- targets, placed in different areas of the scenario.

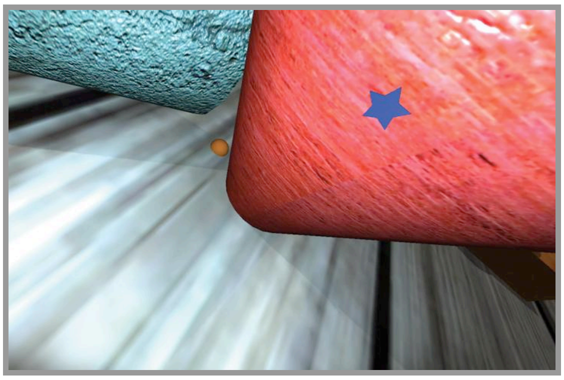

Figure 4: a screenshot of task 2

2. *hand – eye – coordination (HEC):* This task aims to evaluate the ability to work with the non-dominant and dominat hand.
The camera is static.
Two different exercise were chosen:

Exercise 3: the student have to touch a defined point in an “circular target” with the left and right instrument simultaneously

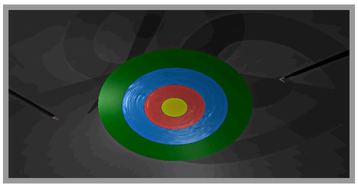

Figure 5: a screenshot of task 3

Exercise 4: the student have to touch a lot of spheres that appear sequentially and in random positions. There is a time limit to center and touch each sphere with the right and left hand. In this task, the camera is static.

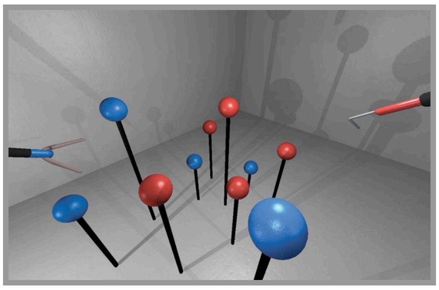

Figure 6: a screenshot of task 4

Exercise 5: the student have to grasp 3 objects and to put these in a selected form.

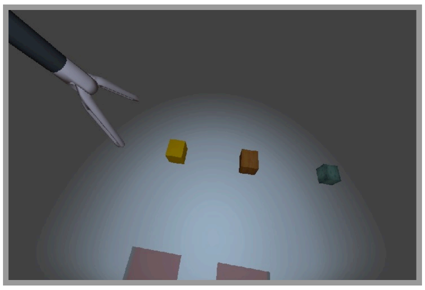

Figure 7: a screenshot of task 5

For each of these tasks, a certain number of metrics have been automatically recorded.
Metrics are defined as follows:

- *Total time.* Time that the user needs to accomplish the task
- *Fulfillment.* Percentage of partial tasks done within the established time.
- *Penality:* number of penality about each task.
- *Score: task's* score
- *Coordination*
- *Accurancy*

Which metrics are recorded for each task is shown in Table 1.

Task	Description	Metrics
Navigation	ability to navigate a laparoscopic camera with a 30º optic	Fulfillment (%) Total time (s) Score penality
Navigation and focusing	the student have to focus different solid targets in a static scenario	Fulfillment (%) Total time (s) Score penality
Coordination (HEC) 1st exercise	the student have to touch a defined point in an “circular target”	Fulfillment (%) Total time (s) Score Penality Coordination Accurancy
Coordination (HEC) 2nd exercise and 3rd exercise	the student have to touch a lot of spheres that appear sequentially and in random positions. The student have to grasp 3 objects	Fulfillment (%) Total time (s) Score penality

Table 1 “Metrics and Tasks” in the Construct Validity

2.7 Setting

The setting has been the same during all the parts of the process. To increase the subject 's perception of the scenario in which it will operate, every subject had to dress surgical gloves, coat, mask and headdress.
Similarly, the platform has been prepared with the virtual utilities present on the surgical field to make the handpieces movements more adherent to reality.

2.8 Data analysis

We have collected for each group several variables about the level of confidence with virtual platforms, and data about execution time, score, penalty where applicable, motion accuracy where applicable, motion coordination where applicable.

2.9 Face validity questionnaire

All Expert and intermediate subjects were requested to fill a Face validity Questionnaire, referred to characteristics of the eLaparo4D simulator (11 questions).
The questions had to be answered in a 5-point Likert Scale:

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

2.10 Statistical Analysis

The results are expressed as mean ± standard deviation, median, minimum/maximum values, and percentages. The Shapiro-Wilk test was applied to evaluate the normal distribution of continuous variables. Differences for answer scores between validation and reference group were evaluated using the Wilcoxon-Mann-Whitney test. The Spearman's rho was used for correlation analysis. A two-tailed P value ≤0.05 was assumed for statistical significance. Statistical analysis was performed using the R software/environment (version 3.2.5; R Foundation for Statistical Computing, Vienna, Austria).

3. RESULTS AND DISCUSSION

3.1 Results

3.1.1 Face Validity

The questionnaire analysis (submitted to experts and intermediate) allowed to obtain the following data:

Experts opinion:

- A real confidence in the ability of this device to allow an accurate performance measurement (4 ± 0,81)
- A great degree of realism in the management of the optic in the virtual scenario (3,9 ± 0,87)
- An excellent realism of targets (4,1 ± 0,56)
- An excellent degree of realism of the positioning of the instruments (3,9 ± 0,56)
- An high quality of the images (4 ± 0,81)
- A great Haptic feedback (sensation) (3,3 ± 0,67) Excellent degree of usefulness of simulation in reference to 'acquisition of skills, "basic" hand-eye coordination (4,4 ± 0,69)

Intermediate opinion:

- An excellent degree of realism in the management of the 30° optic
- A great quality of scenario
- A very good capability of the simulator to teach gestures and action
- The devices position show a good degree of realism

Characteristics	Experts (n=12)
Realism	3,6 ± 0,84
Degree of realism of the positioning of the instruments	3,9 ± 0,56
quality of the images	4 ± 0,81
Realism of targets	4,1 ± 0,56
Degree of "realism" movement	3,4 ± 0,96
Haptic feedback (sensation)	3,3 ± 0,67
Degree of realism in the management of the optic	3,9 ± 0,87
Degree of utility of the haptic feedback	3,5 ± 0,70
Degree of usefulness of the simulator about acquisition of "basic" skill (hand-eye coordination)	4,4 ± 0,69
Degree of usefulness of the simulation about acquisition of skills with non-dominant hand	3,9 ± 0,63
Degree of overall usefulness of the simulator about acquisition of basic laparoscopic techniques	3,8 ± 1,03
Confidence in the ability of this device to allow an accurate performance measurement	4 ± 0,81

Table 2 Face Validity (expert) Questionnaire results

3.1.2 Construct validity

About construct validity, there were significant differences between the expert group, the intermediate group and the novices group in several tasks, while a difference non statistically significant has been appeared between experts and intermediates.

The tasks 3, 4 and 5 (about coordination) discriminates between experts and novices in all the evaluated parameters.
There were significant differences between the experienced group and non-experienced group in the task 3, in terms of “total time”, “score”, “coordination” and “accurancy”; this task shows a better executions accomplished by experts than the ones accomplished by novices.
The task 2, about navigation, shows a better percentage of fulfilment in favour of expert group (90/100% fulfillment).
Total time, shows significant differences in task 2,3,4,5.
There weren’t significant differences between the experienced group and non-experienced group in the task 1.
As previously described in the methodology, metrics that are evaluated in all tasks are total time, fulfillment, score and penality.

3.2 Discussion

The advent of new surgical methods and devices, such as endoscopic, laparoscopic and robotic surgery, caused the need for systematic skills training in an efficient and safe environment.
There are several commercial LTBs and VRSs that analyze the volume, distribution, economy, angle and smoothness of instrument movements, and give numerical and/or statistical results to the trainee after completion of the task(s). However, these devices are generally expensive, and not every center can afford to incorporate them into their education curriculum. Besides these expensive training boxes/ simulators, some authors have developed themselves either low-cost laparoscopic simulators with reasonable budgets.
Starting from this point, our group has developed a low cost laparoscopic simulator for basic skills and for cholecystectomy. We have reported the results of the validation process. The validations’ steps of these kind of training system are essential in order to determine their capacity for surgeons training although as far as we know, there is not any mandatory validation strategy.
The Face validity and the Construct validity are two of the more reported in literature.
The Construct validity determines the capacity of the simulator to punctuate the execution according to the level of experience of the subject who is accomplishing the task.
So, a construct validated simulator will be able to distinguish between surgeons with different levels of experience in laparoscopic surgery.
The Face Validity is just based on the opinion and experience of surgeons and cannot be used in every case to define the validity of a new simulator.
As the face validity is very subjective, it is usually used at the first stages of validation.
The aim of this work is to validate “eLaparo4D” simulator accomplishing a face and construct validity in order to determine whether it is adequate for basic skills training. Expert group and intermediate group agree with usefulness of the simulator in reference to 'acquisition of skills, "basic" hand-eye coordination and confidence in the ability of this device to allow an accurate performance measurement.
The realism of the targets and the scenario is a great characteristic, like the position of the instruments.
The haptic feedback is considered by expert as acceptable, most important elements in this kind of virtual simulators.
The results of the study show that there are significant differences between the tasks execution by novices and by experts and intermediates for the evaluated metrics.
Among all, navigation and coordination tasks show the clearer results.
The task 1 about navigation not present any difference between the different levels of experience: this result can be due to the fact that novices have experience virtual games and in video camera use.
In task 3,4 and 5 the difference between novices and experts is evident; total time, score and penalty are in favour of experts.
In task 3, the expert group showed a better coordination and accurancy than novices.
The “total time” are evaluated in all tasks because is an important variable; novices need more time than experts to finish the tasks in all cases and experts fulfil the majority of the tasks and more efficiently than novices.
To evaluate the reliability, we decided to perform the correlation index to the metrics: total time and score.
The results of this test show an high value of correlation for the total time and a lower value for the score.
From these values, the Split half Methodology was applied, to calculate the coefficient of Reliability; we applied the Spearman-Brown correction and the final result was: 0.91
The thin difference between intermediates and experts in several tasks could probably be explained in the definition of “experts”. These subjects revealed a strong surgical experience but not peculiarly in laparoscopy.
This conclusion leads us to the point that eLaparod4D could be used in training programs as an assessment tool.

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TITANIUM CRANIOFACIAL PROSTHESES: A DESIGN PROCEDURE FOR IDENTIFYING THE OPTIMAL FIXATION SYSTEM AND ITS APPLICATION TO A CASE STUDY

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ABSTRACT
Cranioplasty is a surgery in which a prosthesis must be anchored on skull bone to repair a defect. One of the most used materials is the titanium. However, titanium prostheses could be made using the incremental sheet forming (ISF). Since titanium and bone are characterized by different Young modules, a detailed design of anchoring system is required to avoid cranial rupture. Aim of this study was to present a design procedure in order to identify the optimal anchoring system in case of craniofacial prostheses made with ISF. In detail, an optimization process and a predictive model for bone stress were used, choosing the numerical outputs of different FEM analyses as input data. The results indicate that our predictive and optimization models are accurate and, so, that this procedure could be very helpful for the prosthesis design, as demonstrated by the application of the procedure to a real case study.

Keywords: titanium prosthesis, anchoring system, incremental sheet forming, design procedure

1. INTRODUCTION

Cranioplasty is a neuro-reconstructive surgery that repairs structural or morphological defects (Solaro et al. 2008) -created by congenital, developed or accidental causes-, using a prosthesis, which must be anchored to skull bone both for functional and aesthetic aspects (Toso et al. 2015).
Even if different bone substitutive materials are available (Neovius and Engstrand 2010), the most used ones are Titanium and its alloys because they are biocompatible, experimental and clinically tested (Calderoni et al. 2014), with excellent mechanical properties (Gepreel et al. 2013), and favor the osseointegration with the bone, that is to say the direct contact between implant and bone (Albrektsson et al. 1981).
Since the craniofacial implants have also an aesthetic function (Drstvensek et al. 2008), titanium customized prosthesis has been recently used in order to improve the aesthetics and obtain a normal appearance (Cho et al. 2015; Castelan et al. 2014).
Regarding the manufacturing process, craniofacial prostheses could be made using the incremental sheet forming (ISF), an innovative technology that presents significant vantages (Ambrogio et al. 2015; Castelan et al. 2014; Lu et al. 2014; Lu et al. 2015), such as the possibility to create both patient-specific and generic prostheses and low set-up cost. With this technique, the prosthesis has a greater area and, so, a larger perimeter in respect to the defect (Lu et al. 2015), but no information regarding the anchoring system is available, in terms of overlap length and diameter of screw shank.
Moreover, titanium and bone have different elastic modules (reported in Vosough et al. 2013 and Raul et al. 2006 respectively). So, the anchorage system must be correctly designed in order to avoid the skull bone rupture.
The aim of this study was to present a procedure for correctly designing the anchorage system in case of titanium prosthesis made using ISF.

2. DESIGN PROCEDURE

In order to identify the best anchoring configuration, in term of screw dimensions and overlap length between prosthesis and skull bone and for a specific damage area, considering the worst accidental load, an optimization process was carried out, using the response surface methodology - RSM - (Asiltürk et al. 2016).
First, a predictive model of the skull bone stress was identified considering five factors (damage area, screw shank, overlap length, load and its tilt angle) and just one response (skull bone stress). Moreover, the degree of this model was established comparing different polynomials by means of the analysis of variance (ANOVA) and choosing the best one through an optimization process.
Since the skull bone near the prosthesis and the anchorage system must resist to accidental loads, the maximum stress on bone due to loaded prosthesis was evaluated by means of FEM structural analyses. So the numerical results were used as input for the optimization process.

2.1. Design of experiment

As previously reported, the damage area, the screw shank, the overlap length, the load and its tilt angle are the factors. So, for each of them, the values range was defined, as reported in Table 1.

The number of simulation necessary to carry out this design could be calculated as

$$N = L^v \quad (1)$$

where L represents the levels number of factors and v represents the number of factors. So, since four factors have three levels (3^4) and one factor has two levels (2^1), the number of simulations is equal to 162.

Table 1: Design factors information

Factor	Name	Unit	Level	Values
A	Screw Shank	mm	3	1.5 - 2.0 - 2.5
B	Overlap Length	mm	3	7 - 10 - 13
C	Tilt Angle	Degree	3	0 - 45° - 90°
D	Load	N	3	100 - 300 - 500
E	Damage Area	mm^2	2	2,100 – 2,600

2.2. Structural FEM modeling

In order to create the dataset for the predictive modeling and for the optimization process, different structural FEM analyses were carried out.

2.2.1. Geometrical model

A 3D solid model of a healthy skull was reconstructed starting from CT images by means of the segmentation process, using the open source software Invesalius (de Moraes et al. 2011), and the reverse engineering (Maravelakis et al. 2008).

A circular defect was created in the fronto-parietal bone, considering the two values of the damage area (Figure 1A). According with these holes, different prostheses were modeled with each overlap length established in the design of experiment and with a thickness of 1.5 mm, as our titanium prototype made with ISF (Ambrogio et al. 2015).

Moreover, three micro-screws were inserted considering the same angle of 120°, to fix the prosthesis to the bone, placing the first one in correspondence of the sagittal plane (Figure 1B).

In order to reduce the computational cost and because of the axial-symmetry of the virtual model, a simplied model of 20° (Figure 1C) was used in the FEA analyses.

2.2.2. Material properties

Skull bone was approximated as a cortical one (Raul et al. 2006) and the Ti6Al4V (Vosough et al. 2013) was used for prosthesis and screw. Both materials were assumed to be homogeneous and isotropic (Raul et al. 2006), defined by linear elastic laws.

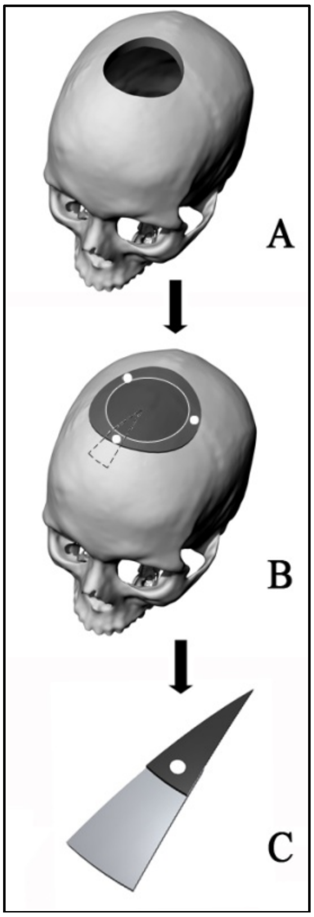

Figure 1: Geometric model of a skull with a circular fronto-parietal defect (A), of a skull repaired with prosthesis and three micro-screws (B) and of a simplified 20° model (C).

2.2.3. Boundary conditions

The bone was fixed in the bottom surface in order to model the remaining bone skull not considered in the geometrical model.

Moreover, a distributed compressive load was applied to the top surface of prosthesis to simulate accidental load. In details, the load has three intensities and three tilt angles, as specified in Table 1.

Furthermore, titanium is commonly used in cranioplasty because it favors the osseointegration, creating a perfect adherence between titanium components and bone, and, consequently, a permanent anchorage (Albrektsson et al. 1981). For this reason, a perfect osseointegration was implemented as boundary condition in this FEM modeling between bone and implant and bone and screw. Moreover, as the osseointegration was modeled, a rigid connection was assumed between prosthesis and screw.

Finally, a symmetry boundary condition was applied in the lateral faces of skull and prosthesis due to their axial-symmetry.

All boundary conditions are reported in Figure 2, in which each color represents a boundary condition: green represents symmetry, red represents fixation and black represents load. Also the symmetry axis is reported.

2.2.4. Simulation details

COMSOL 5.0 (COMSOL Inc, Stockholm, Sweden), a finite-element-based commercial software package, was used to perform all numerical simulations and for the post process. Furthermore, in all cases, a fine tetrahedral mesh was used, for a total of about 75,000 elements.
As the skull bone near the prosthesis and the anchorage system must resist to accidental loads, the maximum stress on bone due to loaded prosthesis was evaluated by means of the Von Mises criteria (Baggi et al. 2008).

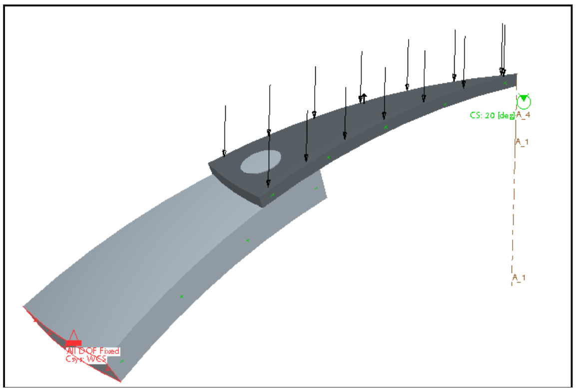

Figure 2: Boundary conditions.

2.3. Statistical analysis, predictive modeling and optimization process

As reported before, five factors were considered in the predictive modeling and their correlation with the bone stress (the only response) was statistically evaluated by means of the Design Expert Software (Stat-Ease, Inc., Minneapolis, USA - trial version).
Moreover, the optimal degree of the model was identified comparing 7 polynomial orders (linear, 2Factorial Interaction, quadratic, cubic, quartic, fifth and sixth) by means of ANOVA analysis. The best one was chosen considering a right compromise between complexity and reliability of the prediction, which can be expressed as number of polynomial terms and predicted residual sum of squares - PRESS - (Ho et al. 2002), respectively. Furthermore, a p_{value} threshold of 0.05 was adopted to select the statistically relevant parameters interactions.
The objective of the optimization process was to prevent the achievement of ultimate compression stress of skull bone (Raul et al. 2006) and, so, the rupture in case of accidental loads, in order to establish the optimal anchoring system for specific skull damage, in term of screw geometry and prosthesis overlap length, considering a worst unforeseen load.

3. RESULT AND DISCUSSION

As reported previously, the numerical results of skull bone stress obtained with the FEM structural simulations were used to create the dataset for the optimization process. Considering our 162 objects, the skull bone varies in the range [3, 300] MPa, with a mean value of 75.89 ± 73.00 MPa.

3.1. Statistical analysis and predictive modeling

The correlation value is -0.663 for tilt angle and 0.568 for load. So, the maximum stress occurs with the highest load (500 N) and the lowest tilt angle (0°). On the other hand, the correlation rate for shank and for overlap length is -0.008 and -0.181, respectively, indicating that skull stress decreases if screw shank and overlap length increase and that the last one is the most significant factor (0.181 compared with 0.008). Finally, the correlation rate for damage area is -0.078, so the stress increases with the decrease of damage area.
To establish the optimal degree of the polynomial for the predictive model, the PRESS value and the number of terms for all polynomials were calculated with the ANOVA and then were normalized in the range [0, 1]. The two waveforms are illustrated in Figure 3. The optimal result is obtained between the quadratic and cubic equations. So, the third degree model was chosen as the referenced one and it was reduced considering only the terms with $p_{value}<0.05$ (Lee at al. 2006).
Moreover, all R^2 variables are very high and almost equal to 1 (Table 2).
Using the reduced cubic polynomial, the stress in the skull bone could be predicted as:

$$\sigma_{bone} = c_1 \cdot A^2B + c_2 \cdot A^2C + c_3 \cdot A^2D + \cdots + c_{n-4} \cdot A + c_{n-3} \cdot B + c_{n-2} \cdot C + c_{n-1} \cdot D + c_n \cdot E \quad (2)$$

in which c_1- c_n are the coefficients.
Furthermore, the normal plot of the residuals was employed to verify the normal distribution of data, that was confirmed (Figure 4).
To investigate the reliability of the prediction, the predicted versus actual values diagnostic plot was analyzed (Figure 5). All data were properly predicted, also around the ultimate compressive stress value (145 MPa).

3.2. Optimization process

Since statistical results have indicated that the worst compression tilt angle was 0° and that loads greater than 350 N always exceeded compression threshold of 145 MPa, the optimization process was carried out considering a maximum load of 350 N with 0° and a limit of 140 MPa. Moreover, the statistical analysis has highlighted that bone stress is negatively correlated both with screw shank and prosthesis overlap length. So, the optimization model was implemented minimizing the shank and the overlap length in order to identify the lower limit of these variables that generates the highest stress.
The results of this modeling, considering seven different damage areas, are illustrated in Table 3. Obviously, since stress value is less affected by shank geometry respect to the value of overlap length, all shank values of our initial range (1.5- 2.5 mm) can be used, whereas only high values of overlap length ensure stress less than 140 MPa.

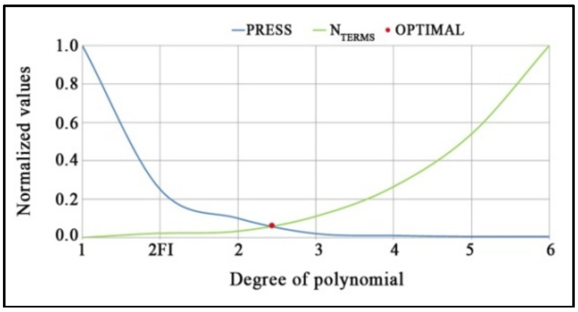

Figure 3: Identification of the best polynomial degree considering the normalized number of polynomial terms (N_{TERMS}) and the normalized PRESS value.

Table 2: ANOVA results of the reduced cubic model

Factor	Value		Factor	Value
Std. Dev	3.74		R-Squared	0.9979
Mean	75.89		Adj R-Squared	0.9974
C:V: %	4.92		Pred R-Squared	0.9963
PRESS	3,149.57		Adeq Precision	174.338

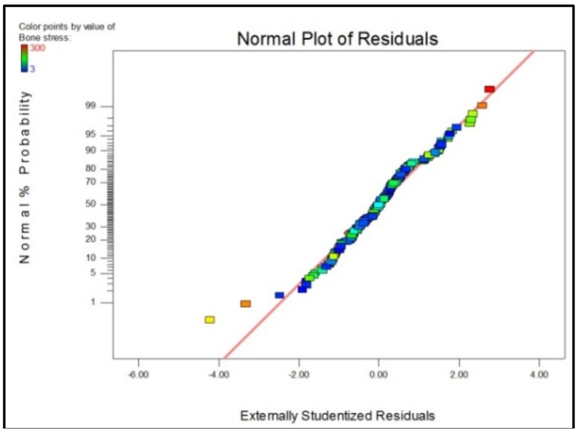

Figure 4: Normal plot of residuals for the reduced cubic model

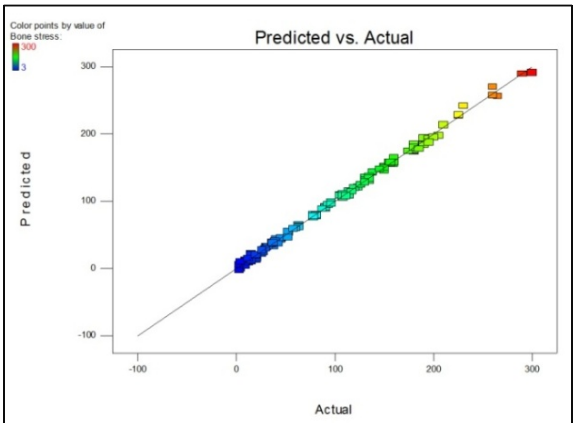

Figure 5: Predicted vs actual values for the reduced cubic model

3.3. Validation

To validate the design procedure three FEM analyses were carried out modeling different damage areas and anchorage systems (Table 4). Furthermore, an accidental load of 350 N with 0° was applied. As reported in Table 4, the error between the predicted stress and FEM skull bone stress is very low. So, our predicted model has a very high accuracy, generating a valid optimization process and a design procedure.

Moreover, these results indicated that bone stress overtakes the limit if low values of overlap length are considered. This means that our optimized model provides the best ranges, thanks to which the optimal anchoring system could be realized.

Table 3: Optimal screw shank and prosthesis overlap length ranges for specific damage area

Damage area [mm^2]	Range of Screw Shank [mm]	Range of Prosthesis Overlap Length [mm]
2,100	1.5 - 2.5	12 - 13
2,200	1.5 - 2.5	12 - 13
2,300	1.5 - 2.5	11 - 13
2,400	1.5 - 2.5	11 - 13
2,500	1.5 - 2.5	10 - 13
2,600	1.5 - 2.5	10 - 13
2,700	1.5 - 2.5	10 - 13

Table 4: Validation of the design procedure

	Model 1	Model 2	Model 3
Damage area [mm^2]	2,100	2,400	2,700
Screw Shank [mm]	2.5	2	1.5
Overlap Length [mm]	10	10	9
Predicted Skull Bone Stress [MPa]	148	148	147
FEM Skull Bone Stress [MPa]	147	141	141
Error [%]	0.68	3.55	4.26
Mean Error	2.83		

4. CASE STUDY

In order to test the presented procedure, it was applied to a real case study. The five steps illustrated in Figure 6 were followed in order to obtain the prosthesis.

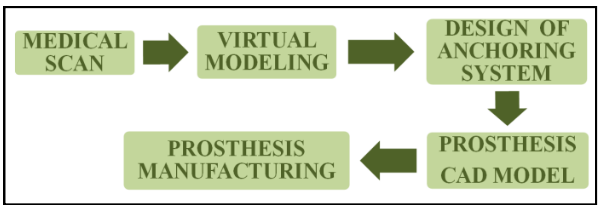

Figure 6: Realization steps of the case study

4.1. Medical scan

A series of in-vivo contrast-enhanced axial CT-scan 2D-images of a 65-year-old man, who presented a fronto-parietal defect, was acquired for clinical reasons. In details, 512 x 512 slices were obtained with a pixel spacing of 0.468.

4.2. Virtual modeling
Starting from the CT slices, a 3D virtual model of the skull and of the defect was reconstructed by means of the segmentation process that was performed by Invesalius. Since it produces an STL file, the model was subjected to the reverse engineering process in order to obtain a solid model (IGES or STL formats).

4.3. Design of anchoring system
As previously reported, the prostheses made with the ISF can be anchored to the skull bone creating an overlap between the prosthesis and the skull near the defect. So, to make the prosthesis with a greater area and, so, a larger perimeter in respect to the defect, the design procedure presented in the paragraph 2 was used, considering that the case study defect had an area of 2,680 mm^2.
The final anchoring system consisted of a prosthesis with an overlap length of 10 mm and three micro-screws with a shank of 2.0 mm.

4.4. Prosthesis CAD model
In order to manufacture the optimized prosthesis, the CAD model was modified to create the optimized overlap length (Figure 7).

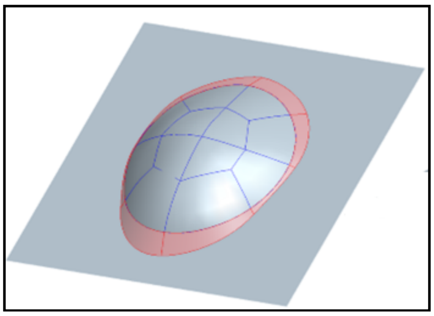

Figure 7: Craniofacial CAD prosthesis

4.5. Prosthesis manufacturing
Since the ISF is a CAD/CAM process, its code was created to describe the ISF operations on the CNC machine. This program was generated by means of the manufacturing module of Pro-Engieering.
The first step to manufacture the prosthesis was the right shape positioning on the sheet plane, done to respect the technological constraints. Moreover, a backing plate with a circular hole was positioned under the sheet in order to support it during the manufacturing. After that, the sheet was positioned on the CNC table and deformed using a hemispheric punch (diameter of 15 mm) with a continuous movement (constant tool depth step of 0.1 mm and a tool feed rate of about 2000 mm/min), following the trajectory generated by a CAD/CAM program (Figure 8).
The obtained prosthesis is reported in Figure 9.

5. CONCLUSION
During the cranioplasty, a prosthesis is anchored to the skull bone. So a detailed design is required. This study has presented a design procedure to identify the best fixation system for different damage areas.
In details, the method consists of a preliminary statistical analysis, the creation of a predictive model using the ANOVA analysis and finally the development of an optimization model based on the RSM.
The validation results have suggested that this methodology has a good accuracy, both in the prediction and in the optimization. Finally, the application of the methodology to a real case study has demonstrated that its use is very helpful in the manufacture of craniofacial prosthesis.

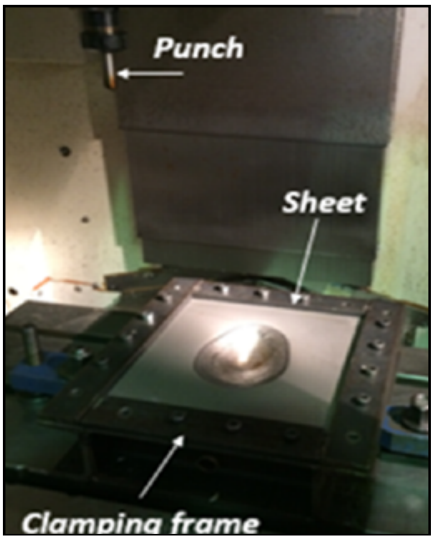

Figure 8: ISF machine

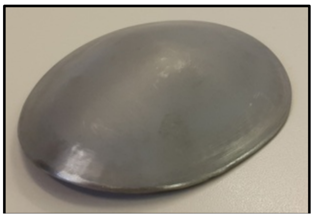

Figure 9: Craniofacial prosthesis made with ISF, applying the design procedure for the anchoring system.

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REHABILITATION MONITORING AND BIOSIGNAL IDENTIFICATION USING IOT-MODULES

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ABSTRACT
Microelectronics and high level integration provide in combination with simulation and modeling of embedded systems new approaches in biotechnology and medical therapy. The integration of intelligent systems as well as sensors and actors in an adaptive hardware/software-platform increases flexibility and provides a scalable measurement and identification platform. Based on modeling and simulation methods, different applications, like biosignal identification, prosthesis control and rehabilitation monitoring, offer completely new treatment and therapy options. In this paper we focus on the platform extensions of the modular biosignal acquisition and identification platform by using Internet-of-Things modules and introduce new applications for rehabilitation monitoring and evaluation of motion sequences.

Keywords: ENG-based prosthesis control, rehabilitation monitoring, system identification, system verification, simulation framework, simulation and modeling in computer aided therapy, robot-manipulators

1. INTRODUCTION
Embedded systems provide new approaches in biotechnology and medical therapy. Based on modeling and simulation methods, biological, physical and technical relationships can be described and verified (Kandel, Schwartz, and Jessell 2000), (Law and Kelton 2000), (Zeigler, Praehofer, and Kim 2000), (Klinger 2014).
The integration of hardware- and software-components provides an intelligent, smart and application-specific system. Using a platform paradigm, the partitioning between hardware- and software-components is adaptable concerning project-specific requirements. Furthermore the platform characteristic enables a modular architecture with high-level flexibility. The integration of sensors and actors in this adaptive hardware/software-platform increases flexibility and provides a measurement and identification platform for lots of applications.
In (Klinger and Klauke 2013), (Klinger 2014) and (Klinger 2015) we have presented a modular platform focused on the acquisition of electromyogram (EMG) and electroneurogram (ENG)-signals and a data-based identification approach.

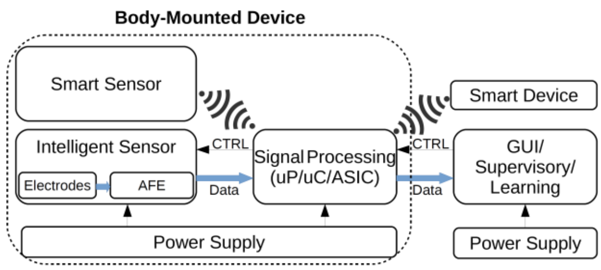

Figure 1: Block diagram of SMoBAICS

In addition to a continuous improvement of the system core features (in particular the identification), we are working on new fields of application and an enhancement concerning flexibility. In
Figure 1 a block diagram of ram of the smart modular biosignal acquisition, identification and control system (SMoBAICS) is shown.

The SMoBAICS-platform consists of several stages and modules, described in the following overview:

- A Data acquisition and stimulation
  The ENG or EMG (ExG) data or further sensor data have to be acquired and sampled according their signal characteristics. The number of channels has to be determined by the application. In particular applications a stimulation is necessary, for example to trigger movements by activating muscle groups.
- B Data processing
  Data processing focuses on two key priorities: Data conditioning and identification.
  - B.1 Data Conditioning
    The acquired data have to be processed to improve the signal conditioning. Besides the programmable filters and amplifiers are resampling functions available to provide periodic samples. The acquired data (action potentials) are disturbed by intrinsic and a substantial extrinsic noise, originated for example by EMG from surrounding muscles. Therefore we have to condition the recorded data with integrated analogue filters and additional digital filters. Several filters like specific high-pass, low-pass, band-pass and notch

filters are available. A further data processing is necessary to generate events from the action potentials like the activity level of a muscle group or the detection of an exposure scenario.

B.2 Identification

The identification feature is required for prosthesis control or any type of high level signal evaluation, like gait analysis. The identification is based on machine learning and recognizes different information sources: The action potentials from brain to muscle, the action potentials from the proprioceptors and additional sensor data from microelectromechanical system (MEMS) of force sensors. The identification method and the corresponding verification scenario have been introduced in (Klinger and Klauke 2013), (Klinger and Klauke 2015) based on results in (Bohlmann, Klinger, and Szczerbicka 2009), Bohlmann, Klinger, and Szczerbicka 2010), (Bohlmann, Klinger, and Szczerbicka 2011), (Bohlmann, Klinger, and Szczerbicka 2012). The identification is subdivided into three levels. In the first level, the algorithm recognizes patterns of axon related action-potentials. This set of solutions is checked to well-known parameters, like impulse frequency, the relative magnitude of the nerve impulse amplitude and the refractory period. In addition clusters are build up to model the different groups of activation and their related sensory information (proprioceptors). So, certain clusters in the neural bundle can be arranged to map muscle groups and their corresponding receptors. In the second level the agent-based set of solutions is combined to global solutions taking the causality between actor and sensory information into account. The third level correlates the first and second level solutions with trajectory information from the camera-system or the MEMS, using inverse kinematic algorithms.

C Data archiving

A local data archive is necessary due to two scenarios, online and offline operation.

C.1 Offline Operation

For offline operation the identification needs sets of model parameters, data from the learning outcomes and RAM for algorithm execution. Furthermore all data can be logged on the system for a later offline analysis. During event recognition all data are logged, only event data, for example an exceeding of a maximal force, are sent to the host system.

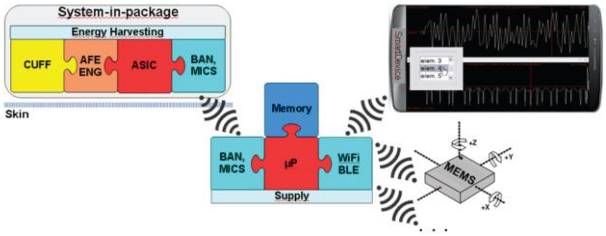

Figure 2: System Architecture

C.2 Online Operation

During online operation all local algorithms need memory for an efficient execution. This local memory reduces the requirements for data bandwidth to the host system.

D Data exchange / Connectivity

With regard to Figure 1, the processing of data goes in two different directions, either the local signal processing (operating phase (Klinger and Klauke 2013)) or the host processing (learning phase (Klinger and Klauke 2013)). Furthermore the data can be saved locally or on the host, transferred using the communication link (cable or wireless).

E User interface

The graphical user interface (GUI) allows access to the different system functions and presents either a configuration or a data display.

F Configuration

The system functions can be configured for different use cases and specific GUI.

F.1 Learning

The control application helps to adapt parameters and to initiate different learning phases.

F.2 Operating

The operating GUI allows to start and stop the application and to load specific parameters.

F.3 Logging

The logging collects not only events but all system data for a later offline analysis.

F.4 Event

The different events and their corresponding limits have to be defined and selected.

In Figure 2 the block diagram is transformed in the platform layer, where the architecture and the functional system components are visualized. This figure shows the future design roadmap, where the key component is integrated into a system-in-package (SIP) to provide an implantable device.

Furthermore this figure shows the wireless integration of the MEMS-device, which is a smart sensor providing the required connectivity shown in the block diagram (Figure 1). This wireless connection improves the flexibility and simplifies the system integration. With regard

Table 1: Comparison of selected connection opportunities and ranking from the wireless point of view

Issue	Ranking	Comment
The device has to provide an own power supply	-	Cable linked, the device can be powered by the main system.
Wireless connection flexibility	+	No number of inputs have to be specified)
The device has higher complexity	-	Design effort
Local intelligence	+	Local intelligence provides more features
No cable link	+	Cable link makes trouble due to the mobile system

to the platform, the advantages (+) and disadvantages (-) of this wireless connection type are opposed in Table 1. Based on this comparison and with regard to platform paradigm, system flexibility and mobility, the wireless connection has been chosen for the integration of all external sensors into SMoBAICS. This decision opens the perspective of using Internet of Things (IoT)-modules which have the added benefit of the future availability of legio of IoT-sensors and actors. The internal sensors, like the cable wired cuff-electrode (Klinger and Klauke 2013), cannot be connected using wireless techniques according to the current state of the art.

2. IOT-BASED EXTENDED MODULAR SYSTEM ARCHITECTURE

The Internet of Things creates new opportunities to link sensors, actuators or intelligent decentralized systems either with each other or with other systems (Bassi et al 2013). The IoT-Roadmap promotes new technologies and, therefore, new challenges. Based thereon the availability of technologies and components offers good conditions for a platform-based system such as SMoBAICS. The extension or adaptation of the system may then, depending on the application, benefit from existing developments and/or modules.

The SMoBAICS platform is used to acquire EMG- and ENG-signals and to provide a data-based identification of movements and trajectories. The identification method is model-based and uses simulation for the continuous model improvement and for verification purposes. The data of the external sensors, here especially of the 9-axis tracking device, are essential for the model- and simulation-based identification method. First we introduce in the following with the general properties of these systems. Then we focus on a first own IoT-module for SMoBAICS that already uses components developed based on this new technology.

2.1. IoT Characteristics

An analysis of different use cases shows the need of an integration of additional sensors in the acquisition and identification platform. This includes the MEMS-device, which is needed to provide motion data of the prosthesis. The connectivity is here one key factor. Lots of smart devices, like smart phones or tablets, provide a communication- and computing- infrastructure. Based on this the flexibility and scalability of the platform can be increased significantly. In addition the number of intelligent components rises within the scope of the IoT rapidly (Bassi et al. 2013). Thus intelligent sensors can be integrated to the platform. This decentralized periphery extends the application spectrum of the platform considerably. Nevertheless, some key aspects have to be taken into consideration:

- The core platform is an essential part. It enables an efficient and performant integration of different modules and provides smart services.
- The modular character of hardware and software and their platform characteristics is of particular relevance. The platform paradigm provides a flexible partitioning and relocation of functions and services on specific hardware and software modules. Especially the open system gateway initiative (OSGI) is one of the key features realizing the software platform.
- Connecting more than one or two devices, the Smart- Device and/or the CPU-module of SMoBAICS has to provide gateway functionality. Based on new Bluetooth- (mesh) or WiFi- (802-11ah) standards, the communication environment with these characteristics can be realized.
- The service orientation of the interface is an essential aspect due to the integration of IoT components. An efficient linking and communication require a defined quality-of-service level to realize a seamless integration of services and modules.
- Using IoT-modules security aspects are a further key point. Without secure data transfer and a secure module interconnection an IoT-based system is applicable in a limited way. Every connection has to be secured using pairing-based or certificate-based strategies.

In Figure 3 the essential features of an IoT-device are depicted. The base functionality of an IoT-module contains an actor/sensor element, and processing, memory and connectivity features, adapted to the specific application. For example, the connectivity may be based upon a wireless or wired connection. Moreover, all modules are designed regarding low-power strategies providing an autonomously operation. Here, energy harvesting is one of the main future topics for IoT-systems.

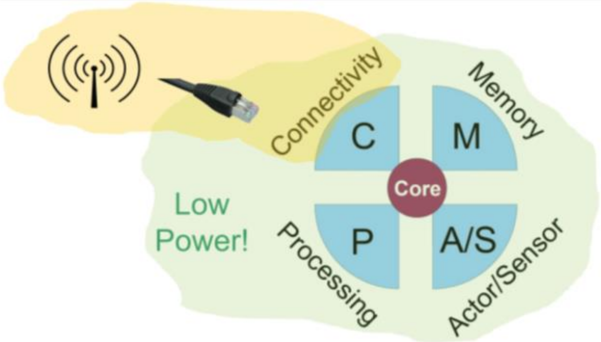

Figure 3: Platform circle, covering the major system features

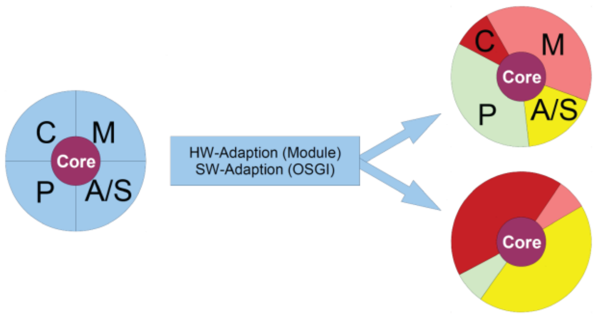

Figure 4: IoT instances based on an IoT-platform

Figure 4 shows different specifications of IoT-systems designed for specific applications. For example processing features (above) or connectivity (below) are more pronounced than other features. Based on the platform paradigm every IoT-system can be designed according its specific project requirements.

2.2. SMoBAICS IoT-Modul

As described in (Klinger and Klauke 2013) and (Klinger 2014) the SMoBAICS is a modular system for identification and prosthesis control. Based on the acquisition of action potentials via ENG, the information of the peripheral nervous system is used to identify movement patterns. A MEMS (mobile phase (Klinger and Klauke 2013) and/or camera system (learning phase (Klinger and Klauke 2013)) is necessary to get information about the movement trajectories. To integrate the MEMS, an IoT-module was designed to improve flexibility and to simplify the integration of the sensor using wireless connection. Figure 5 shows the block diagram of the SMoBAICS IoT-module. The first prototype with a rectangular base has the system dimensions shown in this figure. The design can be shrinked massively, due to design for test considerations we did not shrink the prototype further. It is realized according to the platform paradigm and consists of a modular design. According to the platform circle, shown in Figure 3, all essential features are realized:

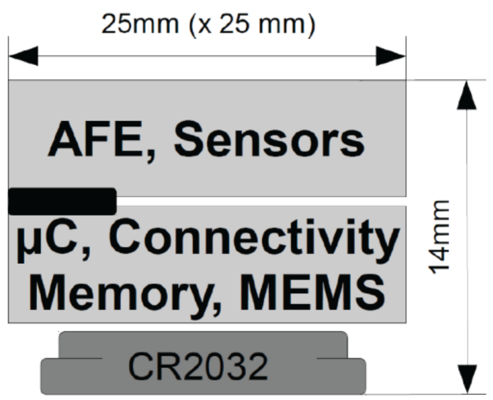

Figure 5: SMoBAICS IoT system: Base System (Lower Board); Sensor Extension (Upper Board)

- µController
  ARM-based controller for data and event processing, system control and analog-digital conversion.
- Connectivity
  In the current version Bluetooth is supported to provide a communication link to the body area network (BAN), connecting all devices of the platform.
- Memory
  For logging and data buffering a SD-card is integrated.
- Sensor
  The MEMS is an integral part of this IoT-module because the acceleration and gyro data are for all relevant applications around this project important. To provide further sensor support an interface is designed to connect additional sensors to the IoT-system. This additional sensor system can be connected to the base system as shown in Figure 5. In subsection 3.2 we show a corresponding application scenario using additional sensor support.

The prototype attached button-cell battery provides enough energy to independently operate the IoT-device for several days. The intelligent power management helps to reduce power consumption according to the activity cycles. In Figure 6 activity cycles for different use cases are shown, ranging from training applications to different rehabilitation scenarios. The four operation modi are characterized by power consumption and wake-up capability:

- Off
  The device is powered off, no power consumption.
- Standby
  The device is in the lowest power consumption mode, waking up by interrupt of the MEMS-device.
- Activity
  Data acquisition is activated automatically from standby; depending on the communication status (logging, event mode, transmit continuously, transmit periodically) the power consumption differs considerably.
- Training
  Data acquisition is activated manually and the communication mode is selectable according the activity mode.

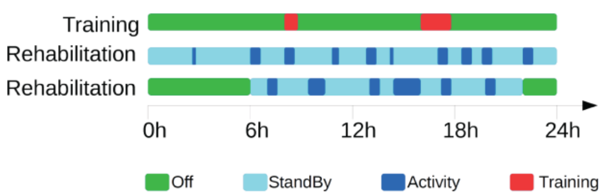

Figure 6: Application specific time-of-use: Day Schedule

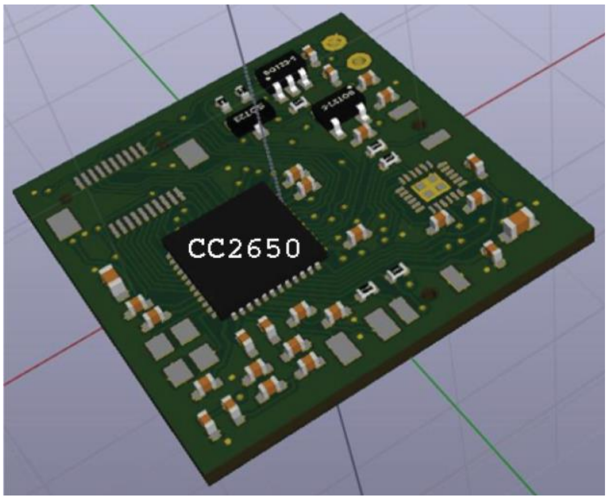

Figure 7: Design overview of the current CPU-module

In Figure 7 the current design of the CPU-module is shown. To realize the IoT-system according platform paradigm we have chosen the large CC2650-package providing more I/Os. Realizing a product-based design, the IoT-system can be shrinked considerably.

3. APPLICATIONS

A wide range of applications in the field of biosignal measurement, signal processing and biosignal monitoring are existing. We focus on two specific examples, demonstrating the further development of the known platform (Klinger and Klauke 2015) and the flexibility of the platform paradigm.

3.1. Prosthesis Control System and Gait Identification

Based on the idea of an ENG-based arm prosthesis control we are still working on the identification to improve the identification algorithms and to make it more robust. Using signals from the peripheral nervous system, the objective of a prosthesis control is adaptable to leg prosthesis, too. In Figure 8 the application schematic is shown, consisting on the same elements like the system for the arm prosthesis control (Klinger and Klauke 2013).

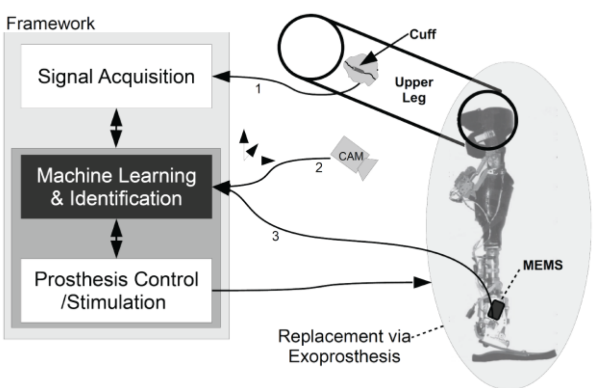

Figure 8: System overview

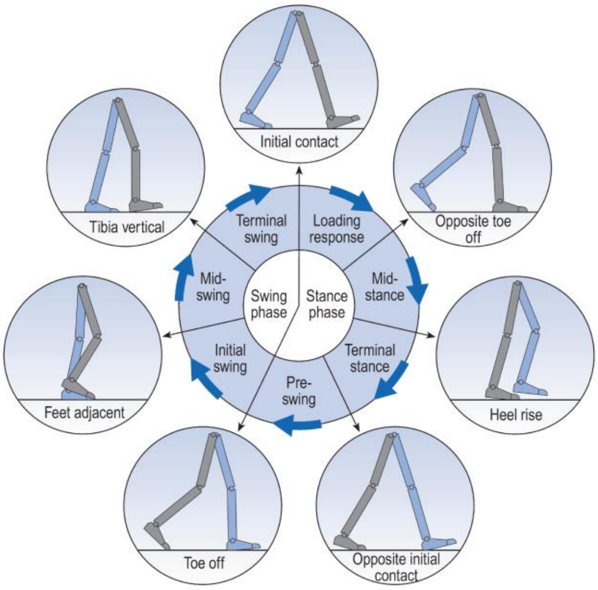

Figure 9: Positions of the legs during a single gait cycle by the right leg (gray) (Levine, Richards, and Whittle 2012)

According to this scenario we need to integrate a MEMS to get information about zero space movements during the operating phase (Klinger and Klauke 2013). This MEMS contains a 9-axis motion tracking device (gyro + accelerometer + compass). During the first identification runs it turned out, that the MEMS-signals are not sufficient to correlate with the information from the nervous system due to signal drift. So it was not possible to realize a gait identification which is necessary to provide a leg prosthesis control. Therefore we add force sensors to the MEMS, called now MEMS+F. The design was made according to the description in section 2; the wireless integration of this so called smart sensor was realized according Figure 1 and Figure 2. Using force sensors, it is possible to get more precise information about the force progression over time and therefore about the gait cycle, shown in Figure 9. The gait cycle information and the force sensors are essential requirements for an identification process (Aziz, Park, Mori, and Robinovitch 2014), (Ito 2008), (Kugler et al. 2012), (Tao, Liu, Zheng, and Feng 2012). Furthermore, the gait cycle information triggers another application, shown in the following subsection.

3.2. Rehabilitation Monitoring System and Gait Evaluation

Deploying the MEMS with additional force sensors (MEMS+F) there are a lot of rehabilitation monitoring systems and gait evaluation systems possible.

- Rehabilitation Monitoring
  Using the MEMS+F device it is possible to measure, evaluate and archive all forces acting on the foot vertically (z). With additional sensors, adaptable to the MEMS+F-device, it is possible to take the other forces (xy) and tor-

ques into account. During a rehabilitation phase after a fracture, dislocation, etc. the physical stress can be observed continuously. Therefore a correlation between stress type, stress duration and recovery progress is possible. In addition the accumulated load per time period can be taken into account. Furthermore the monitoring can be used to optimize the gait during rehabilitation to realize a normal gait. If the specific permitted limits are exceeded, an event can be triggered, informing the patient or the treating physician to take the situation into consideration.

- Gait Monitoring
  The evaluation of gait of apparently healthy persons is an important method to analyze an imbalance or dysfunction which can result in health problems. These problems can be evaluated using a continuous gait monitoring to identify pathological or abnormal gaits. Paying attention to how you walk and run reduces unnecessary muscle strain. In addition this gait monitoring can be used to monitor and optimize movement sequences within the sports segment.

4. RESULTS

In this section we focus on the first measurements taken by the new SMoBAICS IoT-device. This device is necessary for all applications and use cases with identification to provide a positioning information. Both applications in section 3 are using this device as MEMS+F-device. Focusing on the second use case in subsection 3.2, the whole system can be downsized with regard to the platform paradigm. In Figure 10 a small cutout of the block diagram in Figure 1 is shown, emphasizing an additional direct connection between the smart sensor MEMS+F and the smart device used in this class of application. In addition to the 9-axis motion tracking device, the prototype is using currently three force sensors to provide a mobile measurement of forces as well of accelerations and gyro data according a gait evaluation. The current resolution of the analog digital converter (ADC) is 12 bit at a sampling rate of 10 kHz for all force, acceleration and gyro data. These parameters are adequate to detect all effects with sufficiently accuracy.

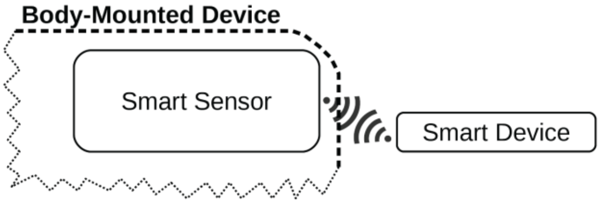

Figure 10: Direct connection from the MEMS+F-device to the smart device

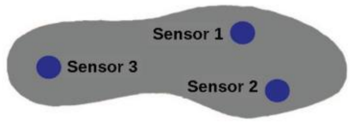

Figure 11: Sole configuration with 3 sensors for vertical force

The position of the three force sensors, used by the current prototype, are depicted in Figure 11. The force sensors extend the information from acceleration and gyro data to identify the center of gravity and to determine the different phases of the gait cycle (see Figure 9). In contrast to fixed installed measurement plate (Heidenfelder 2011), providing a one dimensional data stream for the vertical force, the mobile MEMS+F-device supports in the current version three force sensors as shown in Figure 11. Figure 12 shows this one dimensional data stream for the vertical force during two steps (Fzl: Left leg; Fzr: Right leg). Using three force sensors a far more detailed force level and force progression can be detected. In Figure 13 to Figure 16 the load distribution for the sensors 1 (red), 2 (green) to 3 (blue) (see Figure 11) for different scenarios, like step, run, jump and changes in balance are shown.

- Figure 13: Normal gait
  According the gait cycle the different force levels and the force progression for all force sensors over time are shown with regard to one step. From the initial contact on the heel up to the push off, the force levels for all ensors are available over time.
- Figure 14: Running
  In comparison to the gait, here the shorter and more intensive force level, dependent on the way of running, is shown over time.
- Figure 15: Jumping
  All phases of the jump including the short flight (forces=0) between 930 ms and 1110 ms are evident.
- Figure 16: Standing with changes in balance
  At first the posture is inclined slightly to the front moving to posture which is inclined slightly to the back.

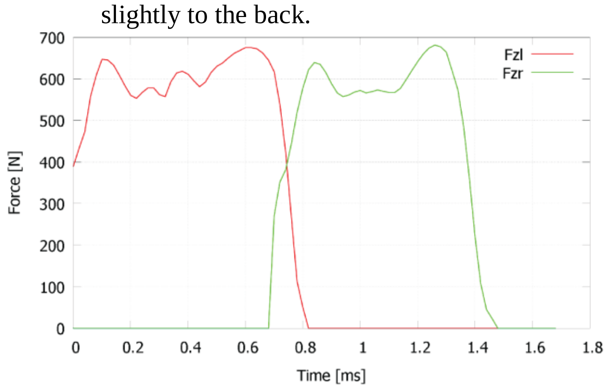

Figure 12: Normal gait: Vertical Force plotted over time on a fixed installed measurement plate (Fzl: Left leg; Fzr: Right leg)

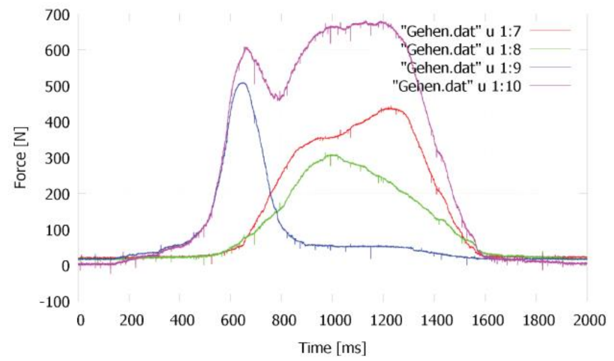

Figure 13: Normal gait: Vertical Force plotted over time on a fixed installed measurement plate (Fzl: Left leg; Fzr: Right leg)

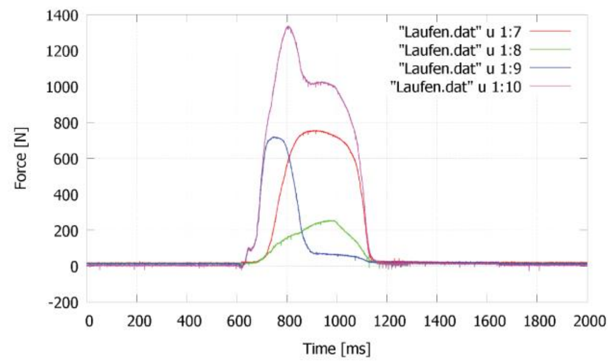

Figure 14: Normal gait: Vertical Force plotted over time on a fixed installed measurement plate (Fzl: Left leg; Fzr: Right leg)

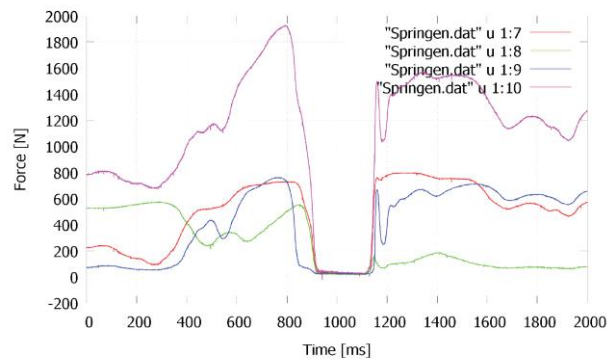

Figure 15: Normal gait: Vertical Force plotted over time on a fixed installed measurement plate (Fzl: Left leg; Fzr: Right leg)

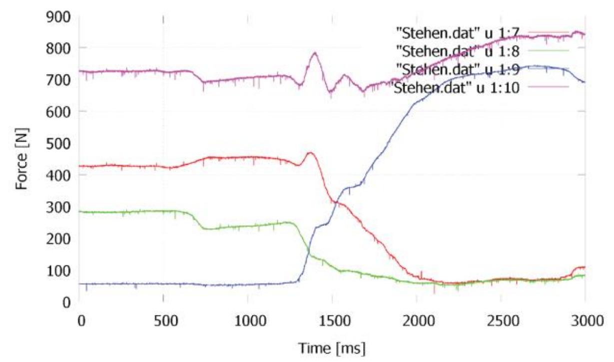

Figure 16: Standing with changes in balance, right leg: Vertical Force plotted over time for 3 sensors (1 (red), 2 (green), 3 (blue), sum(1,2,3) (magenta), see Figure 11)

5. SUMMARY AND FURTHER WORK

The presented approach for a platform-based embedded biosignal acquisition and identification system offers a wide range of medical applications. The modular system character based on the platform paradigm provides adaptability to different diagnostic, rehabilitation monitoring and control scenarios with regard to computing power, connectivity and analog frontend characteristics.
The embedded EMG- and ENG-based biosignal data acquisition and identification system, using a flexible hardware and software-platform, offers considerable potential. Additional tests and clinical applications are ongoing to improve the system characteristics and the identification method further.
The use of monitoring platforms based on platform architectures allows flexibly tuning the system to different application scenarios. The additional integration of IoT systems further expands the range of applications and allows the correlation of data and thus the sensor fusion and context recognition. The new IoT-device, also designed according the platform paradigm, helps to acquire missing data, like MEMS- and force data for identification, and provides a smart integration into the platform using wireless links. Based on the developed IoT-device new applications are constantly emerging, like rehabilitation monitoring, gait evaluation and training-based motion sequence optimization.

The current research and development activities have a dual focus: On the one hand the further development and verification of identification algorithms and the integration of MEMS- and force data, on the other hand the deployment of a software framework for monitoring applications.

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AN ACTIVE SURFACE APPROACH FOR SEGMENTATION OF BONE FRAGMENTS IN TRAUMA SURGERY PLANNING

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ABSTRACT
Recent developments of 3D computer technology, as computer graphics, haptic interaction, and 3D rapid prototyping, show promising potential for accurate, patient specific surgical planning. Traumatic surgery may potentially benefit from novel 3D technologies, both in the context of diagnosis and surgical planning. An inevitable prerequisite is accurate morphological segmentation, especially in trauma surgery, where all bone fragments, after a traumatic impact are mostly not clearly distinguishable using common segmentation techniques. A novel method is presented for the separation of these fragment clusters; the concept of adaptive surfaces. A flexible grid of control points is subject to motion, controlled by internal and external attracting forces to assess the outer surface of the bone, applicable for both joints and fractures. Internal forces control the stiffness of the surface and external forces act between the lattice and the landmarks on the bone surface, represented by principal gradient magnitudes. The algorithm yields proper classification of fracture parts and was successfully tested with geometrical phantom data and CT patient data from a heel bone fracture.

Keywords: segmentation, active contours, surgical planning

1. INTRODUCTION

The reconstruction of traumatic fractures is amongst the most challenging tasks in surgery. The number of bone fragments, the disorder caused by the impact, where the parts may be substantially displaced, rotated and even stuffed into each other, need certain experience from the surgeon, as well as a high degree of spatial sense combined with a survey over the surgical situs.
Modern medical imaging devices, e.g. multi-slice CT, provide high resolution 3D image data, allowing accurate diagnosis and staging of the severity of injury. Though there exists a broad spectrum of 3D visualization methods, the systems allowing for manipulation and rearrangement of bone fractures are limited.
The complexity of bone traumata, e.g. fractures of the ankle joint, make it sometimes difficult to reconstruct the original state of morphology and function. Besides these constraints surgery is always a kind of stress situation, requiring distinct decisions in a very narrow temporal slot. Tools for careful identification, repositioning and fixation of bone fragments prior to surgery are desirable and will fit into surgical planning systems (Gorres et al. 2016).
In this work an adaptive surface model is developed to enable the separation of bone fragments after rough pre segmentation by robust methods as thresholding and region growing. The concept of the developed method is in the category of algorithms as evolving or self-adaptive contours, implementing various physical concepts: the propagation of wave fronts (Osher and Sethian 1988), snakes, active contours, and level sets (Bookstein 1996, Wang et al. 1996, Zhu and Yan 1997). The novel segmentation technique is the base for a planning system, comprising general methods for morphological modelling using robust algorithms with little user interaction. The object models are supplied to a manipulation tool, allowing for easy replacement of bone fragments and planning the position of bone plates, screws, and nails.

2. METHODS

The method is applied to a show case of standard CT data taken from a heel bone fracture. Data is acquired on a multi-slice CT, the volume consists of slices with 512x512 pixels, pixel-size 0.72mm x 0.72mm and 0.5mm slice thickness. The number of slices ranges with these type of studies from 300 to 500, thus defines the depth of the volume of interest. Voxel data is represented in Hounsfield units (HU) with 16 bit/voxel.

2.1. Data preprocessing

Image data are reformatted to isotropic voxel-size, i.e. the slice thickness of 0.5mm. Scaling data up in-plane sampling distance is reduced from 0.72mm to 0.5mm, increasing the amount of data roughly by 40%. Cubic spline interpolation is used to calculate the isotropically resampled image data. For display voxel intensities are

rescaled to provide optimal contrast in the bone-window. Bone density shows a wide range of variation, ranging from hard cortical bone (HU=2000) to weakly absorbing spongy bone (HU=300).
A strong prerequisite for generation of accurate models is proper segmentation of all relevant parts. This is challenging, since the wide dynamic range of bone tissue in CT images and the irregular pattern of bone ruptures. The distinction of fragments is complicated by strain of parts into each other.
An edge preserving smoothing filter is applied to flatten intensity variations of image data in order to prepare for segmentation. A locally variant Gaussian shaped linear filter is applied to image data. The filter mask is derived from local gradient magnitude inversely weighted by an edge constant (Li et al. 2009).

2.2. Segmentation

The segmentation is a field of intensive research in medical image processing, where several approaches employing sophisticated mathematical and statistical method were developed (Nascimento and Marques 2005, Liang et al. 2006). Various frameworks are developed for segmentation of abdominal organs (Boes et al. 1994, Campadelli et al. 2010, Muralidhar et al. 2010). In this work a processing pipeline for segmentation of bones, i.e. a semi-automatic classification process under user supervision, is developed, under the constraint of minimal user interaction. It is a hierarchical two-steps process. The first step aims into rough segmentation of all bones contained in the volume of interest (VOI), it is important to identify all bones in the VOI since they build the base for further refinement to achieve final proper segmentation. For this initial segmentation thresholding is applied. The proper threshold values, to distinguish bone from surrounding tissue, are estimated using the optimum thresholding algorithm (Vala and Baxi 2013). The method achieves a large set of voxels representing the main bone morphology, but with no classification of single bones, and traumatic fragments.
This classification is implemented as supervised process with user intervention. The mainly grouped pixel-sets are segmented by seeded region growing. The seed-points are defined manually and the subsequent growing algorithm is realized in 3D. The identification of major well manifested bones is achieved, but a big number of smaller bones are tied together. This is sufficient for all bones not affected by the traumatic event, but to allow careful modelling and surgery planning further, detailed segmentation of the focused fragments is needed.

2.3. Active grid

In many cases the methods described above are not sufficient to achieve object classification of a trauma situs to allow accurate surgical planning. The broken and splintered fragments are partially wedged into each other, or not clearly separated in images, thus clusters of fragments are falsely identify as a single object. Further thresholding or methods from mathematical morphology are not appropriate to achieve final results, thus a novel method, relying on physical principles is developed to isolate the parts by building compartments.

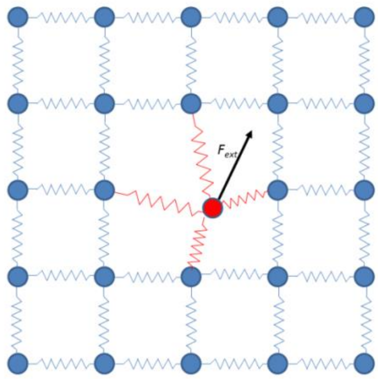


Figure 1: *Sketch of the adaptive grid.*

An adaptive surface is positioned interactively between the fragments. Starting from this initial position the surface is adapted to the shape of the fragments driven by external and internal forces. The external forces attract the surface to the external boundaries of the object; the internal forces control the smoothness of the surface. The active surface is assembled by four-sided patches, cf. Figure 1. Motion and deformation of the surface is controlled by the vertices of the patches. They are arranged on a lattice and joint to each other by springs, controlling the stiffness of the surface. External forces also affect these points, enabling the adaption to morphology. The kind of external force influences convergence and roughness of segmentation, possible choices are:

- spring like linear force,
- $1/r^2$ force like gravity,
- constant force to simulate convection.

Motion is calculated for all mass points during iterative steps. In small time intervals *Δt* the motion of all grid-points is calculated along the resulting force, corresponding to the equation of motion

$$m\ddot{\vec{x}} = \sum_{i=1}^{N} C_i \left(\|\vec{d_i}\| - l_{0i}\right) \frac{\vec{d_i}}{\|\vec{d_i}\|} + \overrightarrow{F_{ext}} \quad . \qquad (1)$$

The above equation describes the motion of a mass point, accordingly the resulting forces. Acceleration a is the second temporal derivate of the position vector $\vec{x}$, the sum describes the forces generated by the springs, N is the number of adjacent mass points, C_i is the spring constant of the respective conjunction, and l_{0i} is the length of the *i-th* spring in resting state. The vector $\vec{d_i}$ is the distance vector to the neighboring mass point. The external force $\overrightarrow{F_{ext}}$ is chosen in this work as gravity like force of the form

$$\overrightarrow{F_{ext}} = \sum_j G \frac{M_j m}{\|\vec{r_j}\|^2} \frac{\vec{r_j}}{\|\vec{r_j}\|} \quad . \qquad (2)$$

It sums up the attraction forces of all surface bound mass points M_j of interest, i.e. morphological landmarks, where $\vec{r}_j$ is the distance vector from the actual grid point to these morphological landmarks. The constant G and the fictive masses M_j allow the fine tuning of the algorithm. Since this type of external force reaches infinity when the distance approaches zero, a limit corresponding to a minimal distance r_{min} is defined, to avoid accidental sticking of the surface at some random landmarks, especially when the separation of two parts is desired and the surface has to fit into a small gap.

The morphological landmarks are generated by calculating the magnitude of gradients. To restrict the landmarks to points of the surface, thresholding is performed and the number of landmarks is reduced. The magnitude of the gradient is a guess for the mass of the landmark.

Calculating the evolution of the lattice is a very complex multi object problem, but the observation of small time intervals allow the linearization of the problem and thus decoupling of the multi body system. During a single iteration the trajectory of a grid point along its resulting acceleration vector is calculated. The iteration is completed when all grid points have been considered. This simplification allows easy computation but yields very realistic motion behavior.

For special purposes, e.g. the separation of loosely connected bone particles, selected grid points may be defined as static. This means, they remain at their initial positions; usually the outer borders of the lattice are defined static, building a stationary frame for the evolving surface. But also some arbitrary point of the lattice may be fixed to the bone surface, i.e. some kind of pretension of the surface, to further accelerate the evolution to the final segmentation form.

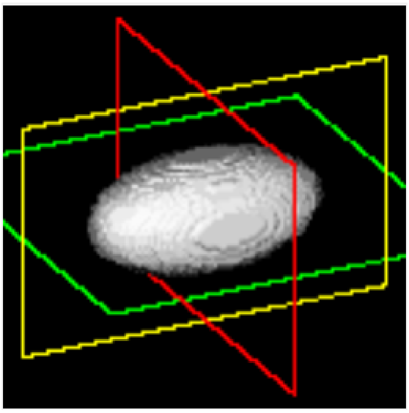


Figure 2: *Volume rendering of the ellipsoid phantom data set. The green, red and yellow frames indicate the axial, coronal and sagittal cutting planes.*

3. RESULTS

The active grid concept is demonstrated with simulated phantom data and a showcase of clinical data, the comminuted fraction of a heel bone.

3.1. Phantom data

Phantom data represent a homogeneous ellipsoid positioned at the center of a 128x128x80 image volume of isotropic voxels. The lengths of half axis are 40, 20, and 20 pixels. A volume rendering of the data set is shown in Figure 2.

Landmark points upon the surface are calculated using an unsharpen enhance filter. To speed up calculation and to easily exclude distant points, further than a certain threshold, a potential map is generated, based on the surface landmarks. In this case the potential field is calibrated to zero at the landmarks and a simple Euclidean distance field is applied. The three major cutting planes through the center of the potential field are displayed in Figure 3.

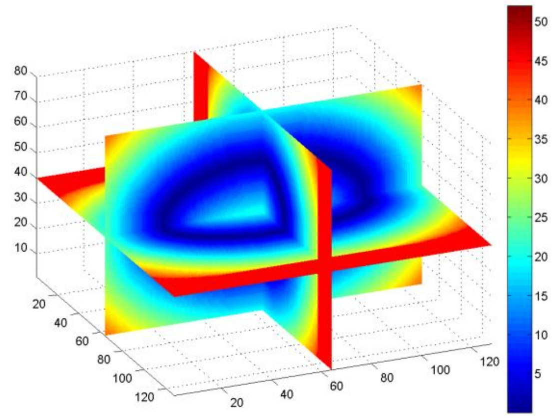


Figure 3: *Potential field of the ellipsoid's surface landmarks. A simple Euclidean distance metrics is implemented. The field values are limited to 45.*

A grid with 11x11 equally spaced control points is positioned in coronal orientation cutting the first quarter of the long axis of the ellipsoid. The four corner points of the grid are defined *static*. In Figure 4.a the grid is depicted, superposed to a transparent axial plane through the center of the ellipsoid. The opacity value of the plane is 0.7. After an evolution of 1000 iterations along the negative gradients of the potential field, the deformed plane yields its final shape. It is positioned exactly on the border landmarks of the ellipsis, cf. Figure 4.b.

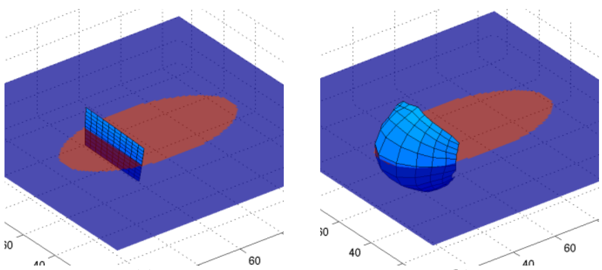


Figure 4: *Evolution of the grid. A grid with 11x11 control points, fixed at the four corners, evolves 1000 steps along the descending gradient of the potential field. The initial position (a) and the final position (b) are depicted.*

3.2. Patient data

Real patient data, as acquired prior to surgery, are usually contaminated with modality inherent noise. Noise reduction and emphasis of edges in image data facilitate successful segmentation with the evolving surface algorithm. During the first processing step image data is smoothed. The effect of the edge preserving adaptive filter is shown in Figure 5, with different settings of the edge parameter and the mask size. The native image is shown in Figure 5.a, the slice is slightly below the ankle, and thus the metatarsal bones are shown on top, followed by the tarsal bones and finally the fractured calcaneus (heel bone). The images (b) and (c) are calculated with mask size 3x3 and 10% and 40% of maximal gradient magnitude. The results with mask size 5x5 and 10% magnitude scaling are shown on the right in sub-image (d).

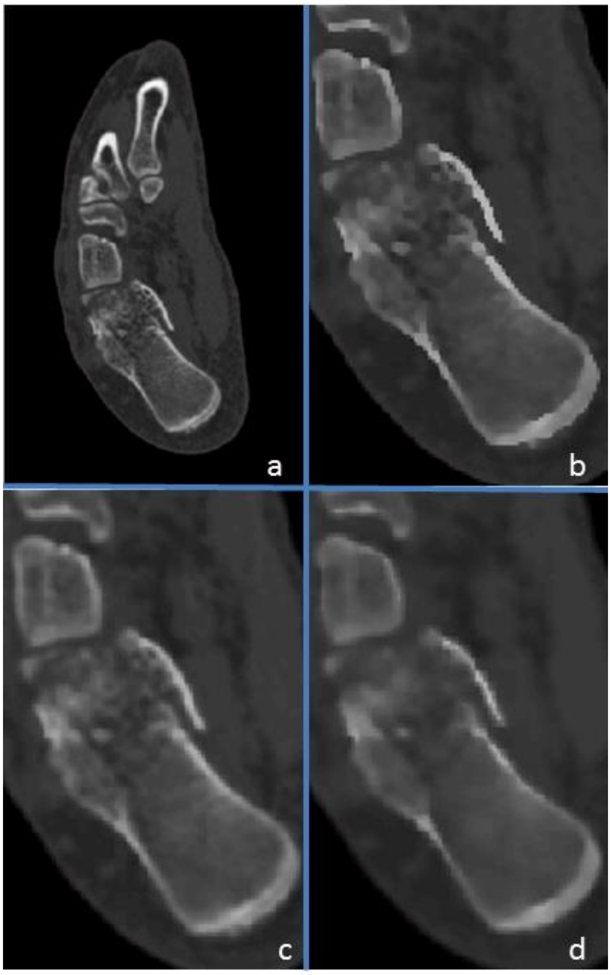


Figure 5: *Edge preserving smoothing with different parameter settings for mask size and edge strength.*

The results of the pre-segmentation step are shown in Figure 6. A simple thresholding followed by a seeded region growing is performed. The method is sufficient for accurate separation of soft tissue and bones, but classification of all bones as separable objects, as required by a planning system, is not achievable.

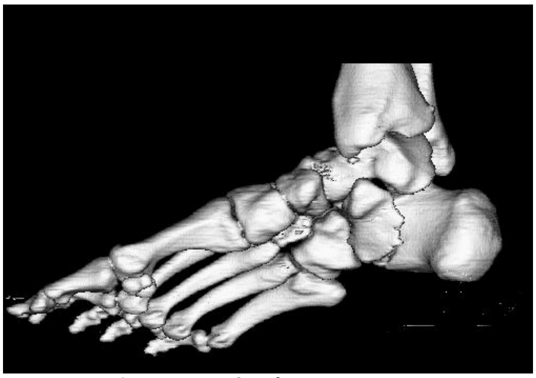


Figure 6: *Results of pre-segmentation*

The potential field yielded from the surface of the pre-segmented volume is shown in Figure 7, three perpendicular representative slices through the image volume are displayed.

The active grid approach, based on the primary segmentation, keeps the chosen thresholds. Increasing thresholds are in most cases along with the erosion of substantial parts of bone morphology, not tolerable with accurate reconstruction of the injured extremity. The feasibility for the active grid segmentation approach is demonstrated with tarsal bones and the upper ankle joint. The position of the initial 15x15 grid is shown in Figure 8.a on top of two transparent perpendicular slices, with opacity value 0.7. It is manually localized by defining the four vertices. In its initial position it traverses the ankle bone (talus), thus only the uncovered edges are clearly visible. The final surface is shown after 1000 iterations with a time increment of 0.2s, cf. Figure 8.b. It fits exactly into the joint gap and

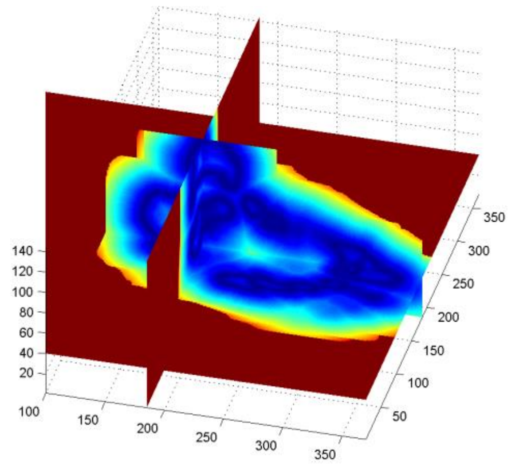
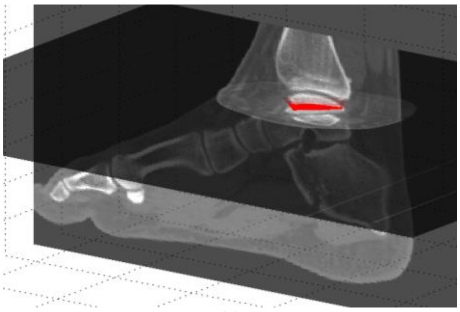
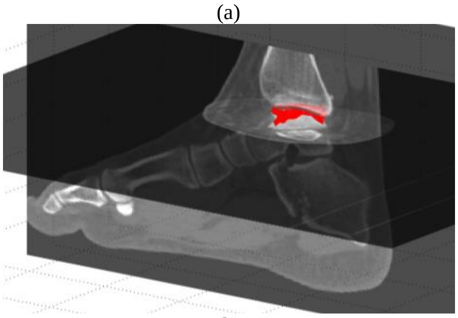


Figure 7: *Potential field of the landmarks at the bone surfaces of the CT examination of the heel bone fracture.*

facilitates easy separation of the talus and the shinbone (tibia). The applicability of the method is also demonstrated with smaller joints in the tarsal area. The position of the manually defined, initial 11x11 lattice is shown in Figure 9.a. The result after 1000 iterations merely fits to the shape of the tarsal bone and defines a distinct border for separation of both parts, cf. Figure 9.b.

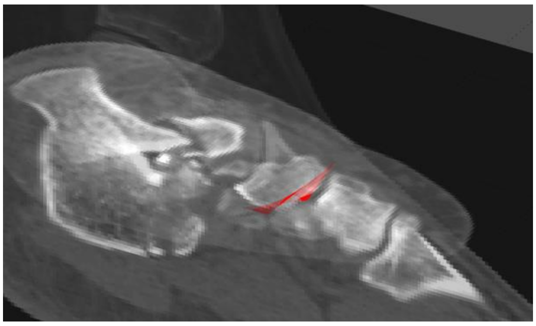


(a)

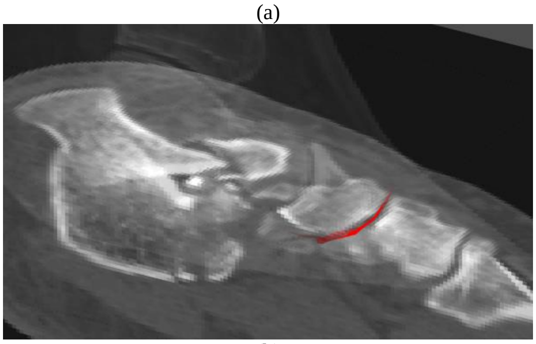


(b)

Figure 8: *Segmentation of tibia and talus with the active grid approach. The lattice is drawn red at its initial position (a) and after 1000 iterations it fits perfectly into the gap between the bones (b). The grid is drawn over two perpendicular cutting planes, with an alpha value of 0.7.*



(a)



(b)

Figure 9: *Separation of tarsal bones. A 10x10 lattice (red) at the initial position (a) and after 1000 iterations with time constant 0.2s it perfectly masks the joint surface (b).*

The final result of segmentation achieved with the adaptive surface algorithm is depicted in Figure 10. The mainly linked bone morphology, obtained by pre-segmentation with thresholding and region growing is further separated in detail, employing the adaptive surface method. The colored segments are shown in Figure 10, the heel bone is represented in olive color, the fragments of the heel bone are colored blue and turquoise, the broken and displaces tarsal bone is shown in red. The bone is rotated in such a way that the joint surface is oriented backwards.

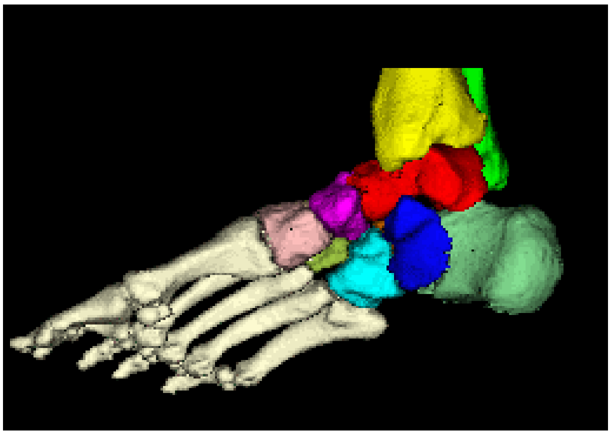


Figure 10: *Final result of adaptive surface segmentation*

4. DISCUSSION

A novel segmentation algorithm employing an active layer for proper separation of pre-segmented bone fragment is presented. The algorithm is integrated into a pipeline of sophisticated image processing steps, facilitating accurate 3D surgical planning. The algorithm is mainly designed to separate agglomerated bones from each other, after a rough pre-segmentation step. It differs from existing approaches like active contours or snakes, since the internal forces operating on grid nodes are solely attracting forces. They provide no stiffness to the evolving surface, thus a close approximation to the given surface is possible. The adaption to the surface is mainly achieved by the external forces. This composition has certain potential to remove random outliers from the resulting segmented parts. Furthermore this design of internal forces is suitable to fit into small joint spaces, the approximation is only controlled by the adjacent joint surfaces and the internal forces just act as shear forces to optimize the energy within the grid.

In further work the influence of weighting the surface landmarks with scene dependent point loads and the choice of other potential functions on the convergence of the method will be investigated.

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LEARNING EFFECTS IN PROFESSIONAL TRAINING FOR EMERGENCIES MANAGEMENT IN INDUSTRIAL PLANTS WITH SERIOUS GAMES

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ABSTRACT

The complexity of situations and potential error connected to maxi-emergencies and disasters management are increasing in the last years. The analysis of natural disasters and related possible dysfunctions of the "emergency chain" leads to well-encoded rescue plans. The simulation has allowed in recent years to improve and optimize the management of these events. This study presents results of a new serious game that simulates activities, procedures and processes that have been implemented to train figures entitled in the management and aid activities during the maxi-emergencies that may occur in industrial plants.

In particular, the serious game presented is based on a discrete event simulator and it is able to reproduce emergency situations in which the players can assess their own abilities. The results presented show how the use of such training simulator significantly improves the initial score, increasing the awareness of coordination and decision-making abilities in emergency situations.

Keywords: simulation, serious games, maxi-emergency, health

1. INTRODUCTION AND MOTIVATION

Virtual training offers a huge potential to reduce the time and effort of traditional hardware training (Ordaz et al., 2015). However, before being deployed in an industrial environment, virtual training systems need to prove their reliability and user acceptance: with this purpose Ordaz et al. (2015) determined the impact of gaming experience on the learning process of a manufacturing operation using a serious game that simulates manufacturing environments in order to train operators to perform manual tasks; ten operators participated in the study, which found that gaming experience influences positively on training completion time. Boyle et al. (2016) developed a systematic literature review where most frequently occurring outcomes related to games for learning was knowledge acquisition, while entertainment games addressed to broader range of affective, behaviour change, perceptual and cognitive and physiological outcomes. Games for learning were found across varied topics with Science, Technology, Engineering and Maths (STEM) subjects and health the most popular. Smith (2010) underlined how military field used games for training, tactics analysis, and mission preparation for Centuries: the challenge in that field is computer gaming, that offers a dynamic representations of the physical world and proposes interesting and useful tools for operating training where real-life simulations are not possible or not convenient (i.e. considering economic or logistic aspects). Wiemeyer and Kliem (2012) discussed the impact of serious games (SG) on prevention and rehabilitation, applying different criteria: effectivity and efficiency, as well as additional benefits of serious games that can be described and explained by different models including social, psychological, physiological and sensory–motor factors. The main aim of the study proposed by Knight et al. (2010) was to evaluate the effectiveness of such a serious game in the teaching of major incident triage by comparing it with traditional training methods. As a main result of the work they conclude that serious game technologies offer the potential to enhance learning and improve subsequent performance when compared to traditional educational methods. Concerning the role of serious games to facilitate sustainable change in aviation industry, Zon et al. (2012) presented A Learning, Training & Mentoring Framework (LTM) that supports change initiatives involving training and competence development for change management skills, in order to facilitate the implementation of these skills in practice. Finally, next to the world of training, Longo et al. (2014) applied serious games and simulation to develop a mobile device application for tourists that can enjoy digital contents through interactive and virtual experiences. In the same work the authors also presented another mobile app, based on augmented reality and on an intelligent personal assistant, aimed at creating new patterns of interaction with real contents and historical findings during a real tour in a museum or in an archaeological site.

A particular area for the development of serious game is the “health sector”, with particular emphasis on the games for professional training, e.g. simulations for medical staff training, emergency management, ... In

these areas the decision-making process is very dynamic and complex. Strohschneider et al., (1999) analysed the complex decision-making processes and the human tendency to make certain kinds of mistakes. Danielsson et al. (1997), focusing their study on the analysis of emergency management, concluded that in these areas it is essential to have high information and training: in such situations, an error in the decision-making process can become very dangerous and have a possible disastrous impact on the entire system. Emergency management is based on "staff work" that focuses on the design, coordination and monitoring of the operational procedures (Orasanu et al., 1996). A list of serious games developed for emergencies management is shown in Table 1: no simulator appears compliant with the Italian Regulation and might be suitable for training Italian's emergency staff.
The serious game presented in this work aims at proposing a model of reality that allows the evaluation and prediction of dynamic and interactive execution of a series of events and processes, enabling operators (the player assumes the role of Medical Disaster Manager - MDM) to experience countless situations, and to define best practices to be adopted in all possible scenarios and variants, thus increasing their experience and preparation. In particular, the actions that the player can choose are designed in compliance with the Italian Regulation.
Main aim of this research is to investigate how the usage of this new developed serious game by different skilled operators may help their learning process.
The remainder of the paper is organized as follows: Section 2 describes the assumption and the logic of the simulator, Section 3 presents the structure and the functionalities of the simulator. The main findings on learning effects while using the tool are discussed in Section 4. Finally, conclusions and future research developments are summarized.

Table 1: Characteristics of serious games for emergencies management

Name	Developer	Description	Regulation area
CERRTS – Civil Emergency Reaction and Responder Training System	Raytheon	Training Emergency Operation Centres (EOC) Operators	USA
A-TEAM, Advanced Training System for Emergency Management	Environmental Software and Services GmbH	Real-time training experience in the field of emergency management	USA
Emergency Preparedness Incident Command Simulation (EPiCS)	U.S. Army Training and Doctrine Command Analysis Center (TRAC)	Set of tools that allow to simulate, visualize and record the activities carried out during the management of an emergency	USA
NCBR - Nuclear, Chemical, Biological, And Radiological Environment Ser- ver	ITT Industries, US Army Soldier and Chemical Biological Com- mand, Defense Threat Reduction Agency	The NCBR is a set of simulation and modeling tools that allow you to analyze and manage nuclear disasters, chemical, biological and radiological	USA
VERTS - Virtual Emergency Response Training Simulation	U.S. Army STRICOM	VERTS is a powerful simulation software used by the US National Guards	USA

2. ASSUMPTION AND SIMULATION LOGIC

In this section the main structure of the simulator is provided, by explaining the key objects and parameters. In particular, the simulator is divided in two main sections: a scenario configuration section, where it's possible to set the scenario for the game, and a game section where the scenario is played. Below are listed the different scenario configuration areas; the game section is presented in Section 3.
In figure 1 the entities of the simulator and their relationship are presented. In the specific, it's possible to set up:

- Scenario description
- Victims
- Emergency vehicles
- Accidental event
- Activities and human resources.

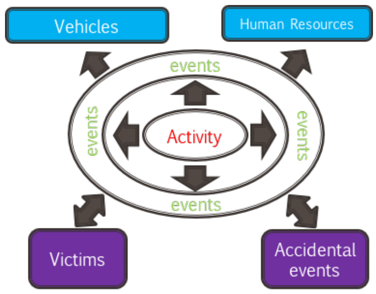

Figure 1: Entities of the simulator

Scenario description setting
The first section to configure is the discursive scenario description which has to include the text that describes the initial situation of the scenario and all initially information. This text will be shown to the player in a special dialog box before the game start. This permits to communicate to the player the appropriate information about the game.

Victims setting
This section contains a list of all persons involved in the event that has caused the unexpected emergency, precisely named "Victims". In particular, it should be decided ex-ante how many victims to consider and their characteristics. It's no limitation on the number of victims, however, the scenario appears likely if the number of victims is comparable with the number of resources (emergency vehicles and human resources) that the player has available (to be configured in separate sections). Of course a large number of victims, ceteris paribus, increases the difficulty of the scenario. Each victim, besides being uniquely identified, is characterized by the following configurable parameters:

Gravity

Allowed values: W (White), G (Green), Y (Yellow), R (Red), B (Black).
Description: Specifies the starting severity code of the victim: from slightly injured (White) to the deceased (Black).

Victim Awareness
Allowed values: Yes (the victim is known and the player can act on it), No (the victim is not known).
Description: Indicates whether the victim is initially known to the player. Likely only a low percentage of victims will be known at the initial time. The other victims will be discovered only if and when the player decides to make a reconnaissance of the event place.

Location
Allowed values: INT (Trapped), LOC (Localized).
Description: This field identifies the position of the victim in the rescue process.
Initially, the victim can be (1) trapped (INT), so that before being taken from rescuers, he/she has to be vacated (e.g. extracted from the rubble), or (2) localized (LOC) that he/she may be treated immediately and then recovered (transported to Collection point). During the simulation, it is expected that the victims position can take on different states: once completed the first medical treatment (preparation of the victim to the recovery phase) he/she reaches the state of treated (TRT), once recovered, he/she has the recovered status (REC), and then completed the phase of medication, he/she gets the status of medicate (MED) and finally, once identified the transport vehicle to the hospital, he/she reaches the final state of evacuated (EVA), that represents the completion of the rescue process of the victim.
Once the victim is sent to a hospital, the simulator considers the rescue process for the specific victim as completed; downstream stages are not covered.
It must also consider that the severity of the victim is modified over time according to a stochastic law set in this section. In particular, this law generates a parameter indicating after how long the victim's status is changed from the current one to the next with a consequent increase of severity.
During the rescue phase the main objective is to ensure the safety of victims and to stabilize their condition, not to cure (in the strict sense) victims. Therefore, it is not possible that a victim in Green code can change its code in White and so, recursively, for all other colour codes.

Emergency vehicles setting
This section contains a list of all the emergency vehicles. In a similar manner to the victims setting, in the scenario definition phase it's possible to decide ex-ante the number, type and other characteristics of all the resources that the player may request for the intervention. Also in this case there is a limit to the maximum number of vehicles that it's possible to make available. However, the number of available vehicles must be related to the victims involved as mentioned above. Of course, the lower the available vehicles the more difficult will be the emergency management. Per every vehicles it's possible to specify the type; you can choose from five different varieties: ambulance (MSB), equipped ambulance (MSA), helicopter (ELI), firefighters vehicles (APM) and finally police vehicles (VOL). In the scenario setting, it's possible to set up the time that the vehicles need in order to arrive at the event place.
Having the opportunity to decide the time of arrival of each vehicle, it allows to simulate different starting points for each type of vehicles and between vehicles of the same type. In this way, for example, by configuring appropriate times of arrival, one can establish that a number of ambulances can leave from a certain place and some other from a different site.
The last parameter that must be defined is the time required for a vehicle to transport a victim to the hospital, starting from the event place (this parameter should only be considered for those types of vehicles able to transport the victims: ambulance and helicopter).
Who configures the scenario cannot characterize the single resource, or the specific rescuer, doctor, policeman etc. In reality, however, during the simulation it will be also possible to act on the individual resources. In fact, any type of rescue vehicle, upon arrival at the event place, makes available a predetermined amount and type of resources. These, unlike the emergency vehicles and victims, are not uniquely identified but are managed "at group" (it is managed only the type and relative amount). All other parameters, such as the time required to perform a given activity, will be differential between only one type of resource and another. The following table shows for each type of emergency vehicle, type and quantity of contained resources.

Table 2: Composition Vehicles / Resources

Vehicles / Resources	Emergency medical technicians (EMT)	Medical Doctors (MD)	Firefighters	Policeman
MSB	3	0	0	0
MSA	1	2	0	0
ELI	2	2	0	0
APM	0	0	5	0
VOL	0	0	0	2

Accidental Event Setting
In this section, all the accidental events can be entered, such as fires or gas spills. Who set up the scenario must decide ex ante all the accidental events that may occur. There is no maximum number of accidental events; however, the number of events must be related to emergency vehicles that the player may request. Each accidental event is characterized by a textual description, a severity indicator and some parameters that determine its temporal evolution. Of course, increasing the number of scheduled events, their severity and speed of development, it will increase the overall difficulty of the scenario. In detail, the fields to be defined are the following.

Gravity

Description: Defines the initial severity code for each accidental event. Gravity is measured on a scale of three numeric values: 1 (minor), 2 (bad enough), 3 (very severe) and 4 (hopelessly severe)

Start
Description: Indicates at what point in time, from the beginning of the simulation, the specific accidental event will take place. It's possible then configure one or more accidental events both at the initial instant, or after a certain time since the start of the simulation. Hypothetical maxi-emergency due to an explosion may for example provide a set of fires already at the start of the simulation and a leakage of harmful fluids after a certain period of time.

Description phenomenon
Description: This field (optional), which describes the type of accidental event, will be shown to the player when the event occurs and at each deterioration stage of the event. Whereas it is not possible to define different types of events, this field has the objective to provide the player a concise description to facilitate the management of resources to be used for resolution of the event.

The evolution of the state of severity of each event partially follows the one of the victims. When an accidental event occurs, it takes on the severity code set in the field and it continues to deteriorate until it reaches its last possible value, or 4. The intervention of one or more resources to deal the accidental event, after the time required to perform the treatment, causes a reset of the event itself, or its severity code is reset and its temporal evolution is cancelled.

When an accidental event occurs or when it undergoes a worsening of its severity code, it will have negative repercussions on the victims. This special feature is designed to assure that the player quickly manages the accidental events, in order to minimize the worsening of the condition of the victims. The following table describes the effects on the victims for each severity code.

Table 3: Description severity code

Severity	Victim's effects
1	No effects
2	Increasing of the worsening speed (default 10%)
3	Increasing of the colour code Gravity for victims in the state (LOC, INT and TRT)
4	All victims in the state LOC, INT and TRT become Black (B)

Activities setting
This section contains all the tasks that the player may decide to implement during the simulation session. During the scenario simulation each activity is represented by a command button in a dialog box. In this way the player can decide which activities to perform and their sequence. Each task can be configured by editing the appropriate parameters. Each activity is represented by the following parameters:

- The first field contains the description of the activity.
- The second set of parameters has the aim to define which types of resources can be assigned to an activity and the time needed to complete the action. It's possible to sort the various types depending on the efficiency in performing a task.
- The third set of parameters is represented by the minimum and maximum number of resources that the player may decide to assign to the specific activity. The number of resources that the player assigns to each activity is reflected on the related execution time: for each additional resource, the previously defined execution time is reduced by 25%. This methodology prevents that the execution time of any activity becomes zero due to the high number of allocated resources.
- The fourth and final set of parameters describes the effect that each activity will have on other variables (emergency vehicles, accidental events and victims). For some effects, it's possible to change the value of the parameter that determines the amount (weight) of the effect described. In the following section the activities and the related effects are reported.

3. THE SIMULATOR

The developed simulator models the rescue management in a maxi-emergencies that may occur in an industrial plant. The overall objective is to evacuate the maximum number of victims in the shortest possible time with the rational use of the available resources. The model predicts the existence of certain classes of variables, which are characterized by specific attributes, as described in the previous paragraph.

Time passing, the victims and accidental events worsen their status. To contrast this development, the player will trigger the activities that will allow him/her to use resources and vehicles in order to accomplish the actions on the victims and on the accidental events. Noting that, as explained above, the objective of the game is the rescue of the victims, in order to avoid that the player is brought to ignore accidental events, the model predicts that any worsening of the severity of an accidental event produces a health worsening of the victims. In this way the player will be brought to dedicate part of the resources available to treat even accidental events.

The most critical aspect in emergency situations is certainly the time. For this reason, the simulator is equipped with a virtual time line, connected to the game timer, inside which are placed all events that entail a change of the attributes of the classes listed above. At the beginning of the game, some events based on information imported from the scenario setting are automatically loaded. Subsequently, each time the player decides to start a specific activity, the simulator will generate other events that will place on the virtual time line as a function of the durations and delays computed

by the probability distributions. In general, the game timer runs constantly throughout the simulation session. However, in the event that, due to the temporary unavailability of resources due to the actions undertaken by the player, it is not possible to do any activities, the simulator will implement an instantaneous temporal advancement to the next event on this virtual time line. This prevents the player to spend time without being able to take any action.
The model has been coded in MS® Excel® with Visual Basic® for Applications routines. The choice of this simple environment was to guarantee the portability and the easy development of the prototype. The next step will be to implement the model in a Web-based environment.

Starting the game simulator.
At the start time, once the scenario is chosen, it is shown to the player a dialog box containing a text description of the scenario that will be simulated. The text has the purpose of presenting the scenario, describing in a generic way the main features, such as the type of plant, the type of incident, the logistic characteristics of the area and other information that distinguish the situation of departure.

Allowed gaming action.
After starting the phase of real simulation, a graphical interface is shown containing some dialog boxes. In figure 2 it is shown the simulator dashboard.

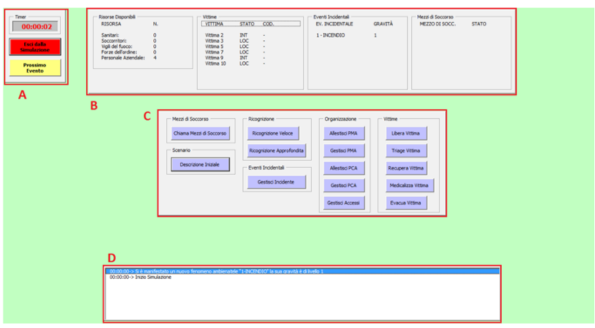

Figure 2: Simulator's dashboard

At the top of the screen there is a window, named "Status Bar" [B], where on-time conditions of the known victims are shown, together with emergency vehicles, available resources and the state of accidental events. in this way it's possible to check at any time the overall state of all the elements involved. In the central part of the screen it's possible to see another window, i.e. "Dashboard Activity" [C] dialog box where the player can see all the activities that he/she can undertake during the simulation, in order to arrange the logistics of the emergency area and manage resources at its disposal. The activities mentioned above are contained in "Activities" section. In the upper left part of the dashboard there is another window, named "Timer" box [A], that keeps track of time throughout the simulation session. Finally, it is provided a space dedicated for alerts [D] that informs the player on the duration of the simulation, as well as on the events and changes in the status of the variables involved.
The dashboard of the activity is organized in sections that group activities according to their characteristics. In the following all the activities that the player can undertake during the simulation are described.

Call emergency vehicles.
This is the only activity that does not require the use of resources or emergency vehicles to be activated. For this reason, even if the player is not formally forced to follow a predefined sequence during the simulation, this appears to be the first action to be performed. In fact, if the player decides to activate another activity, the simulator, verified the unavailability of resources, would return an error message and prevent the player to move on. After pressing the call button, the player can select user-emergency vehicles appropriate. In this phase it is important that the player considers that each rescue vehicle contains a given number and type of resources. Completed the selection of the vehicles, the simulator will calculate the instant when each vehicle will arrive on the place of the event. This is a fundamental activity for the success of the game: an inadequate sizing of the emergency services available on the place of the event will result in a bad final performance. In case additional vehicles and resources are required during simulation, the player-user is still able to do another (or more) call.

Fast reconnaissance and Deep reconnaissance.
Both reconnaissance can be used only once during the game. Furthermore, the start of deep reconnaissance automatically inhibits the fast: this is because the deep reconnaissance is nothing more than an extension of that fast. When you start a survey, the simulator will ask the player to select the type and amount of resources to be allocated to this activity. As explained earlier, each resource type can have a different execution time. So, it is necessary to carefully choose the most suitable type of resource for each activity. Also, the greater the number of resources allocated to the activity, briefer will be the running time. What distinguishes fast respect to deep reconnaissance are the completion times (the deep one will take longer) and the effects they generate on other variables. In fact, if the player will choose to perform a fast reconnaissance the unknown victims, who are inside the event place but which are not trapped, will be revealed. Using the deep reconnaissance instead, it will be revealed to the player also the trapped victims.

Accidental event control.
This activity allows the management of an Accidental event. The player can start this business a certain number of times, until there is at least one active Accidental event. When the button is pressed, the player has to specify on which of Accidental events he/she intends to act and then he/she selects the type and amount of resources to be allocated. Once the activity is set and confirmed, the simulator, on the basis of type and number of allocated resources and seriousness, will calculate the

actual duration of the action. At the end of this operations, the player can see an alert information and the treaty event is solved.

Build AMP (Advanced Medical Place).
This activity can be undertaken only once during the simulation and it allows the user to prepare an Advanced Medical Place. When the button is pressed, the player will have to specify the type and amount of resources to be allocated. The construction of an AMP has no direct effect on the variables involved (victims, resources, etc.); however, it allows the user to be able to undertake the activity entitled "Activate AMP".

Activate AMP (Advanced Medical Place).
This activity allows to allocate resources for the management of the AMP. The activation of the AMP will have the effect of reducing the percentage of the treatment time.

Build ACP (Advanced Command Place).
This activity can be undertaken only once during the simulation and allows the player to put on an Advanced Command Place. When the button is pressed, the player will have to specify the type and amount of resources to be allocated. The construction of an ACP has no direct effect on the variables involved (victims, resources, etc.); however it allows the user to be able to undertake the activity entitled "Enable ACP".

Activate ACP.
This activity allows to allocate resources for the management of the ACP. The activation of the ACP will have the effect of reducing the percentage of the execution time of all the operations carried out by resources.

Access management.
This activity allows to allocate some resources to the management of the input and output of emergency vehicles passages. When the button is pressed, the player will have to specify the type and amount of resources to be allocated. This type of activity does not provide a time duration, so the allocated resources will not be available for other activities throughout the duration of the simulation. Access management will have the effect of reducing the percentage of the time of arrival and evacuation of emergency vehicles.

Free victims.
This activity allows to free any trapped victim. The user-player can select this activity every times that there is at least one known victim in "INT" position, or trapped. When the button is pressed, the player will have to specify which victim of "INT" he/she intends to free and later he/she will have to select the type and amount of resources. The simulator, on the basis of type and number of allocated resources, will calculate the actual duration of the action. At the end, it's possible to see an alert information, the victim will be released (their status will become "LOC") and the previously committed resources will be available for other activities.

Victim's Triage.
This activity allows to treat any non-trapped victim who is on the place of the event. The player can start this activity if there is at least one known victim in "LOC" position, or localized. The player will have to specify which victim of "LOC type", he/she intends to treat and later will have to select the type and amount of resources to be allocated. The simulator, on the basis of type and number of resources allocated and the severity of the victim, will calculate the actual duration of the action. So, the status of the victim will pass from "LOC" to "TRT" (treated) and previously dedicated resources will be available for other activities.

Victim's recovers.
This activity allows to carry a victim from the localization place to the collection point, or AMP. The player can start this activity if there is at least one known victim in "TRT" position or treated. The player will have to specify which victim, type "TRT", intends to recover and later will have to select the type and amount of resources to be allocated. The simulator, on the basis of type and number of allocated resources, will calculate the actual duration of the action. So, the status of the victim will change from "TRT" to "REC" (recovered) and the previously dedicated resources they will be available for other activities.

Medicalizes Victim.
This activity allows to medicalize any victim who is at the point of collection. The player can start this activity if there is at least one known victim in the "REC" position, which is recovered. The player will have to specify which victim of "REC type", he/she intends to medicalize and later will have to select the type and amount of resources to be allocated. The simulator, on the basis of type and number of resources allocated and the severity of the victim, will calculate the actual duration of the action. So, the victim's status will change from "REC" to "MED" (medicalized) and previously dedicated resources they will be available for other activities.

Evacuates Victim.
This activity allows to evacuate any victim previously medicalized. The player can start this activity if there is at least one known victim in the "MED" or medicalized, and at least one rescue vehicle for the transport of the victims. The player will have to specify which victim of "MED type", he/she intends to evacuate and later will have to select the type and amount of resources to be allocated and the rescue vehicle to use. So, the status of the victim will change from "MED" to "EVA" (evacuated) and consequence will end the rescue process of the specific victim. The simulator, according to the type and number of assigned resources and to the vehicles chosen, will calculate the actual duration of the

action. At the end of this activity, previously dedicated resources and vehicles will be available for other activities.

Simulation term.

When all the victims have been evacuated or died, the simulation finishes. A report of the simulation session is shown, listing all the actions taken by the player and the situation of all victims, resources, transport and accidental events. In addition, it is computed an overall score that will allow the user to compare any other simulation sessions and evaluate improvement (or deterioration) over time. It's important to consider that the simulator presents two game mode: easy and hard mode. In the easy mode the player can see the list of the choices made during the game. In the hard mode, no information is supplied during the game. The hard mode tries to simulate the real situation during a maxi-emergency when it's hard to have updated information.

4. GAME'S RESULTS ANALYSIS

The goal of the presented serious game is to increase learning and the preparation of emergency managers. Particular attention is then placed to the analysis of simulation results, thus two macro-investigations are carried out.

The considered topic does not allow the validation of the simulator with field-tests (Experimental validity). So we have validate the simulator with test validity; the simulator would in general be a valid measure of emergency management skill if performance on the simulation was a good indicator of emergency management performance on real context in a real emergency. In particular, the simulator contains content that relates to the knowledge that is required in the area of emergency management. In fact, the simulator is based on the skill of a group of experts. They agree that the simulator allowed for the evaluation of critical technical and non-technical skills in emergency management area (Content validity).

The first is aimed at understanding the influence of various actions that can be taken by the player on the overall result of the simulation. The second is aimed at understanding the learning effect induced by the serious game.

Analysis of the effects of the player action on the final result

Table 4 shows in detail the results of the game sessions performed.

Table 4: Table of scores achieved on 15 analysis sessions 1

Game session	Initial score	Game mode	Victims gravity	Undiscovered victims	Vehicles	Accidental event	Final score	Time [min]
1	1000	200	192	120	180	60	***248***	***33***
2	1000	200	192	0	180	80	***348***	***49.2***
3	1000	200	192	0	180	60	***368***	***37.3***
4	1000	200	192	120	0	60	***428***	***34.2***
5	1000	200	136	0	120	0	***544***	***33.4***
6	1000	200	120	0	70	0	***610***	***38***
7	1000	200	104	0	80	0	***616***	***41.4***
8	1000	200	104	0	70	0	***626***	***41.3***
9	1000	200	112	0	60	0	***628***	***39.3***
10	1000	200	104	0	60	0	***636***	***41.3***
11	1000	200	96	0	60	0	***644***	***38.4***
12	1000	200	96	0	60	0	***644***	***41***
13	1000	200	96	0	60	0	***644***	***38***
14	1000	200	112	0	40	0	***648***	***39.7***
15	1000	200	88	0	50	0	***662***	***39***
MIN	***1000***	***200***	***88***	***0***	***0***	***0***	***248***	***33***
AVG	***1000***	***200***	***129***	***16***	***84.7***	***17.3***	***553***	***38.9***
MAX	***1000***	***200***	***192***	***120***	***180***	***80***	***662***	***49.2***

In particular, the simulation sessions carried out for the first analysis have the following features:

- all game sessions are performed by a single player;
- all game sessions are performed on the same computer;
- all game sessions are performed on the same scenario;
- the player who uses the simulator knows the general rules of the emergency management.

The game sessions are sorted in ascending order according to the final score. Each row of the table shows, in detail, the components that produce the final score of the simulation sessions performed and the execution time. Moreover, in the lower part of the table three parameters are shown indicating the minimum, maximum, and average values of each score component. In particular, the fields in the table are:

Initial Score: constant value in all game sessions: it indicates the starting point from which the penalties are then subtracted. Theoretically it represents the maximum score, although in practice is unachievable.

Penalties for game mode: in this analysis the player performs all game sessions in "Easy" mode, therefore, at each simulation session is applied a penalty of 200 points. In the "Hard" mode no penalties are applied.

Increase Penalties for victim's gravity: adopting very different task sequences with each other the value of this penalty has a fairly broad range of variability; it can vary from 320 to 88 points, with an average value of 146 points. The reason why the first four games recorded the highest penalty values is due to the activities undertaken by the player. In fact, in the first case the user does not perform any action that will improve the health of the victims. Consequently, victims worsen their health up to code "N" (deceased) and this determines the maximum achievable penalty value on this scenario. Another aspect to note is the correlation between the penalties linked to the worsening of the victims and the final score. Higher penalties are found in the game session with a worse final score and, conversely, the lowest penalty value on the deterioration of the victims is manifested in the game sessions with the best overall score. As shown in the graph in Figure 3, the trend of the deterioration of the victim's penalty is mirrored in the final score. This shows how this type of penalty is of fundamental importance for the determination of the final score. Consequently, during a simulation, if the player's objective is to maximize the final score, it is essential that he/she focuses on those activities which directly or indirectly allow the victim's rescue.

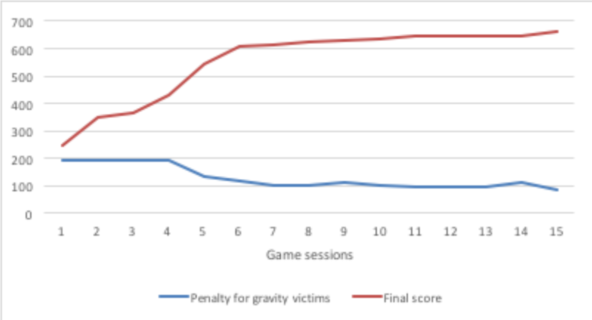

Figure 3: Comparison between the final score and the penalty for victim's gravity

Penalties for undiscovered victims: this type of penalty is closely linked to the activity of reconnaissance. In all simulation sessions the player makes the deep reconnaissance (which ensures the discovery of all victims which are not yet known) with the exception of the first and fourth case where the user is limited to observe the spontaneous worsening of the victims without taking any action. Note that there is no case where the player decides to exclusively undertake the fast reconnaissance, so this series cannot be analysed. Therefore, it is possible to observe a single evidence: if reconnaissance is not performed, the final score undergoes a curtailment of 120 points (depending on the number of not discovered victims). Then the player has to evaluate whether to employ operators for reconnaissance or reassignment to other activities in order to maximize the scoring.

Penalties related to vehicles: for each emergency vehicle requested during the simulation are subtracted 10 points to the final score. As explained above, this penalty is intended to prevent that the player asks for the intervention of an excessive number of vehicles and resources than the real needs. As reported in the table in Table 3.1 the value of this penalty varies from a maximum of 180 points, corresponding to the case where the player requests all vehicles available, up to a minimum of 40 points, that is the case where the player only selects 4 vehicles. The graph in Figure 4 shows the trends of the final score and the penalty related to the request for emergency vehicles. As it can be seen, the highest final scores are obtained in the game session where the number of emergency vehicles employed is reduced. This phenomenon is due to two factors: the first is the minor penalty, inflicted by the simulator, for the requested vehicles; the second is due to the choices made by the player. In fact, in the last simulation sessions the player has increasingly adequate and weighted better the chosen actions and this allowed him/her to handle the emergency by rationalizing the number of necessary resources.

Figure 4: Comparison between the final score and the penalty for vehicles

Penalties for accidental events: the scenario considered in this analysis predicts the existence of only one accidental event. As it can be seen in Table 4, in most cases this penalty assumes a null value: this is due to the choice of solving the accidental event player. Only in the first four games, the event is not managed, and hence the penalty is not null. In three of the four cases just cited the magnitude of the penalty is 60 points, corresponding to a final severity level equal to 3. While in only one case (the third played) the penalty assumes the maximum value, equal to 80 points. This peculiarity is due to the overall time. As it can be noted, in the second piece of skill, the latter is greater than the other three cases. This peculiarity is due to the overall simulation time and it is allowed an incidental event to reach the last level of gravity predicted by the model which consequently generated a penalty of 80 points.

Final Score: this field is no more than the sum of the initial score and all penalties just commented. Being a combination of all the other components, this field has the maximum variability, it changes from the minimum value of 248 points up to the maximum value of 662 points, with an average value of 553 points. In the graph in Figure 5, for each game it shows the final score and the amount of all penalties.

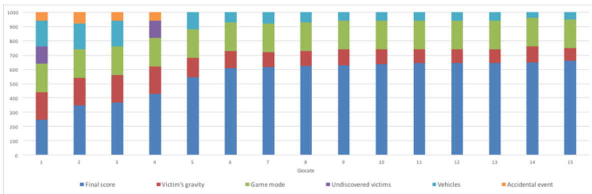

Figure 5: Summary of the score

Overall time: as the last parameter is provided the total time taken for the entire simulation. The total duration of each simulation mainly depends on two factors. The first is the speed of the player in performing the activity, or the ability to make decisions rapidly. The second factor, not controllable by the player, is represented by time values that the simulator assigns to each operation as a function of the probability distributions defined during the initialization of the scenario: this is the reason why a number of game sessions, carried out by the same player considering only one scenario, determines different values of total time of simulation. In particular, in these game sessions the average time spent by the player is equal to about 39 minutes. Moreover, the minimum recorded value is of 33 minutes, while the maximum is equal to about 49 minutes.

In summary, in the first analysis it is discussed and deepened the meaning of the components that make up the total score of each simulation. in the following, a second analysis is discussed: by this second analysis two players are compared, with the goal of verifying the simulator training function.

Analysis about the simulator training capacity.

The second analysis is characterized by a series of game sessions carried out on different scenarios. In this case, the simulation sessions have the following features:

- the game sessions are held on 10 scenarios;
- the game sessions are performed by two different players who are identified as PLAYER 1 and PLAYER 2;
- the game sessions are performed on the same computer;
- each player plays two game sessions for each scenario, one game session in "Easy" and one in "Hard" mode;
- players using the simulator know the general rules for the management of emergencies.

In this analysis, each player faces both game modes available in the simulator. In the "Easy" mode the status of the simulation in real time throughout the game is shown, while, in the "Hard" mode the status of the default simulation is not known by the player.

The objective of this second analysis is to verify that the simulator is a training tool. More precisely, the expected result is a continuous learning of the player during the execution of the various game sessions due to the learning of new knowledge for the resolution of emergencies. In this way, during the game sessions, applying the new knowledge obtained, the player should be able to better manage the emergency and then get a higher score. The scenarios available to the player are sorted in ascending order according to the difficulty. More precisely, scenario A is characterized by a lower difficulty compared to scenario B, which in turn presents a lower difficulty respect to the scenario C, and so on up to the scenario L. For both players, scenarios are played in the same order and with the same game modes: the experiment begins from the scenario A, first in "Easy" mode and then in "Hard", and ends with the scenario L.

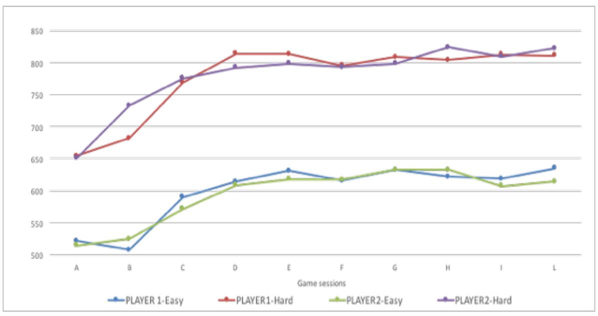

Figure 6: Simulation sessions for the two players

Figure 6 shows the scores of the various simulations carried out. The x-axis identifies the scenarios, while on the y-axis the final score of the simulation is shown. The results of the two players, despite the increased difficulty of the scenario, show a continuous improvement in final scores of the various game sessions. In particular, observing the tables of results, it can be seen on the scenarios A and B that the two players have not performed an initial deep reconnaissance. Due to this, undiscovered victims died (black code "N") and consequently the simulator has applied a strong penalty. Moreover, the first game sessions are characterized by a request of emergency vehicles quite high, which has further decreased the score. Considering subsequent game sessions, it can be seen that both players improve their skills in emergency management. Already from the simulations performed on the scenario C, the players properly perform the initial recognition and improve their performance. In later game sessions the victim's management is rather stable and the management of the emergency resources is optimized. Therefore, the results obtained are in line with initial forecasts and show the training feature of the simulator.

In a maxi-emergency, the main objective is to save as many victims as possible. For this reason, it is interesting to look at the factors that influence the management of the victims during the simulation. In the present case, according to the results obtained from simulations, it is carried out an analysis that compares the simulation time employed in the various game sessions with the relative situation of the life management of the victims, represented by the sum of the penalties relating to the increase in the victim's severity and victim's undiscovered. This analysis allows to understand whether the time taken by the player to carry out rescue operations significantly affects vital status of the victims. Times of the various activities have been extracted from statistical distributions and are therefore subject to variability during the game session.

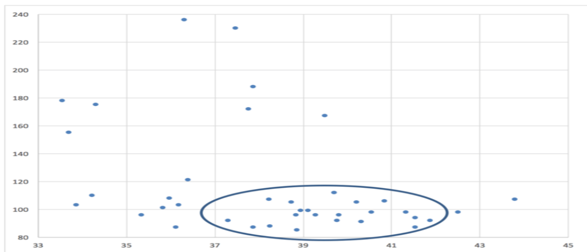

Figure 7: Simulation time - Worsening of the victims"

In Figure 7 horizontal axis represents the simulation times in minutes of the various game sessions while the vertical axis represents the penalty points achieved. As it can be noted, in general the time does not affect particularly on the victim's health during simulations. In fact, comparing the game session with quite similar simulation time, it's possible to see that some of the records have a high penalty on the deterioration of the victims while others report the opposite results. So, the victim's management depends mainly on the method by which the emergency management activities are carried out, and only secondarily from the simulation execution time. Simulation time lies between 37 and 42 minutes. As shown in the Table 5 and 6, these cases are linked to simulations carried out on the latest scenarios, where the player is more "expert".

Another aspect to consider is the importance of the reconnaissance: the graph shows how the lack of initial reconnaissance penalizes the score. The player is still "inexpert": he prefers to manage the discovered victims, and forgets to use the resources for reconnaissance. In this way the discovered victims are treated faster but in the meantime, the undiscovered victims die and produce a strong penalty on the final score. The results obtained from the analyses suggest that the simulator can be used as support for the training of maxi-emergency managers. In particular, over the different scenarios tested, it allows to investigate the behaviour of the different players and their related learning effect while reiterating the simulation.

5. CONCLUSIONS

The main objective of the proposed research is to create a serious game dedicated to the management of emergencies in industrial plants. The aim of the simulator is to provide support for the training process of the operators called to manage and coordinate complex emergencies. In particular, in order to investigate the learning effect of the operators, different players are selected to carry out several simulation sessions on specific scenarios. These simulations allowed to test the validity of the game and subsequently to analyse such results with the aim of verifying the effective training capability of the tool. The use of a simulator can substitute real practice in the development of the management skills. Moreover, one option to further test the validity of the simulation game is to check the behaviour of the operators with different level of practice in a physical simulation of emergency. However, it should be considered that using a simulation game for training may have the effect of mainly improving the capability in the tool itself (Owen et al., 2010).

One aspect that can be the subjected to a possible future development is the addition of instruction errors in the rescue chain. The next step will be the development of an integrated simulation environment capable of integrating different role in the management of the industrial emergencies: this will be the central point of the ongoing project named DIEM-SSP (Disasters and Emergencies Management for Safety and Security in industrial Plants), which details can be found in Bruzzone et al. (2014).

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HYBRID OPTIMISATION-SIMULATION APPROACH FOR THE DESIGN AND OPERATION OF AN URGENT CARE CENTRE

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ABSTRACT
This paper presents an optimisation-simulation approach for the design and operation of an Urgent Care facility. The Urgent Care Centre (UCC) could be an answer to decrease overcrowding in Emergency Departments, which is a common problem around the World. Despite Urgent Care Centres being widely used in Anglo-Saxon countries they are almost inexistent in the majority of Europe. A proper design of the UCC will increase its chances of doing well. This problem is focusing on the daily operation of unscheduled primary care needs that take place in an Urgent Care Centre. Unfortunately there are no tools for the design and operation of the UCC in the literature. The purpose of this work is to develop an optimization-simulation approach for the design and analysis of a new UCC facility that operates under certain uncertain conditions.

Keywords: simulation-optimisation under uncertainty, health-care system, rolling horizon technique.

1. INTRODUCTION

Urgent care Centres play a key role in Anglo-Saxon countries but they are inexistent in others parts of world such as European countries. Urgent Care Centres are a great option for minor illnesses and injuries that are urgent but not life-threatening. Those non-life-threatening injuries and illnesses put extra pressure on the ED (Emergency Department) in central Hospitals.

This extra pressure may create some problems, increasing the possibility of misdiagnoses which threaten patient's lives, and also increasing the patient's waiting time, which affect directly in the cost of the service, regardless of whether the cost will be paid by the government, patient or by an insurance company.

The overcrowding of European EDs has been increasing over recent years (Sánchez et al., 2013). Richardson (2006) studied that quantifies the effect in the dysfunction in EDs caused by the overcrowding associated with longer waiting times, delays in admission and even the increase of risk of infectious disease. The magnitude of the effect in 10 day mortality in an Australian hospital was about 13 deaths per year.

From the economic point of view this overcrowding in EDs could be beneficial for private hospitals. But from a holistic perspective this multifactorial problem resulted in increased waiting times, decreased patient satisfaction and had a deleterious domino effect on the entire hospital operation. In Europe unlike the US, healthcare is viewed as a utility for everyone. All European countries have a legal framework for healthcare delivery for the general population, and so the implementation of a solution like US could be seen as governmental policy (Jayaprakash et al., 2009).

Despite it not being possible to extrapolate these results to calculate the deaths that are caused in Europe because of overcrowded EDs, it is clear that it is necessary to look for solutions to decrease the pressure on the ED.

One possible solution that is highlighted by researchers and practitioners such as Derlet and Richards (2000) and Borkowski (2012) is the use of more Urgent Care Centres to relieve the pressure on EDs.

The Urgent Care Centres are focusing on the delivery of ambulatory care in a dedicated facility outside the traditional EDs.

When patient populations were seeking care for non-life-threatening conditions 60% of them felt that the ED was the best place for them to receive care for their medical problem, thereby creating an inefficient use of expensive resources (Burnett and Grover, 1996.) The authors hypothesise that being unfamiliar with alternative care options and negative opinions about the alternatives were some of the main reasons.

The projected attention time is a major decision factor for the choice of Urgent Care Centres, since if you are going to wait the same time patients prefer to go to the ED. For example Tallahassee Memorial Healthcare offers their patients a guarantee to be seen by a nurse practitioner, physician's assistant or a physician within 15 minutes or they will be compensated with two cinema tickets.

Despite the fact that the majority of Urgent Care Centres do not offer free tickets for patients that stay more than 15 minutes, they do not let patients leave without being seen (LWBS). The time that a patient is willing to wait before leaving varies according to the type of illness or condition.

The design of an Urgent Care Centre is a complex task where we have to minimize the cost of the proposed facility in terms of the number of exam and procedure rooms, and staffing while maintaining a reasonable figure for patients that leave without being seeing.

To the authors' knowledge there are no Urgent Care Centre design models in the literature, so we will bring some ideas from the hospital design and emergency care design

literature. Baesler et al., 2003 used simulation to estimate the capacity of the EDs. Li and Benton (2003) presented research for management and quality control in the design, and Gallivan et al., 2002 made a mathematical model study to calculate the length of stay of the patients to investigate the capacity needed.
These kinds of problems are purely stochastic since the arrival of the patients, the type of disease of the patients, the leave-time without being seen and the duration of the medical treatments is not deterministic. Tackling all the stochastic variables in a mathematical model causes the size of the model grows to an extent that it is impossible to solve with current optimization tools.
Thus, discrete-event simulation emerges as an alternative solution technique for the decision makers to provide good-quality results with reasonable computational effort. The potential of discrete-event simulation for "as-is" analysis has been successfully demonstrated in Connelly and Bair (2004), to study average patient service times in EDs. Other studies have focused to analyse whether or not is able to handle a greater flow of incoming patients, as well as the related impact in their efficiency (Longo et al., 2014).
Despite the similarity in the design of health care facilities, especially between UCC and ED, is that UCC help fill a vital gap when you become sick or injured, but your regular doctor is not available and you cannot wait for an appointment. Then we can focus on the efficiency but we can allow certain number of patients to leave without being see, which is impossible in ED. Also UCC are different to regular medical centre because the main attention is not based on appointments. Moreover the majority of the approaches in the literature are more focus in the operation and not in the design of the facilities, using the simulation to make a daily solution.
In the last 10 years, many applications were developed using simulation techniques and also heuristic and metaheuristic approaches, to deal with the scheduling of patients in EDs. (see Azadeh et al., 2014). Many of these applications provide exact models, generally MILP models, which also represent the behaviour of the system with some simplifications. This kind of MILP models became easily unsolvable with the number of patient's treatments, that is why are commonly combined with decomposition or iterative algorithms to be solved in a reasonable CPU time.
Another important lack of exact models, in comparison with simulation approaches, relies on the stochastic behaviour of the system. For example, two-stage or multi-stage solution approaches can be developed for stochastic optimization using a scenario-based representation, but the number of scenarios to be considered should be reduced in order to deal with the problem in short CPU time.
In this paper we propose an optimisation-based simulation approach for the design and operation of an UCC. The proper interaction between an exact MILP and discrete-event simulation model allows us to solve this complex stochastic problem in a reasonable CPU time, obtaining important improvements at the design and operation costs of the UCC. In order to demonstrate the effectiveness of the solution approach, different scenarios were solved by considering a specific case study designed for this problem.

2. PROBLEM DESCRIPTION

The role of the Urgent Care Centres (UCC) in the health system is to attend to unscheduled primary care needs. This situation occurs when a patient cannot wait days or weeks for an appointment, or when they need treatment for injuries that require immediate Lab testing, X-ray or imaging to evaluate the severity of the injury. All the patients that cannot be attended to by the Urgent Care Centres should be forwarded to the Hospital. The UCCs mainly help the hospital ED by referring non-emergency patients to a more appropriate care setting.
The UCC works 7 days a week from 7 am to 9 pm. But they have to remain open until the last patients leave the centre. However, not all the staff need to remain but only those required finishing the patient's treatment. The staff required to operate the UCC are a Receptionist, Nurses, a General Physician, an Imaging Technician, Orthopaedic Physicians, Orthopaedic Technicians, and the Physician's Assistants.
The UCC is comprised of a registration area, waiting room, triage area and rooms that can be used for examinations and procedures (see Figure 1). For a matter of simplicity the UCC will attend to nine types of patients. The first type (mild sickness) does not require lab testing for treatment and could be attended to by a Physician's Assistant. The second one (standard sickness) requires lab testing and has to be seen by a Physician. The third type (orthopaedic injuries) requires setting and casting of the bone. The fourth type of patient is orthopaedic injury not requiring setting/casting. The fifth one is lacerations requiring stitches. The sixth type is minor cuts/bruises not requiring stitches. The next two types of patients are standard check-up/examinations such as physicals, flu shots, etc., and cardio problems such as mild strokes and irregular/rapid heartbeats. The ninth type is those requiring advanced emergency care who are immediately sent by ambulance to the emergency department.
Tables 1-9 summarize the flow for each of the nine patient types. Each treatment requires different professional staff and depending on the equipment needed the procedures could be done in a Procedure Room, not in an Exam Room.

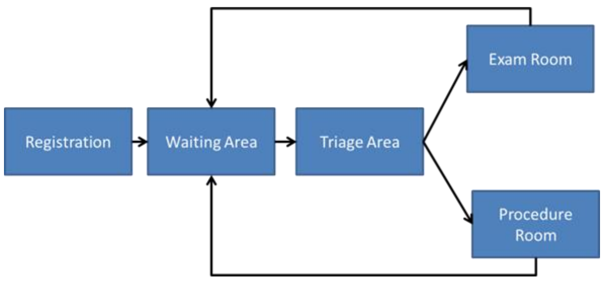

Figure 1: Flow process scheme of a UCC.

Table 1. Mild Sick

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal(2,.3)
3	Exam Room	Physician Assis-tant	Uniform(13,16)
4	Registration	Receptionist	Triangular(3,4,5)

Table 2. Sick

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal(2,.3)
3	Exam Room	Physician	Uniform(15,21)
4	Exam Room	Nurse	2
5	Registration	Receptionist	Triangular(3,4,5)

Table 3. Orthopaedic injury requiring Setting/Casting

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal (5,1)
3	Procedure Room	Imaging Technician	Uniform(10,16)
4	Procedure Room	Orthopaedic Physician	Triangular(9,10,15)
5	Procedure Room	Orthopaedic Technician	Triangular(10,15,20)
6	Registration	Receptionist	Triangular(3,4,5)

Table 4. Orthopaedic injury not requiring setting/casting

Step	Location	Resources	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal (5,1)
3	Procedure Room	Imaging Technician	Uniform(10,16)
4	Procedure Room	Orthopaedic Physician	Triangular(18,20,22)
5	Registration	Receptionist	Triangular(3,4,5)

Table 5. Lacerations requiring Stitches

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangu-lar(1.5,3,7)
2	Triage Area	Nurse	Normal (5,1)
3	Procedure Room	Physician Assis-tant	Normal(25,3)
4	Registration	Receptionist	Triangular(3,4,5)

Table 6. Minor cuts/bruises

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal (4,.5)
3	Exam Room	Physician Assistant	Normal(15,2)
4	Registration	Receptionist	Triangular(3,4,5)

Table 7. Standard Treatments

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangu-lar(1.5,3,7)
2	Exam Room	Physician Assistant	Normal(15,3)
3	Registration	Receptionist	Triangular(3,4,5)

Table 8. Cardio Problems

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse	Normal (5,1)
3	Procedure Room	Physician	Uniform(23,25)
4	Procedure Room		Uniform(45,60)
5	Registration Area	Receptionist	Triangular(3,4,5)

Table 9. Advanced Emergency Care

Step	Location	Resource	Processing Time
1	Registration	Receptionist	Triangular(1.5,3,7)
2	Triage Area	Nurse, Physi-cian	Normal(5,1)
3	Triage Area	Ambulance	

Once the patients arrive they have to go to the registration area, and then all but those receiving standard check-ups are triaged by a nurse and in the event of an emergency a physician will attend. All the movement between the different areas will be performed by the Nurse.
The patients will leave without being seen (LWBS) after a time that will be measured between the period that the patient enters the registration and until they enter an Exam or Procedure room. In Table 10 the percentage by type of patient and the LWBS is displayed.
Table 11 shows the arrival rate of patients. Despite the arrival of new patients and closing at 9pm, it remains open until all the patients leave the facility. Then, it maybe makes sense to schedule staff to stay after the closing time. If a care–provider is required to stay overtime they will receive a 50% premium over the price.

Table 10. Patient type

Patient Type	Mix	LWBS
Mild Sickness	11	Uniform(15,35)
Standard Sickness	32	Uniform(25,40)
1st Injuries Ortho-setting/casting	7	Uniform(30,40)
2nd Injuries Ortho- Non setting/casting	5	Uniform(30,40)
3rd Injuries - Laceration	13	Uniform(25,35)
4th Injuries – Minor Cut Bruise	4	Uniform(30,40)
Standard Checkup/Exams	10	Uniform(10,20)
Cardio problems	10	Uniform(10,30)
Severe Non-Treatable	8	Uniform(5,10)

The overtime is calculated on an hourly basis.
In addition to these arrival patients, the system should be able to handle a mass accident causing 30 patients of type 3-6 in a 15 minute period, which could happen at any moment of the opening hours.

Table 11. Arrival Time Period

Time Period	Patient Arrivals per Hour
7am – 9am	11
9am – 11am	6
11am – 2pm	10
2pm – 3pm	7
3pm – 6pm	11
6pm – 8pm	8
8pm – 9pm	4

Table 12 shows the shift patterns for all care-providers. Each shift pattern has 9 working hours and a 1 hour break. Overtime only considers the last 2 hours of the day.

Table 12. Shift Pattern

Shift Type	Working Periods
Early	7am – Noon, 1pm – 5pm
Late	Noon – 4pm, 5pm -10pm
Overtime	10pm – Midnight

The hourly cost for each care–provider and those who own and operate each operating room and procedure room is summarized in Table 13. Only the operational cost will be addressed. For example, since the cost of a Receptionist room for 3 or 4 people is almost the same, only the cost of the Receptionist will be taken into consideration. The care–providers have to be paid the entire shift even if they are only used for one minute.

Table 13. Resource Information

Resource Required	Cost per Hour
Receptionist	$13
Nurse	$35
Physician Assistant	$55
Orthopaedic Technician	$25
Imaging Technician	$21
Physician	$90
Orthopaedic Physician	$110
Exam Room – Operating Cost	$15
Procedure Room – Operating Cost	$30

All patients have a priority that is based on the patient type as shown in Table 14. A patient with a higher priority will be attended to before one with a lower priority even though the patient with the lower priority has arrived before. But once a patient treatment starts this will not be suspended if someone with a higher priority arrives because not all the procedures are life threatening.

Table 14. Patient's priority

Patient Type	Priority
Mild Sickness	5
Standard Sickness	4
1st Injuries Ortho-setting/casting	2
2nd Injuries Ortho- Non setting/casting	3
3rd Injuries - Laceration	2
4th Injuries – Minor Cut Bruise	3
Standard Checkup/Exams	5
Cardio problems	1
Severe Non-Treatable	1

The data used for the experimentation purposes was taken from an instance used at the Student Simulation Competition of Simio® LLC 2015.

3. MOTIVATION

Given a set of unscheduled patients, with specific features, like LWBS time and processing time, the main idea of this problem is to determine the number of Operation Rooms and Exam Rooms and also the number of Staff we will need to achieve a reasonable value of LWBS with a minimum operational cost. Despite that the ideal value for #LWBS(%) is zero, a percentage value lower or equal to 10% is considered acceptable.

4. DISCRETE-EVENT SIMULATION MODEL

A discrete-event simulation model was developed in Simio® to assess the main features of the problem presented above. Given a specific configuration of staff and rooms, this model is able to represent the daily operation of the UCC.

All the staff is modelled as resources that are required depending on the room and the patient type. The patients are simulated as entities that are created randomly arriving at the system according to Table 11, and once the entities are created the patient type in Table 11 is assigned. Then these patients go to the registration room to fulfil the paperwork and then proceed to the waiting area with the help of a nurse. Once in the waiting area they have to wait until a Triage / Procedure / Exam Room is available while a nurse must be available to go with them to the needed room. This logic is implemented in an Add-On process inside the Nurse, which only accepts the Transport Request if there is a room to take the patient. Once that the procedure is finished in the room the patients come back to the waiting area where they wait for the next procedure until the last assigned task, which is the Reception to make the check out.

The patients could only leave the UCC because:

1. The LWBS time has already passed.
2. They need to be transferred to the Hospital.
3. They have completed the treatment.

The operational cost will be grouped in 3:

1. Cost of the use of the rooms
2. Cost of the use of the staff in regular hours
3. Cost of overtime

4.1. Simulation model features

One of the features of the model is that the manager could allow the model to do the activities that require Exam Rooms in the Procedure Room. The use of the Procedure Room is higher but using it when it is idle could be more convenient than having another Exam Room.
Following the same idea, another important feature allows a more qualified care-provider to perform the task of a less qualified care-provider. For example, allowing the Physician to do the task of the Physician's assistant. Despite the use of the Physician being higher than the Physician's Assistant, using an idle Physician could be better than hiring another Physician's Assistant.
The model also allows imitating the behaviour of the system if a major accident occurs during the operation hour creating a peak of demand.
The simulation model features a dashboard (see Figure 2) that allows the user to see the most important information during the simulation. The control chart is divided into three parts: the first one refers to the operational cost, the second to the patients attended to and the ones that leave, and finally the use of resources.

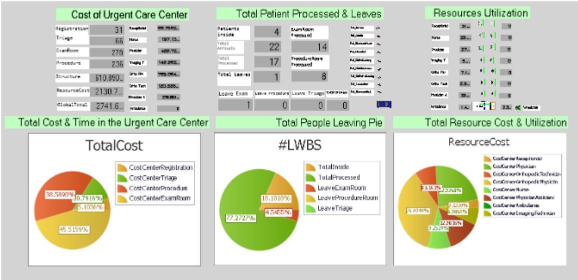

Figure 2: Model Dashboard

In order to facilitate the understanding of the results for healthcare managers a 3D visualization of the Urgent Care Centre was implemented. In Figure 3 we show a screen shot of the model after 570 minutes.

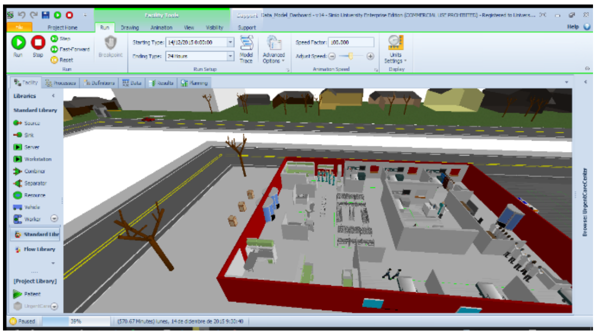

Figure 3: 3D model visualization

The simulation model presented here could be used to evaluate a particular configuration of staff and rooms by running multiples scenarios of uncertainty, but this model does not change the values or propose a different design. For this we use an optimization-based tool for helping us in the search of new configurations.

4.2. Optimisation-based simulation approach

In order to find a good configuration of staff and rooms, we generate and solve a set of 100 possible solutions using a well-known optimisation-based tool named OptQuest®. This tool allows us to test many solutions for many replication runs while varying control values, such as the number of staff and rooms in the system. Based on the information provided at each replication, the tool decides a new configuration of staff and rooms to be tested. After that, according to the results obtained for an initial number of replications, we can select a subset of promising scenarios, of staff and rooms, for in-depth analysis. Otherwise, we can let the tool decide the best promising scenario, using a Kim & Nelson procedure for selecting the best (see Kim and Nelson, 2001). In both cases, a maximum number of replications should be done to finally decide, based on the interval confidence, the best scenario of the system.

5. MATHEMATICAL FORMULATION

An MILP model was also proposed in this work. The main contribution of this model is the possibility to take into account discrete and continuous time characteristics of the problem without losing the global optimal solution. To do this, a general precedence and a STN constraints are combined is order to represent timing and sequencing decisions by Eqs.(1-8), units and resource assignment by Eqs.(9-10) and resource and units availability constraints are represented by Eqs.(18-23). Time-period assignment and sequencing constraints are proposed in Eqs.(11-17) to link both formulations. We consider intervals of 60 minutes (1 hour). Finally, the objective function is stated by Eqs.(24), representing the total cost of the system.

Sets

- I — *patients (i,ii)*
- L — *stages (l,ll)*
- J — *units (j,jj)*
- R — *resources (r,rr)*
- S — *shift (s,ss)*
- T — *time-period (t)*
- TS — *time at shift*
- IL — *tasks*
- ILJ — *units for task*
- ILR — *resource for task*

Parameters

- $tp_{i,l}$ — *treatment time for task (i,l)*
- rd_i — *ready time of patient i*
- $d^r_{r,t}$ — *availability of resource r in time t*
- h_t — *time limit of time period t*
- $c^j_{j,s}$ — *unit cost at work-shift s*
- $c^r_{r,s}$ — *resource cost at work-shift s*
- $LWBS_i$ — *leave time without been seen for i*
- M — *horizon time*
- N — *penalty cost per patient*

Binary Variables

- $x_{i,ii,l,ll}$ — *1 if task (ii,ll) precedes task (i,l)*
- $w_{i,l,j}$ — *1 task (i,l) is performed in unit j*
- $q_{i,l,r}$ — *1 task (i,l) is performed by resource r*
- $wp_{i,l,t}$ — *1 task (i,l) is processed in time t*
- $ws_{i,l,t}$ — *1 task (i,l) starts at time t*
- $wf_{i,l,t}$ — *1 task (i,l) finishes at time t*
- g_i — *1 if patient i violates LWBS constraint*
- f_j — *1 if unit j is available the whole day*

Positive Variables

- $Tf_{i,l}$ — *finishing time of task (i,l)*
- $Ts_{i,l}$ — *starting time of task (i,l)*
- $req_{r,t,s}$ — *resources r required at time t*
- $reqs_{r,s}$ — *resources r required at work-shift s*
- $rec_{j,t,s}$ — *units j required at time t*
- $recs_{j,s}$ — *units j required at work-shift s*

Free Variables

- TC — *total cost*

5.1. Timing Constraints

$$Tf_{i,l} \geq Ts_{i,l} + tp_{i,l} \qquad \forall i,l \in IL \qquad (1)$$

$$Ts_{i,l} \geq Tf_{i,l-1} \qquad \forall i,l \in IL \wedge l > 1 \qquad (2)$$

$$Ts_{i,l} - rd_i \leq LWBS_i + M^* g_i \qquad \forall i,l \in IL \qquad (3)$$

$$\sum_i g_i \leq 0.1^* |I| \qquad (4)$$

5.2. Task sequencing Constraints

$$Ts_{i,l} \geq Tf_{ii,ll} - M(1 - x_{i,ii,l,ll}) - M(2 - w_{i,l,j} - w_{ii,ll,j}) \qquad \forall i,l,j \in ILJ \qquad (5)$$

$$Ts_{ii,ll} \geq Tf_{i,l} - M(x_{i,ii,l,ll}) - M(2 - w_{i,l,j} - w_{ii,ll,j}) \qquad \forall i,l,j \in ILJ \qquad (6)$$

5.3. Resource sequencing Constraints

$$Ts_{i,l} \geq Tf_{ii,ll} - M(1 - x_{i,ii,l,ll}) - M(2 - q_{i,l,r} - q_{ii,ll,r}) \qquad \forall i,l,r \in ILR \qquad (7)$$

$$Ts_{ii,ll} \geq Tf_{i,l} - M(x_{i,ii,l,ll}) - M(2 - q_{i,l,r} - q_{ii,ll,r}) \qquad \forall i,l,r \in ILR \qquad (8)$$

5.4. Unit and Resource assignment Constraints

$$\sum_{j \in ILJ} w_{i,l,j} = 1 \qquad \forall i,l \in IL \qquad (9)$$

$$\sum_{r \in ILR} q_{i,l,r} = 1 \qquad \forall i,l \in IL \qquad (10)$$

5.5. Time-period assignment Constraints

$$\sum_t ws_{i,l,t} = 1 \qquad \forall i,l \in IL \qquad (11)$$

$$\sum_t ws_{i,l,t} = \sum_t wf_{i,l,t} \qquad \forall i,l \in IL \qquad (12)$$

$$\sum_{tt \leq t} ws_{i,l,tt} - \sum_{tt < t} wf_{i,l,tt} = wp_{i,l,t} \qquad \forall i,l,t \in IL \qquad (13)$$

5.6. Time-period sequencing Constraints

$$Ts_{i,l} \geq h_{t-1} - M^*(1 - ws_{i,l,t}) \qquad \forall i,l \in IL \qquad (14)$$

$$Ts_{i,l} \leq h_t - M^*(1 - ws_{i,l,t}) \qquad \forall i,l \in IL \qquad (15)$$

$$Tf_{i,l} \geq h_{t-1} - M^*(1 - wf_{i,l,t}) \qquad \forall i,l \in IL \qquad (16)$$

$$Tf_{i,l} \leq h_t - M^*(1 - wf_{i,l,t}) \qquad \forall i,l \in IL \qquad (17)$$

5.7. Resource availability Constraints

$$q_{i,l,r} + wp_{i,l,t} - 1 \leq \sum_{s \in TS} req_{r,t,s} \qquad \forall i,l,r,t \in ILR \qquad (18)$$

$$req_{r,t,s} \leq d^r{}_{r,t,s} \qquad \forall r,t,s \in TS \qquad (19)$$

5.8. Unit availability Constraints

$$\sum_{i,l \in ILJ} w_{i,l,j}{}^* tp_{i,l} \leq M^* f_j \qquad \forall j \qquad (20)$$

$$rec_{j,t,s} = f_j \qquad \forall j,t,s \in TS \qquad (21)$$

5.9. Resources and units per work-shift

$$recs_{j,s} \geq rec_{j,t,s} \qquad \forall j,t,s \in TS \qquad (22)$$

$$reqs_{r,s} \geq req_{r,t,s} \qquad \forall r,t,s \in TS \qquad (23)$$

5.10. Objective Function

$$TC = \sum_{j,s} (recs_{j,s} cj_{j,s}) + \sum_{r,s} (reqs_{r,s} cr_{r,s}) \qquad (24)$$

6. ROLLING HORIZON

During the last decades, many hybrid time formulations considering discrete-continuous representations have been developed to try to solve medium-term or industrial size problems with an acceptable computational time. Besides this, today there is no single representation that ensures an efficient solution for large-scale problems without any shortfall in the computational performance.
The MILP model of this work has been developed using the ideas of well-known Global Precedence and STN-based formulations. This model considers timing and assignment limitations and availability constraints. The statistics of the full-space MILP model are shown Table 15. This full-space model may become computational intractable due to the number of tasks to be performed in a single day. For example, for some cases, we could not provide a feasible solution after solving the full-space model for a couple of hours.

Table 15. Statistics of the MILP model

MILP full-space model	Statistics
# Equations	1,322,341
# Continuous variables	91,560
# Discrete variables	87,822

So, in order to overcome this limitation, a dynamic decomposition approach based on the main concepts of rolling horizon technique has been proposed to solve each deterministic instance in a reasonable time by scheduling one patient at a time. For this, we consider a relative optimality gap of 5% and a time limit of 60 sec. per iteration.
After that we obtain 10 different solution configurations of the system. The interval confidence of Total Cost $IC_{(1-\alpha=95\%)}$=[9668,13977] and #LWBS $IC_{(1-\alpha=95\%)}$=[3,11] report the quality of the solutions found by the algorithm. The total time consumed by the algorithm for a single replication is about 1 hour, which is so CPU time consuming. This limitation is the main reasons why we do not consider solving a stochastic model using scenario-based approach and alternative solution approach, merging simulation and optimization, have been done for this particular problem.

7. SIMULATION & OPTIMISATION

Solutions obtained by both our simulation model and the MILP optimisation model have been validated using the same data for inter-arrival time, processing time and LWBS time. The results indicate that the MILP can achieve a better configuration of staff and rooms in the system with a reduced total cost. By the way, the MILP

model becomes computational intractable for solving many uncertain instances.
In order to get the benefits of both methods, the results of the previous MILP were used in the upper level to find the initial bounds of the system configuration, after testing 10 specific replications (see Table 16). These bounds are used to restrict the values of the control variables in OptQuest®. Thus, this information is copied in OptQuest® which uses it to obtain a set of solutions. Each solution is run in the simulator by testing 50 replications of uncertain parameters. OptQuest® and Simio® run until a limited number of solutions (100 solutions) are reached (see Figure 4).

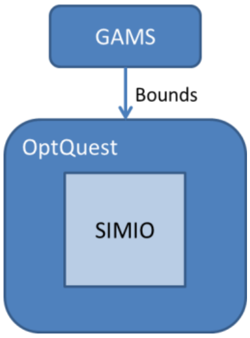

Figure 4: Hierarchical level of the solution approach

8. RESULTS

The experimentation was run under Windows 10 in a desktop PC with an Intel Core i7 processor with 16 GB of RAM. We used the GAMS® commercial software for the mathematical problem and Simio® for the simulation purpose.

Table 16. Solution bound of the MILP model

Resource	Lower bound	Upper bound
Registration rooms	3	3
Triage rooms	3	3
Exam rooms	2	3
Procedure rooms	2	3
Receptionist early shift	2	3
Receptionist late shift	2	3
Receptionist extra time	0	3
Nurses early shift	1	3
Nurses late shift	1	3
Nurses extra time	0	2
Physicians assistants early shift	2	5
Physicians assistants late shift	2	6
Physicians assistants extra Time	0	2
Orthopaedic technician early shift	0	2
Orthopaedic technician late shift	0	2
Orthopaedic technician extra Time	0	1
Imaging technician early shift	1	2
Imaging technician late shift	1	2
Imaging technician extra Time	0	1
Physicians early shift	1	3
Physicians late shift	1	3
Physicians extra Time	0	1
Orthopaedic physicians early shift	1	2
Orthopaedic physicians late shift	0	3
Orthopaedic physicians extra Time	0	1

Results in Table 17 are obtained from Simio® by using OptQuest®. As we explain before, we have used the results provided by the MILP to constrain the search.
Analyzing the results we can estimate an interval confidence for Avg. Total Cost $IC_{(1-\alpha=95\%)}$=[13330,16861] and Avg. #LWBS $IC_{(1-\alpha=95\%)}$=[2,11]. Despite we know that is not a fair comparison, the intervals confidences of the optimization and the simulation models are overlapped. According to this, we cannot infer that the statistical difference between both models is significant enough to decide which model is better. So, we can assume that the quality of the results obtained by the simulation model is good enough to suggest the use of this tool for further analysis.

Table 17. Best ten solutions found

Replica-tions	Avg. Total Cost	Half Width	Avg. #LWBS(%)	Half Width
1	13021	30.15	8.14	1.15
2	15028	32.26	5.91	1.03
3	15040	28.19	8.26	0.86
4	15043	28.28	9.56	1.08
5	15054	24.65	8.63	0.95
6	15207	57.14	3.72	1.16
7	15324	70.16	4.40	2.26
8	15553	28.12	2.97	2.14
9	15726	75.16	8.32	1.65
10	15966	72.16	6.99	1.34

Figure 5 and Figure 6 resume the confidence interval of Avg. Total Cost and the Avg. #LWBS(%)found by OptQuest® by using our operation policy.
One advantage of using simulation relies in the possibility to evaluate other different operation policies without interfering with the real world and make some recommendations.

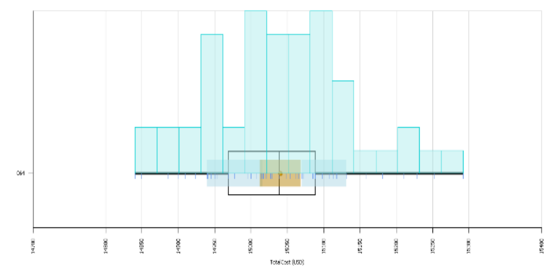

Figure 5: Avg. Total Cost confidence interval

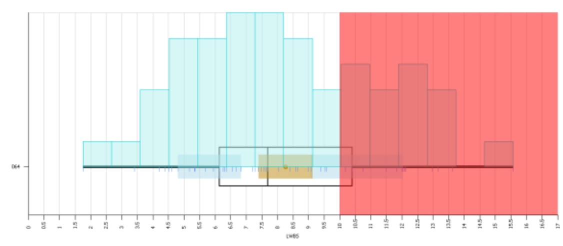

Figure 6: Avg. #LWBS confidence interval

The use of overtime is advisable since cancelling the overtime forces the UCC to have more workers to finish all the treatments before 9pm. Allowing the activities that require an exam room to be done in a procedure room when available gives a saving cost of around 5% but the saving is not so significant since both rooms have an hourly cost. The most interesting recommendation is to allow other care–provider types to tend patients. For example, allowing a Physician to perform the task of a Physician's Assistant has a saving effect of more than 15%, since we incur in a care–provider's cost even though he or she is idle almost all the day.

The other interesting recommendation is that being ready for a mass accident at any time of the day and maintaining the service level has an over-cost of more than 20% compared with the base model. This extra capacity is really costly for almost any health care system. To deal with the event of a massive accident, we need the patients to be split among different hospitals. And maybe if something like that happens all the low priority patients should be sent home so UCC can focus on the mass accident patients.

9. CONCLUDING REMARKS

The design and operation of a UCC represents a challenging problem for the Health-Care and PSE community today. This problem considers different sources of uncertainty, e.g. patient type, inter-arrival time, treatment duration and LWBS, where more than 100 patients per day have to be treated following certain conditions criteria.

These kinds of stochastic problems may be difficult to solve using traditional methods in a reasonable CPU time due to the nature of the stochasticity and also because of the huge number of tasks (>1000) to be assigned and sequenced in the system.

For example, if the design phase is performed using only simulation, the number of possibilities to consider become so high that it is impossible to try to solve them in a reasonable time. That is the case if we setup 0-10 resources for each type and we run the model for many hours without being sure how far from the optimal solution we are. Also, if we try to use only an MILP we could demonstrate the weakness in the computational performance.

One way to mitigate these limitations is by trying to use simple but, at the same time, robust solution procedures to find good solutions for the whole stochastic problem.

So, the integration of simulation and optimisation emerges as an efficient alternative to understand and solve these kinds of stochastic and combinatorial problems. Thus, using the MILP model to provide the best and worst bounds for the next step, and then run 50 simulations to test each scenario created, allows us to solve this complex and challenging problem within a reasonable computational performance.

The contribution of this paper is a simulation and optimisation tool for the Urgent Care Centre that to the authors' knowledge does not exist in the literature. The implementation of the UCC across Europe requires changes in the European healthcare policies. But as a first step the authors suggest running a trial close to the most overcrowded ED and measuring the effect of the UCC impact. The use of optimisation and simulation tools to achieve an appropriate design could increase the chances of success of the implementation.

In the next stage of the research we are looking for new ways to integrate the simulation optimisation, such as giving key information from the optimisation model that allows the simulation model to be more efficient.

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COUPLING BRAIN-COMPUTER INTERFACE AND ELECTRICAL STIMULATION FOR STROKE REHABILITATION AND TREMOR REDUCTION IN PARKINSON'S DISEASE

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ABSTRACT
In this paper we describe the design of a novel Brain-Computer Interface (BCI) system for stroke rehabilitation and tremor reduction from Parkinson's disease. Hereby, the combination of EEG driven BCI with electrical muscle stimulation (EMS) is used with the idea to strengthen the sensory-motor feedback loop in order to stabilize the control of the affected extremities. Before testing the system in healthy people and then with patients, a feasibility study is done first, which is described in this paper.

Keywords: BCI, electrical stimulation, stroke rehabilitation and tremor reduction, sensory-motor feedback loop

1. INTRODUCTION

This paper presents the design of a non-invasive EEG-based BCI system for motor rehabilitation after a stroke and for tremor reduction on patients with Parkinson's disease. Rehabilitation therapy helps people with such conditions relearn to perform simple movements. Regular therapies generally involve physical therapy with or without the use of technology.

Robot-assisted arms, Functional Electrical Stimulation (FES) and BCI combined with exoskeleton are examples of technology-based rehabilitation therapies (Ramos-Murguialday, Schürholz, Caggiano, Wildgruber, Carea, Hammer, Halder and Birbaumer 2012). Methods using robot-assisted arms or classic neuro-muscular electrical stimulation require the patient to repeatedly perform a given movement. Over time, this may affect the patient's interest and decrease his motivation. The latter is an important factor on the success of rehabilitation therapy. A lack of motivation will therefore limit the effectiveness of the rehabilitation process. Combining these methods with BCI helps to overcome that problem.

Previous researches have shown the success of FES and EMG-triggered NMES in motor recovery during stroke rehabilitation (Noma, Matsumoto, Shimodozono, Iwase and Kawahira 2014). We propose an EEG-triggered NMES system - that combines BCI with EMS using a VisionBody ExoSuit, - which extracts features from continuously recorded EEG signals, especially the Movement-Related Slow Cortical Potentials (MRCP) related to volitional movement intention (Lew, Chavarriaga, Zhang, Seeck and Millan 2012), and only when an intention to move is detected, the system activates the electrical stimulation to the muscles via the EMS suit to help them contract until the desired movement is produced. The EMS suit is chosen in order to facilitate the application into real world application instead of using stimulators needing high personal efforts to be applied.

1.1. Stroke

Stroke patients are one target group for this kind of stimulation. Stroke occurs when blood flow to an area of the brain is cut off either by blocked or bursted blood vessels. The lack of oxygen in the brain cells will cause them to die, and thus abilities controlled by the concerned area of the brain such as memory or muscle control are lost (Bornstein 2009). Stroke survivors then need to relearn the skills lost by the stroke-affected part of their brain. That is the goal of stroke rehabilitation, which will help them to regain some independence and improve their quality of life (Kwakkel, Kollen and Wagennar 1999). It may involve either regular physical activities or technology-assisted physical activities.

FES has been used with some success to improve motor control in chronic stroke patients (Noma, Matsumoto, Shimodozono, Iwase, and Kawahira 2014). FES is a form of muscle re-education that uses electricity to stimulate weakened muscles and causing them to contract. These electric stimulations can be triggered by EMG, allowing voluntary movement detection from the subjects. Extremely small electrical EMG signals still measurable in paralyzed muscles after the stroke are detected and used to initiate the stimulation of the same muscles, which will result in actual movement (Qu, Xie, Liu, He, Hao, Bao, Xie and Lan 2016).

Lately, EEG-based BCIs for stroke rehabilitation has been the focus of numerous studies. BCIs translate brain activity into control signal of computer or external devices. Recent research on BCI for stroke rehabilitation shows that they can work as assistive BCI to assist the patient in his daily life, but also as rehabilitation BCI to facilitate neuroplasticity (Sockadar and Birbaumer 2015).

Most research in the area focuses on the control of a robotic device, and consists on attempting repeatedly to perform cue-based movements. The main problem, however, is that this results in a lack of engagement from the subject and an unsatisfying outcome of the training (Bhagat, French, Venkatakrishnan, Yozbatiran, Francisco, O'Malley and Contreras-Vidal 2014). On the other hand, remarkable improvements of motor and cognitive capacities have been noticed in stroke patients who trained daily with a Brain-Machine Interface (BMI) coupled with a goal-directed behavioural therapy (Sockadar and Birbaumer 2015).

1.2. Parkinson's disease

Patients affected by Parkinson's Disease (PD) are another target group. PD is a degenerative disorder of the Central Nervous System (CNS) that affects the motor system. It typically appears between the ages of 50 and 69, and affects the nerve cells in the brain (*substantia nigra*) that produces dopamine (Janvkovic and Tolosa 2007). There is no known cause for primary PD but secondary PD is known to be caused by toxins. To date, there is no cure for this condition. The most apparent and well-known symptom of PD is rest tremor, which appears during rest and affects the patient in his daily living tasks (Grimaldi and Manto 2010; Manto, Topping, Soede, Sanchez-Lacuesta, Harwin, Pons, Williams, Skaarup and Normie 2003). Tremor is the involuntary shaking movement that affects mostly the hands and the head (Janvkovic and Tolosa 2007; Manto, Topping, Soede, Sanchez-Lacuesta, Harwin, Pons, Williams, Skaarup and Normie 2003). It is approximately rhythmic and roughly sinusoidal, with a frequency between 3 and 6 Hz (Grimaldi and Manto 2010).

Tremor has been quite unsuccessfully treated with medication, but has been well controlled by Deep Brain Stimulation (DBS) (Benabid 2003; Limousin and Martinez-Torres 2008). DBS requires electrodes to be surgically implanted into parts of the brain, the *subthalamic nucleus*, the *globus pallidus interna* or the *thalamus*. These electrodes are used to stimulate the brain to inhibit the signals that cause the motor symptoms. Unfortunately, apart from its invasiveness, the process to choose patients for a DBS surgery is very selective (Munhoz, Picillo, Fox, Bruno, Panisset, Honey and Fasano 2016)

Electrical stimulation has the potential to counter the effect of tremors, with the advantage of being non-invasive.

2. TOOLS AND METHODS

Motivation and engagement are important factors that can affect the outcome of stroke rehabilitation training. The goal of this study is to design a non-invasive BCI system that detects the subject's volitional movement intention and provides a feedback in the form of an electrical stimulation to the targeted muscles for rehabilitation; and to detect tremor onset in order to counter its effect by stimulating the muscle responsible for PD patients. In both cases an EMS suit will be used to facilitate the application in real life environments.

2.1. Movement Intention Detection

Voluntary hand and foot movements are preceded by a slowly increasing surface-negative cortical potential called Readiness Potential (RP). The RP, also known as Bereitschaftspotential (BP), is a negative cortical potential that develops beginning 1.5 to 1s prior to the onset of a self-paced movement (Jahanshah and Hallett 2003). It is measured over the primary motor cortex M1 and is maximal over the frontal rather than the occipital area, with amplitudes ranging from 10 to 15 µV. BP amplitude increases with intentional engagement and reduced by mental indifference of the subject. Yilmaz et al. (Yilmaz, Birbaumer and Ramos-Murguialday 2015) investigated movement-related Slow Cortical Potentials (SCPs) in severe chronic stroke patients with no residual paretic hand movement, and found that the SCPs appeared and peaked earlier during paretic hand movement compared to healthy hand movement. Paretic hand movement also elicited larger amplitude over the midline brain while for healthy hand movement, contralateral and midline amplitudes are much larger than ipsilateral activity.

Movement intention is also characterized by a decrease of power in the alpha bands (8 - 15 Hz) and an increase of power in beta bands (16 – 31 Hz) (Bhagat, French, Venkatakrishnan, Yozbatiran, Francisco, O'Malley and Contreras-Vidal 2014; Kornhuber and Deecke 1965; Shakeel, Navid, Anwar, Mazhar, Jochumsen and Niazi 2015; Shibasaki and Hallett 2006).

2.2. Tremor Onset Detection

There are some on-going researches to extract the best parameters from BCIs to detect tremor onset, and differentiate them from voluntary movements. These parameters include Event-Related Synchronization / Event-Related Desynchronization (ERS/ERD), muscle activity and MRCP (Grimaldi and Manto, 2010). In (Wu, Karwick, Ma, Burgess, Pan and Aziz 2010), the authors predicted PD tremor from recorded EMG signal using Radial Basis Function Neural Networks; they found that the tremor onset signal is between 1 and 10 Hz and that the pre-tremor signal contains a large amount of activity between 10 and 30 Hz.

2.3. Signal acquisition

In our experimental set up EEG signals are measured using a 16-channel g.USBamp amplifier at 256 Hz. Electrodes are placed according to the 10-20 system at C3, C4, Cz, F3, F4, and Fz. BCI2000 is used to extract features from the EEG signals and classify them. The experiment is performed using two computers: one for the stimulus presentation and another one for the acquisition and processing of the physiological signals.

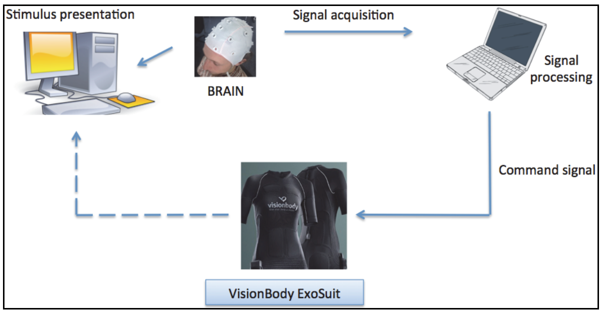

Figure 1: System Design

Fig.1 shows the design of the system. During the experiment, the subject is seated in a chair, in front of a computer screen where the cues are presented using BCI2000. He is asked to avoid moving too much to reduce muscle artefacts. The experiment is divided into two sessions: a system calibration session and a training session.
Each session has a certain number of trials, not too many to prevent fatigue. Each trial starts with a fixation period of 1000 ms, and is composed of 10s of Motor Imagination (MI)/Motor Execution (ME) followed by 3s of rest (Fig. 2). At the end of the fixation period, the subject is asked to wait at least 2s after the cue before attempting to perform a movement. The wait period is to avoid the presence of Contingent Negative Variation (CNV) in the recorded signal (Lew, Chavarriaga, Zhang, Seeck and Millan 2012). CNV is a negative cognitive Event-Related Potential (ERP) component related to expectancy. It peaks 260 to 470 ms after a warning stimulus, which requires a physical or mental response. It is most prominent at the vertex with maximal amplitude of 20 µV (Walter, Cooper, Aldridge, Mccallum and Winter 1964; Nagai, Critchley, Featherstone, Fenwick, Trimble and Dolan 2004).

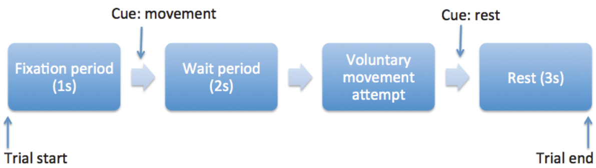

Figure 2: Experimental Setup

During the calibration session, brain signals are recorded during MI/ME, and during rest depending on the cue presented on the screen. The features extracted are MRCP and ERS/ERD of beta and alpha waves respectively. These features are used to train a classifier. During the training session, brain signals are recorded and the same features as in the calibration session are extracted. Volitional movement intention is detected using the trained classifier.
The detection of a voluntary movement or a tremor onset will trigger the electrical stimulation of the VisionBody ExoSuit, with an amplitude chosen between 0 and 50 mA, and a frequency of 20 to 50 Hz. Stimulation is sent by pulses of 0 to 0.5 ms and inter-pulse delays between 10-100 µs (Lee, Lin, Cheng, Wu, Hsieh and Chen 2015; Qu, Xie, Liu, He, Hao, Bao, Xie and Lan 2016; Ono, Mukaino and Ushiba 2013). The electrical stimulation is turned off once the subject reaches the end of the movement.

3. PRELIMINARY RESULTS

As mentioned previously, the aim of this project is to build a system that takes into account stroke and Parkinson's disease patient's motivation during rehabilitation using BCIs combined with a BodyVision ExoSuit that generates electrical stimulation to muscles.
EEG signals are very susceptible to artefacts that come from ocular and/or muscle activity, and from the external environment. First, we want to investigate how the electrical stimulation produced by the VisionBody ExoSuit is affecting the brain signals. This preliminary study is done to assess the feasibility of the project. To do so, we designed an experiment, which consists on simultaneously recording brain signals when the ExoSuit is producing electrical stimulation.
The EEG signals are acquired using a 16-channels g.USBamp amplifier, with 6 electrodes positioned at C3, C4, Cz, F3, F4, and Fz according to the 10-20 system. The ground and the reference electrodes are situated respectively at AFz and FCz (Yilmaz, Birbaumer and Ramos-Murguialday 2015).

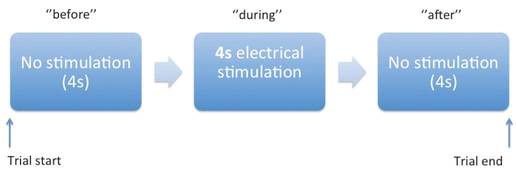

Figure 3: Experimental setup for the interference study.

During the experiment, the subject is wearing the BodyVision ExoSuit. The ExoSuit can be calibrated to deliver electrical stimulation raging from 0% (no stimulation) to 100% (maximum stimulation) on the arms and/or the legs among other locations. This study is done with stimulations ranging from 0 to 35% with an increment of 5% in each trial.
Each trial starts with a 4 seconds period without stimulation ("before") followed by a 4-second electrical stimulation period ("during") and another period without stimulation ("after"), as shown in Fig. 3.

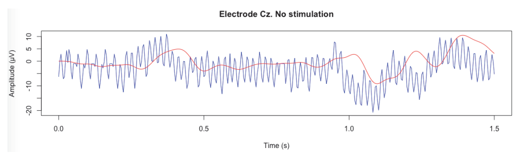

Figure 4: EEG signal recorded without electrical stimulation (ES). Raw signal are in blue, and filtered signal are in red.

Figure 4 shows a portion of EEG signal recorded at electrode Cz without electrical stimulation. The raw signal is presented in blue, while the signal in red represents the EEG signal after a 10 Hz cut-off low-pass filtering.

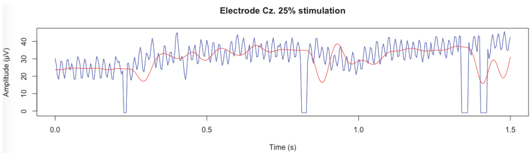

Figure 5: EEG signal recorded during a 25% ES. Raw signal are in blue, and filtered signal are in red.

It appears that starting at 20% ES, rectangular signal bursts arise from the EEG signal. Their amplitudes increase with an increase of the level of stimulation. Figure 5 shows a portion of EEG signal recorded while the BodyVision is delivering a 25% ES. It is reasonable to assume that these bursts are caused by the electrical stimulation, since they do not appear on the EEG signal "before" and "after" said stimulation.

As seen in the figure, the bursts are largely reduced after filtering. And since the characteristics of the electrical stimulation are known, these artefacts could be easily removed using convention artefacts removal methods like independent components analysis .

4. CONCLUSION

The paper describes an EEG-based BCI combined with electrical stimulation for stroke rehabilitation and tremor reduction for Parkinson's disease patients. SCPs are extracted from the recorded EEG to detect the subject's intention to move. Once a movement intention is detected or a tremor predicted, the targeted muscle is electrically stimulated to help the subject produce the movement, or to counter the effect of the tremor. Such system can make it possible to get more positive engagement from the subjects and a better outcome of the stroke rehabilitation process, and to reduce fatigue and improve the daily lives of PD's patients.

First experiments show, that starting at 20% stimulation intensity, the electrical stimulation contaminates the EEG signal with a number of rectangular bursts, but these artefacts are reduced by filtering and could be further removed by existing artefact removal techniques. This suggests the feasibility of the project from a technical point of view. Future direction will involve first healthy subjects, to prove feasibility in general, before targeting stroke patients.

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Authors' index