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Review Article

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Post Natal Mothers Satisfied and Happy with the Outcomes of their Deliveries after Individualized Precision Maternal Monitoring using 3D-Printing Technology in a Maternity Unit in the Developing World - A Case Study of Jaramogi Oginga Odinga Teaching and Referral Hospital in Western Kenya

Arthur Ajwang

Uzima University School of Medicine, Kenya

ABSTRACT

Background: In the low and middle income countries' healthcare system for medicine and surgery training and service provision, the use of computing technologies would be of great help in creating faster and transformational solutions by creating software applications and hardware fabrications for faster diagnosis, which are absent currently, hence leading to efficient treatment interventions in the developing world.

Objective: The objective of this study was to assess the potential of using computing innovation of 3-D printing technology in producing medical solutions using 3-D printing of fetoscopes to solve the challenge of the frequency of monitoring fetal heart rates in the maternity department.

Methodology: A randomized case-control study was used to analyze the impact of having one fetoscope per mother on shortening the frequency of monitoring of fetal heart rates and promptly intervening in case of non-reassuring fetal status. This was done by 3-D printing fetoscopes increasing the numbers at the Maternity department of Jaramogi Oginga Odinga Teaching and Referral Hospital.

Findings: The frequency of monitoring heart rates increased to hourly instead of 3 hourly in 24 hours, leading to timely interventions, as compared to previous days when there was only one fetoscope serving the whole unit. Mothers with a 3-D printed Fetoscope reported a lower proportion of emergency caesarean section done compared to mothers who were sharing a 3-D printed Fetoscope (13% vs. 38%, $p = 0.021$). No fetal death was reported among mothers with a 3-D printed Fetoscope each, while maternal satisfaction was higher among mothers with a 3-D printed Fetoscope as compared to those who were sharing (94% vs. 63%, $p = 0.002$).

Conclusion: We concluded that computing technology is useful in designing and fabricating medical equipment and parts, which help save lives in the maternity, emergency room and the operating room in low and middle income countries.

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Keywords: Post Natal, Mothers, Satisfied, Happy, Outcomes, Deliveries, Individualized, Precision, Maternal, Monitoring, 3-D-Printing Technology, Maternity Unit, Developing World

Introduction

In a general way, computing can be defined to mean any goal-oriented activity requiring, benefiting from, or creating computers. Thus, computing includes designing and building hardware and software systems for a wide range of purposes; processing, structuring, and managing various kinds of information; doing scientific studies using computers; making computer systems behave intelligently; creating and using communications and entertainment media; finding and gathering information relevant to any particular purpose, and so on. The list is virtually endless, and the possibilities are vast. In the healthcare system for medicine and surgery training and service provision, the computing technologies that would be of great help in creating solutions include 3D printing, Artificial Intelligence (A.I), Internet of things (IoT), creating medical software applications through coding for faster diagnosis and quantum computing [1,2].

Artificial intelligence is the science and engineering of making intelligent machines, especially intelligent computer programs, when a machine simulates functions that humans associate with other human minds, such as learning and problem solving. The internet of things describes the network of physical objects "things", which are embedded with sensors, software, and other technologies for the purpose of connecting and exchanging data with other devices and systems over the internet. Application software (app for short), is a program or group of programs designed for end-users and normally refers to all applications collectively. Quantum computing is an area of computing that allows the computers to do large scale equations, such as in large molecular modelling [3-6].

3D printing is a rapid prototyping mode without mold making. It is also known as the material additive manufacturing. Based on the 3D digital model file, it constructs the object through printing the materials layer by layer. This technology needs the raw material much less than the traditional one which uses rough pruning forming. Through changing the model's configuration, it could respond to the consumers' demand more flexibly. The academia and the industry think it will subvert the production rules, set from the first industrial revolution together. The social, economic, and technical 3D printing revolution is on the way. The entrepreneurs, policy makers, and society at large will encounter unforeseen opportunities and challenges [7].

In recent years 3D printing technology continued developing, especially the breakthroughs in the material application. More than one hundred of raw materials can be used for 3D printing. They include thermoplastic plastics, metal, nylon, acrylic, plaster, ceramic, and edible material. The expansion of the material type will promote the application of this technology in more productive areas. Nowadays this technology could be used to produce spare parts, singular parts, bio-constructs, micro-machines, electronics, and even jewelry. Although, the study of 3D printing impact on the society is lacking and more concentrated in the business reports. The academic quantitative analysis is not enough [8-15].

Medical 3D printing was once an ambitious pipe dream. However, time and investment made it real. Nowadays the 3D printing technology represents a big opportunity to help pharmaceutical and medical companies to create more specific drugs, enabling a rapid production of medical implants and changing the way doctors and surgeons plan procedures. This technology has multiple applications, and the fastest growing innovation in the medical field has been represented by the advent of the 3D printing itself. Five technical steps are required to finalize a printed model. They include selecting the anatomical target area, the development of the 3D geometry through the processing of the medical images coming from a CT/MRI scan, optimization of the file for the physical printing, and the appropriate selection of the 3D printer and materials. This filer represents the guidance for the subsequent printing, "slicing" that digital design model into cross sections. That "sliced" design is then sent to a 3D printer, which manufactures the object by starting at the base layer and building a series of layers on top until the object is built using the raw materials that are needed for its composition. A patient-specific model with anatomical fidelity created from imaging dataset is finally obtained. In this way, the 3D printing has the potential to significantly improve the research knowledge and the skills of the new generation of surgeons, the relationship between the patient and surgeon, increasing the level of understanding of the disease involved, and the patient-specific design of implantable devices and surgical tools and optimize the surgical process and cost. Nowadays, different printing techniques and material are available in order to better reproduce the patient anatomy. Most of the available printing materials are rigid and therefore not optimum for flexibility and elasticity, unlike biological tissue. Therefore, there are nowadays materials able to close the gap between the real anatomy and the reproduced one, especially considering the soft tissue [16-25].

Every year, 3D printing offers more and more applications in the healthcare field helping to save and improve lives in ways never imagined up to now. In fact, the 3D printing has been used in a wide range of healthcare settings including, but not limited to cardiothoracic surgery , cardiology, gastroenterology, neurosurgery , oral and maxillofacial surgery, ophthalmology, otolaryngology, orthopaedic surgery, plastic surgery, podiatry, pulmonology, radiation oncology, transplant surgery, urology, and vascular surgery. Several studies have demonstrated that patient-specific pre-surgical planning may potentially reduce time spent in the operating room (OR) and result in fewer complications. The 3D-printing technology provides to the surgeon a physical 3D model of the desired patient anatomy that could be used to accurately plan the surgical approach along with cross-sectional imaging or, alternatively, modelling custom prosthetics (or surgical tool) based on patient-specific anatomy. In this way, a better understanding of a complex anatomy unique to each case is allowed. Furthermore, the 3D printing gives the possibility to choose before the implantation, the size of the prostheses components with very high accuracy [26-55]. The customization of surgical tools and prostheses by 3D printing, means a reduction of cost given by the additive manufacturing technique [46-50,56]. 3D printing is useful in validating the results achieved by a patient following medical treatment of osteoporotic condition, hence enables an accurate estimation of patient's bone condition and a better decision on the surgical treatment. It is also used to test different devices in specific pathways, like the reproduction of different vascular patterns to tests the effectiveness of a cardiovascular system used to treat peripheral and coronary artery disease. This technology is also used to improve medical education, like in 3D-printed patient-specific models have demonstrated that they can increase performance and foster rapid learning, while significantly ameliorating the knowledge, management, and confidence of the trainees regardless of the area of expertise [28,57-59]. The benefits of 3D printing in education are the reproducibility and safety of the 3D-printed model with respect to the cadaver dissection, the possibility to model different physiologic and pathologic anatomy from a huge dataset of images, and the possibility to share 3D models among different institutions, especially with ones that have fewer resources [50]. On patient education, 3D printing may improve the doctor-patient communication by showing the anatomic model directly. 3D printed rare pathological anatomical models can be stored for educational purposes, allowing the training of surgeons in specific applications [39-41]. A 3D printed model can also be used in a courtroom to easily demonstrate various anatomic abnormalities that may be difficult to jury members to understand using cross-sectional imaging. 3D printing also allows the modelling of implantable tissue, like in burn injuries . Personalized drug 3D printing is used in printing of powdered drug layers that dissolve faster than the average pills. It can be used in printing customized synthetic organs, by presenting an opportunity to save life reducing the waiting list of patients that need transplantation. The bio-printed organs may also be used in the future by pharmaceutical industries to replace animal models for analyzing the toxicity of new drugs [61-63].

Hence, the above examples clearly demonstrate that 3D printing is a technology that has the potential to change significantly the clinical field, improving medicine, and healthcare, making care affordable, accessible, and personalized. As the printers evolve, printing biomaterials get safety regulations and the general public acquires a common sense about how 3D printing works.

In this paper we studied the exponential possibilities in the twinning of computing technology and medicine and surgery for transformational medical solutions in the developing world.

Methodology

3-D printing of fetoscopes was done using the Pennsylvania University School of Engineering prototype, which was donated by the school to the Uzima University School of Medicine. A total of 32 fetoscopes were printed for each maternity room, so that each mother had one for her examination at the Jaramogi Oginga Odinga Teaching and Referral hospital and to compare retrospectively when there was only one for the whole maternity unit, and analyze the timing of detection of non-reassuring fetal status (fetal distress) and outcomes of emergency caesarian sections amongst the two cohorts. A case-control retrospective versus prospective study used for the mothers in labour at the hospital. A case group of 32 mothers were chosen randomly for the prospective study and compared retrospectively with a control group of 32 who were picked randomly from the delivery report book going 6 months backwards when there was a single fetoscope for the whole unit. Their medical records were obtained until the time of discharge after delivery. The frequencies of fetal examinations, the fluctuations, decision time from admission, intervention and outcome of interventions were recorded. The same was done for the prospective group. The maternity nurses and attending doctors who had been in the unit for the last 6 months were interviewed for their experiences before and after the 3-D printing intervention.

Findings

We summarized the categorical variables using frequency counts and percentages, and characterized continuous variables using median and interquartile range (IQR). Pearson's Chi-square / Fisher's Exact test was used to assess the association between categorical variables and the outcome, while for continuous variables, we used non-parametric Wilcoxon–Mann–Whitney test.

Figure 1: Frequency of Fetal Heart Monitoring in Hours

In situations where each mother had a 3-D printed Fetoscope in maternity bedside, it took slightly more than an hour to monitor fetal heart rate while their counterparts with shared Fetoscope used nearly 3-hours, median time in hours= 1.3 IQR (1.1 -1.6) versus 2.5 IQR (1.9 -3.9), $p < 0.001$) as shown in figure 1.

It was the same story with identification of non-reassuring fetal status, with mothers having 3- D printed Fetoscope on bedside having less time in identification compared to mothers who share the 3- D printed Fetoscope, median time in hours=1.2 hrs IQR (1.1 -1.3) versus 2.6 hrs IQR(2.3 -2.8), $p < 0.001$ as shown in figure 2

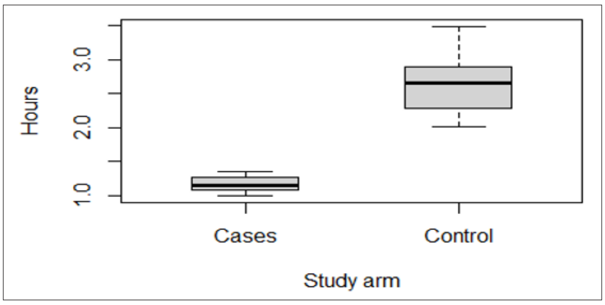


Figure 1: Identification of Non-Reassuring Fetal Status/Each Mother Had A 3-D Printed Fetoscope

Table 1: Association between Hospital Maternal Services and each mother with a 3-D printed Fetoscope

		Mothers in Labour		
Characteristic	**N**	**Cases, N = 32[1]**	**Control, N = 32[1]**	**p-value[2]**
Emergency Caesarean Section done to mothers to save fetus	64			0.021
No		28 (88%)	20 (63%)	
Yes		4 (13%)	12 (38%)	
Fetal death with or without Caesarean Section intervention	64			0.240
No		32 (100%)	29 (91%)	
Yes		0 (0%)	3 (9.4%)	
Maternal satisfaction	64			0.002
No		2 (6.3%)	12 (38%)	
Yes		30 (94%)	20 (63%)	
Monitoring of fetal heart rate	64	1.40 (0.33)	2.52 (0.81)	<0.001
Identification of non-reassuring fetal status	64	1.17 (0.11)	2.63 (0.40)	<0.001

[1]n (%); Mean (SD)
[2]Pearson's Chi-squared test; Fisher's exact test; Wilcoxon rank sum exact test

Mothers with a 3-D printed Fetoscope reported a lower proportion of emergency caesarean section done compared to mothers who were sharing a 3-D printed Fetoscope (13% vs. 38%, $p = 0.021$). No fetal death was reported among mothers with a 3-D printed Fetoscope each, while maternal satisfaction was higher among mothers with a 3-D printed Fetoscope as compared to those who were sharing (94% vs. 63%, $p = 0.002$).

The rate of monitoring of fetal heart rate and identification of non-reassuring fetal status was hourly among cases compared to 3 hours among controls (Table 1)

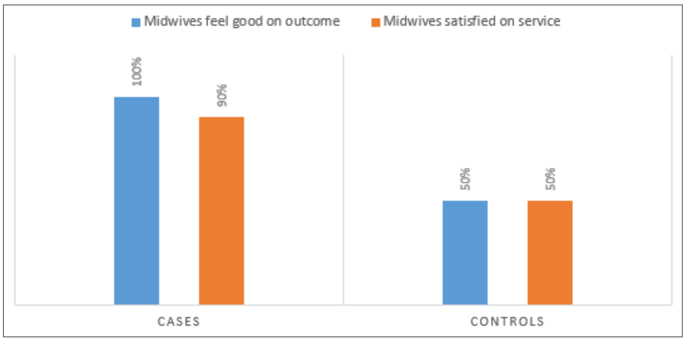


Figure 2: Mid-Wives' Satisfaction on Services and Outcome (each mother with 3-d Festoscope vs. Shared)

In the hospital, the average frequencies of fetal heart monitoring were hourly for the case group as compared to 3 hourly for the control group. The identification of non-reassuring fetal status was 3 hours late in the control group as compared to within one hour in the case group. An average of 12 mothers in the control group had a caesarian section as the intervention to save the fetus as compared to 4 mothers in the case group. The fetal deaths with or without caesarean was at 3 deaths for the control group as compared to none in the case group. The maternal satisfaction of the case group was at an average of 30 mothers as compared to 20 mothers in the control group. The satisfaction of the midwives (nurses, clinical officers and doctors) was at 9 midwives out of 10 post availability of the 3-D printed fetoscopes as compared to 5 midwives out of 10 with 1 fetoscope for the whole maternity. The average feel good effect for service delivery for the fetoscope per patient amongst the maternity staff was at 10 out of 10, as compared to 5 midwives out of 10 in the shared fetoscope group.

There were 12 mothers who had Covid-19 in pregnancy, suspected to have been caused by cross-infection due to sharing of the one fetoscope in the control group as compared to the case group, that had no mother with Covid-19 in pregnancy. An unexpected finding was the increased morale and happiness in seeing almost all of their patients going home with babies after normal deliveries and few caesarean sections. This unexpected finding came out in the review statement form given to the maternity service providers at the end of the action study.

Discussion

The use of artificial intelligence for the development of applications for solving medical problems, like diagnosing of diseases clinically, where laboratory support is not available is a sprouting essential need, especially in the developing world. Artificial intelligence is the science and engineering of making intelligent machines, especially intelligent computer programs, when a machine simulates functions that humans associate with other human minds, such as learning and problem solving [3]. The African populace has a smart phone ownership of approximately 70%, and this could be almost 100% for the medical personnel, hence having such "apps" for 3-D printing, and available already designed parts of medical and surgical equipment.

On the other hand, developing countries are unfortunately also the low economic nations, hence their budgets are constrained with burdens of basic services to the populace and this leaves essential areas like health with inadequate funding to buy equipment for service delivery. Hence equipment as essential, basic, simple and cheap as a fetoscope cannot be bought in required numbers in healthcare centers and hospitals with maternity units for the monitoring of the fetal heart rates in utero to assess its wellbeing.

The findings in the maternity unit of the hospital, shows that a 3D printer can print fetoscopes at a fraction of the price of a new one bought in the medical equipment shop. This came out from the interview of the nurse in charge of the unit who purchases equipment for the maternity, when a comparison was done between the unit cost of 3D printing one fetoscope as compared to one bought at the shop, which is in agreement to the papers that states that the customization of medical/surgical tools means a reduction of cost given by the 3D printing technique. The 3D printing added 32 fetoscopes within 48 hours to just 1 fetoscope that had been used in the entire maternity unit for the previous 12 months despite regular requisition orders, supported by the paper that states that 3D printing consists in "enabling doctors to treat more patients, without sacrificing results" [62]. There is also the finding of early detection of fetal non-reassuring status, which leads to early intervention and saving of lives of the fetuses as compared to when there was only one fetoscope for all the patients, this is supported by the papers that state that 3D printing can be used to manufacture medical/surgical instruments that reduce costs and also save lives. The number of mothers undergoing caesarean section deliveries due to fetal distress, was reduced drastically due to the early detection of non-reassuring fetal status and getting immediate medical intervention to control the distress as compared to the previous situation where there were late detections meaning emergency surgeries to save the fetus [42-44,50]. The number of fetal deaths in utero or peri-natally due to the late detection of fetal distress also declined drastically due to frequent fetal heart rate monitoring leading to early detection and early intervention to stop the deterioration and normalize the fetal heart rate in good time [62]. One fetoscope per mother, increased satisfaction of the mother in the hospital services. The situation also increased the satisfaction of the service providers/midwives and an unexpected finding was the increased moral and happiness in seeing almost all of their patients going home with babies after normal deliveries and few caesarean sections. In the hospital, another unexpected finding was the stated interest by some of the staff in using the 3D printer prototype and a request for availability of the printer in their unit for continuous usage in printing the equipment they need and repairing broken ones like the nursery incubators, despite this paper that states that the 3D printing majorly aids surgical intraoperative and post-operative complications, it is evident that it can also be used in the maternity unit to monitor mothers and prevent emergency sections [63]. These unexpected findings came out in the review statement form given to the maternity service providers at the end of the action study.

These findings show that 3D printing is a necessary technology in the developing world in the hospital set up for manufacturing of essential but basic equipment for the daily usage for service provision [42-44,50].

In the hospital's findings, I may have chosen the bad timing for the control group and a good timing for the case group in terms of pregnancy outcomes and fetal statuses. There is also a possibility that the case arm mothers had the JOOTRH as their first hospital for delivery and the control arm mothers had visited other hospitals with non-progressing labours, before they were referred to the JOOTRH for further management or surgical intervention. There is also the possibility that the control group had other indications for caesarean sections like breech presentation as compared to the case group that had only fetal distress as an indication. This multiple indication for surgical intervention like having fetal distress and cord around neck of fetus in the control group may have contributed to more fetal deaths in the control group despite caesarean section intervention as compared to the control group.

I did not control for above mentioned confounders and did not review the patient records for such likelihood like multiple co-morbidities for the fetus even for the mothers.

The problems I encountered was interpreting results of a mother with triplets in terms of picking all the fetal heart rates and deciding on the outcome of the intervention as early or late with fetal death of the second twin after the first and the 3rd twin were alive and well post-surgery. There is also the problem of not having been able to print flexible organ models, such as the heart in which the lecturer could have shown how the heart beats to pump blood to the lungs and again to the entire body, although nowadays there are materials able to close the gap between the real anatomy and the reproduced one, especially considering the soft tissue [8,9,10-31]. This would have been an additional way of learning about the 1st and 2nd heart beats and the presence of an additional heart beat or murmurs during a heart pathology. The 3D printing technology fraternity should also print organs successfully for transplantation to avoid the long wait for donors, leading to deaths that could have been avoided, which are stated to require more time.

Conclusion

The study concluded that computing is a necessary investment in the health departments of the developing world. The findings also imply that computing technology is useful in accessing readily designed medical equipment and parts in the "cloud", that can be used anywhere to sort out emergent break-down situations and lack of essential equipment, that help save lives in the maternity ward, emergency room and even in the operating room.

The findings show a clear improvement and frequency of services and outcomes in the maternity department, using the 3-D printed fetoscopes to increase availability of a simple monitoring and diagnostic equipment such as a fetoscope. It can be used in various other departments in the healthcare system to solve a multitude of emanating issues and gaps that would be very expensive to undertake by buying new machines/products or parts of the same from the manufacturers. The 3-D computing technology can also be used in non-medical departments in the developing world to improve service delivery and manufacturing of needed products as fast as possible to avoid unnecessary delays of tendering, ordering and supply chain process for plastic equipment and broken parts.

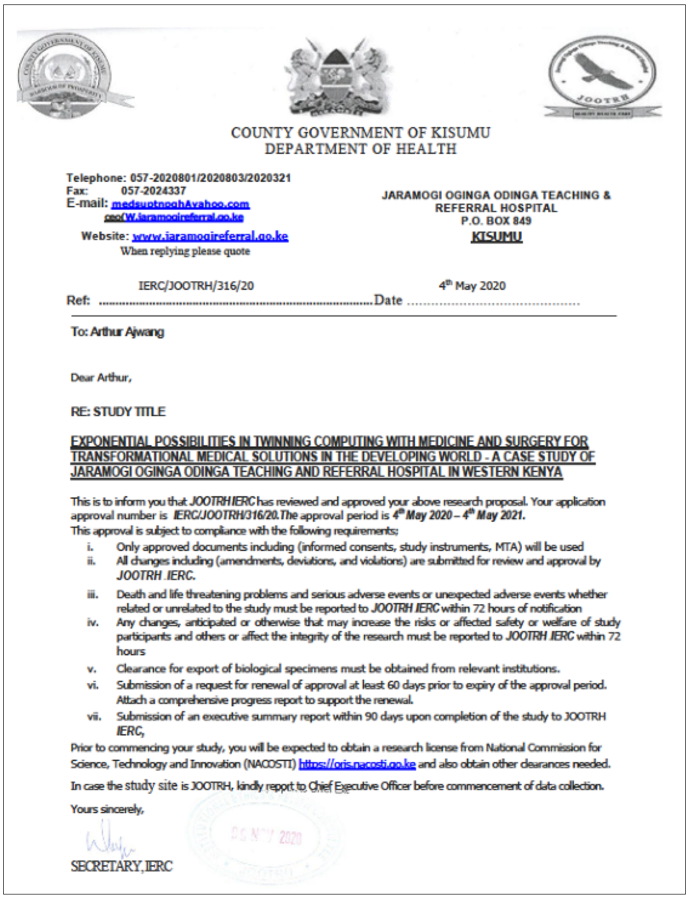
This is an explicit proof of concept and evidence-based support for the twinning of computing with medicine and surgery in producing transformational medical solutions in the low and middle income countries, as evident in the findings in the maternity department of the Jaramogi Oginga Odinga Teaching and Referral Hospital.

Recommendation

The recommendation is that all health institutions in the low and middle income countries, should invest in computing technology and a 3-D printer prototype, that will help with training, diagnosis, planning of surgical operations, during the operation, making custom made prostheses, manufacturing simple equipment and repairing of parts of hospital equipment that break down. The hospital departments should also invest in computing technology and a 3-D printer based in-house for quick access and fast fabrication of needed product/s.
The other non-medical departments should also try the use of 3-D printing technology in their trainings and daily work, to assess the benefits or lack thereof.

I recommend the twinning of computing and medicine and surgery in all the healthcare facilities in the developing world to produce transformational medical solutions to render comprehensive lifesaving service provision in the hospitals.

Appendix 1
Approval for Study



COUNTY GOVERNMENT OF KISUMU
DEPARTMENT OF HEALTH

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Website: www.jaramogireferral.go.ke
When replying please quote

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL
P.O. BOX 849
KISUMU

Ref: IERC/JOOTRH/316/20 Date 4th May 2020

To: Arthur Ajwang

Dear Arthur,

RE: STUDY TITLE

EXPONENTIAL POSSIBILITIES IN TWINNING COMPUTING WITH MEDICINE AND SURGERY FOR TRANSFORMATIONAL MEDICAL SOLUTIONS IN THE DEVELOPING WORLD - A CASE STUDY OF JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL IN WESTERN KENYA

This is to inform you that *JOOTRH IERC* has reviewed and approved your above research proposal. Your application approval number is *IERC/JOOTRH/316/20.The* approval period is ***4th May 2020 – 4th May 2021.***
This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by *JOOTRH IERC.*
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to *JOOTRH IERC* within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to *JOOTRH IERC* within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to JOOTRH *IERC,*

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

In case the study site is JOOTRH, kindly report to Chief Executive Officer before commencement of data collection.

Yours sincerely,

SECRETARY, IERC

Appendix 2
Informed Consent

Literate study personnel will read and explain the consent form to prospective subjects.
Flesch-Kincaid Readability Level: 8.5

Investigator
Dr. Arthur Ajwang – Principal Investigator (Medical Doctor): Clinical Instructor at Uzima University School of Medicine

UUSOM – Uzima University School of Medicine

JOOTRH – Jaramogi Oginga Odinga Teaching and Referral Hospital

Title of the Study: Exponential Possibilities in Twinning of Computing Innovation of 3-D Printing Technology with Medicine and Surgery for Transformational Medical Solutions in The Developing World - A Case Study of Jaramogi Oginga Odinga Teaching and Referral Hospital in Western Kenya.

Introduction

3D printing is a rapid prototyping mode without mold making. It is also known as the material additive manufacturing. Based on the 3D digital model file, it constructs the object through printing the materials layer by layer. This technology needs the raw material much less than the traditional one which uses rough pruning forming. Through changing the model's configuration, it could respond to the consumers' demand more flexibly. The academia and the industry think it will subvert the production rule set from the first industrial revolution together. The social, economic, and technical 3D printing revolution is on the way. The entrepreneurs, policy makers, and society at large will encounter unforeseen opportunities and challenges.

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Medical 3D printing was once an ambitious pipe dream. However, time and investment made it real. Nowadays the 3D printing technology represents a big opportunity to help pharmaceutical and medical companies to create more specific drugs, enabling a rapid production of medical implants and changing the way doctors and surgeons plan procedures. This technology has multiple applications, and the fastest growing innovation in the medical field has been represented by the advent of the 3D printing itself.

Purpose of the research

The objective of this study was to assess the potential of using computing technology with medicine and surgery in producing medical solutions using 3-D printing of fetoscopes to solve the challenge of monitoring fetal heart rates in the maternity department.

Study population, setting and sample size

A case group of 32 mothers, will be chosen randomly for the prospective study and compared retrospectively with a control group of 32 who will also be picked randomly from the delivery report at the maternity wing of the Jaramogi Oginga Odinga Teaching and Referral Hospital.

Procedures

It is your choice to agree to be in this study. If you decide to join the study, we will ask you if we can, use the information collected about you during the study. 3-D printing of the 32 fetoscopes will be done using the Pennsylvania University School of Engineering prototypes, which were donated to Uzima University School of Medicine. A case group of 32 mothers will be chosen randomly for the prospective study and compared retrospectively with a control group of 32 who will also be picked randomly from the delivery report book going 6 months backwards when there was a single fetoscope for the whole maternity unit. Their medical records will be obtained until the time of discharge after delivery. The study will be done at the maternity wing of the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH).

Participation is voluntary

Your participation in this study is voluntary. You may decide not to join the study. You may also decide to leave the study at any time in the course of the research. This will not stop you from getting the standard of care at the maternity department of JOOTRH.

Alternatives to joining the Study

Your alternative to joining the study is to not take part in the study. The maternity wing will continue providing you with the standard of care until you deliver your baby.

Risks or discomfort

This study has no risk at all to you.

Benefits

There is no immediate direct benefit to you in this study. After the study, the data will be used by the maternity and the hospital to improve the services given to pregnant mother and their unborn babies, in this hospital and other hospitals.

Costs to you or your patient

There is no cost to you for joining this Study.

Your records will be private

All the information we collect from you, including the results from any test, will be kept private by the study staff. You shall be given a special study identification number. This number will be used on all of your study records instead of your name. The study records will be kept in locked file cabinets and on computers with passwords. Only study staff will have access to them. Your name and personal information will only be used to reach you to provide to you the study results. Your records may be reviewed by study monitors or Ethics Committee members at their request. None of the reports or publications from the study will include your individual personal information.

Contacts

If you have any questions about this study, please contact Dr. Arthur Ajwang on 0731 714171 {Uzima University School of Medicine}.

If you would like to leave the Study at any time, please contact Dr. Arthur Ajwang on 0731 714171 {Uzima University School of Medicine}.

If you change your phone number or address, please contact Dr. Arthur Ajwang on 0731 714171 {Uzima University School of Medicine}, so we can contact you to inform you about the results of the Study.

If you have any questions about your rights in the Study or you feel you have been harmed in any way or you would like to talk to someone who is not part of the Study team, please contact the Secretary or Chairman of the **JOOTRH/ Ethics Review Committee**, PO Box 849-40100, Kisumu, **Telephone numbers: 057-2020801/2020803/2020321; E-mail address: ercjootrh@gmail.com**

This proposal has been reviewed and approved by the Ethical committees of Jaramogi Oginga Odinga Teaching and Referral Hospital and Uzima University. These committees make sure that Study participants are protected from harm.

CONSENT FOR PARTICIPATING IN THE STUDY

The above study has been explained to me and I agree to join.

- I have been told about the risks and benefits of joining this Study.
- I have been able to ask questions about it and my questions have been answered.
- I have been told that it is up to me if I want to join this study. I know that I can leave the study at any time without any consequences to me and my health care at the hospital.
- I know the study involves taking a questionnaire interview with the study staff and a venous blood sample from me.
- I agree to have Study staff visit me at home if I am not able to be reached by phone or if I am unable to come to the hospital.

If you agree to join the study, please sign your name below. If you are unable to sign, please put your thumbprint on the proper lines, as you do when you seek an identification card.

NOTE: You are not giving up any of your legal rights by signing this informed consent form.

If you agree, please circle "yes". YES

Participant's name signature or thumbprint Date
(Please print)

Witness's name Witness's signature Date
(If participant is illiterate. Please print)
I have explained the purpose of this study to the study participant. To the best of my knowledge, she understands the purpose, procedures, risks and benefits of this study.

Investigator/His Designee name Investigator/His Designee signature Date
(Please print)

NOTE: This consent form with original signatures must be retained on file by the principal investigator. A copy must be given to the study participants.
If the participant refuses to take her copy of the consent form with her, she should state so below and signs and dates her decline statement.
No, I do not wish to receive a copy of this signed consent form.

Participant's name Signature or thumbprint Date

Witness's name Witness's signature Date

Appendix 3
Questionnaire

maternity ward service provision with 3-d printed fetoscopes for each mother to monitor fetal heart rate till birth

DEMOGRAPHY
Name: …………………………………… Participant I/D……………………………
Gender………... Residence…………………………………….
County of residence:…………………… Sub-county:……………………………
Location:………………………………… Sub-location:……………………………
Village/Estate:………………………… Centre/Town/City:.……………………
Nearest School: ………………………… Nearest Market: ……………………
Telephone number: ……………………… Post Office Box: ………………………
Parity:………………………………… Weeks of Pregnancy:…………………………

1. What is your date of birth?

Day …………Month………………Year………………….

A. MIDWIVES (NURSES, CLINICAL OFFICERS AND DOCTORS) SECTION

2. Fetal Heart Rate is monitored how often?
o Hourly
o 2 Hourly
o 3 Hourly
o 4 Hourly

3. How many mothers underwent Emergency Caesarean Section to save the life of the fetus due to non-reassuring status (Physical count in the prospective arm and retrospective arm out of 42 mothers each per arm)?

4. How many fetal deaths occurred with or without C/S intervention to save the life of the fetus (Physical count in the prospective {1 fetoscope per mother} arm and retrospective {1 fetoscope in the whole maternity wing} arm out of 42 mothers each per arm)?

5. Are you satisfied with the outcome of the maternity service (prospective with fetoscope per mother?)
o Satisfied
o Not Satisfied

6. Are you satisfied with the outcome of the maternity service (retrospective with 1 fetoscope serving the whole maternity wing?)
o Satisfied
o Not Satisfied

7. Do you have a feel good effect with the outcome of the maternity service (prospective with fetoscope per mother?)
o Satisfied
o Not Satisfied

8. Do you have a feel good effect with the outcome of the maternity service (retrospective with 1 fetoscope serving the whole maternity wing?)
o Yes
o No

9. How many maternity Covid-19 in pregnancy cases were suspected Covid-19 cross-infection with the fetoscope (prospective with fetoscope per mother?)

10. How many maternity Covid in pregnancy cases were suspected Covid-19 cross-infection with the fetoscope (retrospective with fetoscope per mother?)

B. MATERNAL SECTION

11. Are you satisfied with the maternity services that you got (prospective with fetoscope per mother?)
o Satisfied
o Not Satisfied

12. Are you satisfied with the maternity services that you got (retrospective with 1 fetoscope serving the whole maternity wing?)
o Satisfied
o Not Satisfied

13. How is the baby doing (prospective with fetoscope per mother?)
o Well
o Not well
14. How is the baby doing (retrospective with fetoscope per mother?)
o Well
o Not well

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