UNIVERSIDADE FEDERAL DE MINAS GERAIS
FACULDADE DE MEDICINA
PÓS-GRADUAÇÃO EM CIÊNCIAS APLICADAS À CIRURGIA E OFTALMOLOGIA

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DESENVOLVIMENTO DE PROCESSO DE TREINAMENTO EM CIRURGIA ROBÓTICA BASEADO EM COMPETÊNCIAS

Belo Horizonte
2021

MARCELO ESTEVES CHAVES CAMPOS

DESENVOLVIMENTO DE PROCESSO DE TREINAMENTO EM CIRURGIA ROBÓTICA BASEADO EM COMPETÊNCIAS

Tese apresentada ao Programa de Pós-graduação em Ciências aplicadas à Cirurgia e Oftalmologia da Faculdade de Medicina da Universidade Federal de Minas Gerais, como requisito parcial para obtenção do título de Doutor.
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Linha de Pesquisa: Modelos clínicos e experimentais em técnica cirúrgica
Orientadora: Profa. Dra. Vivian Resende
Co-orientador: Prof. Dr. Rafael Ferreira Coelho

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DESENVOLVIMENTO DE PROCESSO DE TREINAMENTO EM CIRURGIA ROBÓTICA BASEADO EM COMPETÊNCIAS

MARCELO ESTEVES CHAVES CAMPOS

Tese de Doutorado defendida e aprovada, no dia **dez de novembro de dois mil e vinte e um**, pela Banca Examinadora designada pelo Colegiado do Programa de Pós-Graduação em CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA da Universidade Federal de Minas Gerais constituída pelos seguintes professores:

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Aos meus pais, meus maiores exemplos.
E ao meu irmão, meu melhor amigo.

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“Quem ensina aprende ao ensinar, e quem aprende ensina ao aprender”

Paulo Freire

RESUMO

Métodos de educação cirúrgica, como simulação, estão sendo investigados em todo mundo para desenvolver currículos de treinamento em cirurgia assistida por robô (CAR). No entanto, há uma carência de programas de treinamento estruturados e critérios para certificação de cirurgiões em CAR. Além disso, os programas de treinamento em CAR publicados na literatura não satisfizeram a maioria dos pré-requisitos para um processo de aprendizagem validado. Nesse estudo, foi desenvolvido um processo de treinamento em cirurgia robótica com ênfase na aquisição de competências. Para esse propósito, (1) desenvolveu-se o COBRASIL, currículo de treinamento progressivo em CAR, baseado em competências, após revisão sistemática de literatura; (2) desenvolveu-se o estudo piloto de validação de programa de treinamento em cirurgia urológica robótica baseado no COBRASIL; (3) validou-se um treinamento progressivo em CAR no simulador virtual *Mimic dV-Trainer*; (4) desenvolveu-se e validou-se o modelo de simulação ex vivo com placenta humana para o treinamento de CAR e (5) desenvolveu-se e validou-se o instrumento de avaliação SCORE, ferramenta objetiva e estruturada de avaliação de habilidades operatórias de sutura em CAR, do tipo *checklist*. No decorrer do estudo, diversos experimentos foram realizados em ambientes simulados e reais para demonstrar a natureza robusta e escalável desse processo de treinamento relevante na cirurgia robótica. Esse processo de capacitação visou a garantia da assistência de qualidade para que os cirurgiões pudessem continuar exercendo sua profissão de forma adequada e segura mesmo diante do avanço da tecnologia. Salienta-se que as estratégias de aprendizagem e estrutura organizacional utilizadas nesse estudo abrem novos campos de pesquisa que levam a um aprofundamento no conhecimento das competências envolvidas na capacitação dos cirurgiões.

Palavras-Chave: avaliação; simulação; cirurgia robótica; educação; programas de treinamento

ABSTRACT

Surgical education methods, such as simulation, are being investigated around the world in order to develop training curricula for robotic assisted surgery (RAS). However, there is a lack of criteria well-structured training program for board certification in RAS. In addition, the RAS training programs published in the literature did not satisfy most of the prerequisites for a validated learning process. In this study, a training process in robotic surgery was developed with emphasis on competencies acquisition. For this purpose, (1) COBRASIL, a progressive training curriculum in RAS, based on competencies, was developed after a systematic literature review; (2) a pilot study was developed to validate a training program in robotic urological surgery based on COBRASIL; (3) progressive training in RAS was validated in the Mimic dV-Trainer virtual simulator; (4) an ex vivo simulation model for RAS training was developed and validated and (5) the SCORE assessment instrument, an objective and structured tool, checklist type, for evaluating surgical suture skills in RAS, was developed and validated. Several experiments in this study were performed in simulated and real environments to demonstrate the robust and scalable nature of this relevant training process in robotic surgery. This training process aimed to ensure quality care so that surgeons could continue to practice their profession adequately and safely even with technology advancement. It is notepoint that the learning strategies and organizational structure used in this study open new fields of research that lead to a deepening in the knowledge of the competencies involved in the training of robotic surgeons.

Key-Words: assessment; simulation; robotic surgery; education; training programs

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LISTA DE ABREVIATURAS

ACGME - Accreditation Council for Graduate Medical Education

AS - Assessment.

CA - California

CAR – Cirurgia assistida por robô

CASE - Cystectomy Assessment and Surgical Evaluation

CEP - Comitê de Ética em Pesquisa

CMEC - Campos, Marcelo Esteves Chaves

COBRASIL - Competency-Based Robot-Assisted Surgery Instructional Learning

COVID-19 – Coronavirus disease 19

CPR – Castro, Pedro Romanelli

CRF – Coelho, Rafael Ferreira

DL - Dry lab

dVSS - da Vinci Surgical Simulator

dVT - dV-Trainer

EG – Expert group

EL - E-Learning

EPAs - Entrustable Professional Activities

FM-UFMG – Faculdade de Medicina da Universidade Federal de Minas Gerais

FCMMG - Faculdade de Ciências Médicas de Minas Gerais

FELUMA – Fundação Educacional Lucas Machado

GEARS - Global Evaluative Assessment of Robotic Skills

GRS - Global rating scales

ICC - Intraclass correlation coefficient

IG - Intermediate group

IR - Independent rater

JIT - Just-In-Time

K - Knowledge-Based Training

M - Modular-Based Training

NG - Novice group

NIVEL - Netherlands Institute for Healthcare Research

NOTSS - Non-Technical Skills for Surgeons

OR – Operation room

OSATS - Objective Structured Assessment of Technical Skills

OTAS - Observational Teamwork Assessment for Surgery

P - Proficiency-Based Training

PACE - Prostatectomy Assessment and Competency Evaluation

PI - Performance index

PLACE - Pelvic Lymphadenectomy Appropriateness and Completion Evaluation

PR - Proctor rater

PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analysis

PT - Proctoring

r - Pearson's correlation coefficient

RACE - Robotic Anastomosis Competency Evaluation

RAS - Robotic assisted surgery

ROSATS - Robotic assessment of technical skills

RoSS - Robotic Surgical Simulator

RXM - RobotiX Mentor

S - Skill-Based Simulation Training

SC – Suture checklist

SCORE - Suture Checklist of Objective Robotic Evaluation

SPaN - Scoring for Partial Nephrectomy

T - Team-Based Training

TG – Trainee group

TT - Theoretical Training

USA – United States of America

VR - Virtual Reality

WA – Washington

WL- Wet lab

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APÊNDICES

1. CAPÍTULO 1

1.1. INTRODUÇÃO

O treinamento cirúrgico difundido por William Halsted, desde o final da década de 1880, em que os especialistas ensinam aos novatos usando o método "ver um, fazer um, ensinar um", é um processo bem estabelecido e ainda é muito utilizado.(1) Entretanto, ao longo dos anos, vem acontecendo uma mudança nos paradigmas da educação cirúrgica, com um aumento crescente na discussão sobre a segurança dos pacientes. Nesse contexto, a simulação como estratégia de ensino cirúrgico ganha cada vez mais espaço. Esta tem como objetivo recriar particularidades de uma situação real, possibilitando integrar a teoria e a prática com múltiplas repetições, porém em um ambiente seguro de erros e sem riscos aos pacientes.(2)

Na atualidade, a cirurgia robótica tem revolucionado não só a prática operatória como o ensino da cirurgia. Toda nova tecnologia visa a melhora da qualidade de atendimento aos pacientes, mas demanda da classe médica um treinamento especializado e requer uma curva de aprendizado. Para capacitação na plataforma robótica é necessário treinamento fora da sala operatória e vários simuladores têm sido desenvolvidos para tal propósito.(3) Ressalta-se que simulação é técnica de ensino e não tecnologia.(4) Assim, para se alcançar melhores resultados na capacitação, o treinamento com simuladores deve ser estruturado em programas curriculares validados.(5) Além disso, a educação cirúrgica baseada em simulação é apenas um complemento e não substitui a experiência real.(6) Por isso, o clássico método Halstediano, com treinamento supervisionado, não deve ser substituído, e sim complementado com o desenvolvimento de competências mínimas em cirurgia robótica que permite cuidados seguros aos pacientes reais.

Programas específicos de treinamento em cirurgias robóticas são desenvolvidos e discutidos na literatura.(7) Entretanto, a maioria deles enfatiza só o treinamento de habilidades, sem estruturação do aprendizado, baseado em tempo e número de repetições, e não o desenvolvimento de competências, baseado em proficiência.(8)

1.1.1. Competência e *Entrustable Professional Activities*

A palavra competência geralmente é utilizada no senso comum para indicar que alguém é qualificado para realizar alguma tarefa. Entretanto, competência tem um caráter mais amplo e consiste na fusão das habilidades adquiridas com conhecimentos e atitudes, em determinado contexto.(9) As Diretrizes Curriculares Nacionais do Curso de Graduação em Medicina (2014) definem competência como *"*a capacidade de mobilizar conhecimentos, habilidades e atitudes, com utilização dos recursos disponíveis; é também a capacidade de ter iniciativas e ações que traduzam desempenhos capazes de solucionar, com pertinência, oportunidade e sucesso, os desafios que se apresentem à prática profissional em diferentes contextos do trabalho em saúde, traduzindo a excelência da prática médica*"*.(10) Franco et al (2014) descreveram as competências propostas por essas diretrizes para a organização curricular dos cursos de medicina, com o objetivo de orientar a formação baseada na aplicação do conhecimento e no desenvolvimento de habilidades e atitudes.(11) Para avaliar a competência na área da saúde, Miller (1990) propôs um modelo que é representado por uma pirâmide com quatro níveis hierárquicos.(12) A base envolve o "saber", que é o conhecimento para a prática. No segundo nível está o "saber como", que é a capacidade para utilizar esses conhecimentos. O terceiro nível engloba o "mostrar como", que demonstra a habilidade em determinada situação que pode ser simulada. Finalmente, no pico da pirâmide está o "fazer", que se refere à prática em situações reais. Alguns autores têm sugerido o acréscimo de um quinto nível nessa pirâmide que é o "ser", que considera a aquisição de valores, comportamentos, identidades e aspirações profissionais.(13,14)

Com a intenção de se alcançar uma maior especificidade na avaliação dos médicos nas atividades práticas, foi introduzido o conceito de *Entrustable Professional Activities* (EPAs).(15) As EPAs são tarefas clínicas observáveis e mensuráveis que podem ser confiadas aos aprendizes, assim que estes tenham demonstrado as competências necessárias para executá-las sem supervisão. Competências são qualidades dos indivíduos, enquanto as EPAs são unidades de trabalho e requerem a integração de várias competências gerais (domínios) e subcompetências.(16) Por exemplo, uma sutura para controle de sangramento durante uma cirurgia robótica pode ser considerada uma EPA. As competências críticas necessárias para realização de tal tarefa podem ser: (a) conhecimentos médicos; (b) cuidados com o paciente; e (c) comunicação e habilidades interpessoais. Enquanto para as subcompetências considera-se: (a) habilidades técnicas de sutura e fluxo operatório, manuseio/conhecimento da plataforma robótica e seus instrumentos; (b) cuidados com o tecido, economia de movimentos, planejamento operatório durante o procedimento robótico, tomada de decisão e agilidade em responder ao quadro de sangramento; e (c) habilidades não técnicas de comunicação com os auxiliares para planejamento da situação, liderança e trabalho em equipe. Avaliar os comportamentos do aprendiz com ferramentas objetivas de habilidades operatórias técnicas e não técnicas é fundamental para a anuência da tarefa sem supervisão.(17) Nesse exemplo, os comportamentos do aprendiz indicativos de confiabilidade podem ser: (a) demonstração de familiaridade em todos os princípios fundamentais da operação, movimentos ajustados e fluidos com os instrumentos e plataforma robótica; (b) manipulação consistente do tecido de forma apropriada e sem causar danos, evidente economia de movimentos e máxima eficiência no planejamento do curso da operação, sem esforços para avançar no passo a passo da cirurgia; e (c) comunicação eficiente e com o máximo proveito na troca de informações, discernimento de suas limitações, colaboração interprofissional, utilização estratégica dos auxiliares, com o máximo proveito durante todo o tempo.

1.1.2. Capacitação e Certificação

Capacitação implica no desenvolvimento de competências em determinado contexto para lidar com problemas da vida real. A simulação para o treinamento da cirurgia robótica, isoladamente, pode maximizar o desenvolvimento de habilidades específicas dos cirurgiões, mas não assegura a transferência dessas habilidades ao seu ambiente profissional. É necessário, portanto, um planejamento instrucional da estrutura curricular com o objetivo de desenvolver competências e permitir melhorias de resultados aos pacientes.(18) Muitos autores sugerem que os cenários mais eficazes para desenvolvimento de competências são aqueles que estão centrados em problemas.(18) Baseado nesses autores, Merrill (2002) elaborou cinco princípios instrucionais de promoção da aprendizagem que são: (1) deve-se motivar o aprendiz a resolver problemas reais; (2) deve-se ativar os conhecimentos pré-existentes para serem a base de novos conhecimentos; (3) deve-se demonstrar os novos conhecimentos ao aprendiz; (4) deve-se aplicar os novos conhecimentos pelos aprendizes e, finalmente, (5) deve-se integrar os novos conhecimentos ao mundo real.(19) Outro modelo de desenho instrucional é o 4C/ID.(20) Esse modelo apresenta quatro componentes que são: (1) tarefa de aprendizagem, que é o problema a ser resolvido; (2) informação de apoio, que é a teoria para se resolver o problema; (3) informações JIT (*Just-In-Time*), que são orientações sobre como resolver o problema no exato momento em que o aprendiz precise; e (4) prática parcelada, que é o treinamento repetido de partes da tarefa até se resolver o problema como um todo.

Em ambas as diretrizes instrucionais o foco da aprendizagem é resolver problemas da vida real. Para se atingir tal meta, Cook et al (2013) descreveram alguns recursos que devem estar presentes nos currículos de treinamento, como: múltiplas estratégias de aprendizagem, *feedback*, repetição da prática, variação de dificuldades, complexidade crescente, prática distribuída, interação cognitiva, individualização da aprendizagem, variação de contexto clínico e integração do conhecimento.(21) Todos esses princípios são fundamentais para se construir um programa de capacitação.

Tão importante quanto a construção de um programa é a avaliação do seu impacto no treinamento. Para isso, a abordagem mais utilizada é baseada no modelo de quatro níveis de Kirkpatrick.(22) O primeiro nível (reação) inclui a satisfação dos aprendizes. No segundo (aprendizagem), são mensurados os conhecimentos e habilidades adquiridos. No terceiro nível (comportamento ou desempenho), é avaliada a capacidade dos aprendizes em usar seus conhecimentos ou habilidades recém-aprendidos no ambiente de trabalho. Por fim, no quarto nível (resultados), o impacto geral do treinamento é avaliado, incluindo as mudanças nos processos clínicos.

A etapa final de um processo de treinamento em cirurgia robótica deve ser a certificação, que é a comprovação das competências desenvolvidas. A certificação expressa a legitimação social de cirurgiões que passam a ser reconhecidos como capazes de atuar na plataforma robótica. Atualmente, não há padronização para a certificação de cirurgiões robóticos e os requisitos variam de hospital para hospital. Na grande maioria, o critério para se operar sem supervisão não é baseado em competências, e sim no número de casos realizados. Como as EPAs são as tarefas que requerem proficiência em várias competências simultaneamente e os médicos capacitados devem executá-las sem supervisão, a *Association of American Medical Colleges* considera que seria apropriado utilizá-las para a certificação.(23)

1.1.3. Ferramentas de avaliação

O parâmetro recomendado para o aprendiz realizar uma cirurgia robótica sem supervisão, comumente, é o registro de casos que mede a experiência operacional, mas não avalia competência. Além disso, são utilizados critérios subjetivos que possuem baixa confiabilidade e prejudicam o *feedback* nos processos de capacitação e, principalmente, certificação.(24)

Ferramentas objetivas e estruturadas de avaliação das competências são fundamentais nos currículos de treinamentos em cirurgia robótica. Pode-se utilizar *checklist*s, que podem incluir várias subcompetências de determinado contexto e geralmente são classificações binárias (por exemplo: concluído ou não concluído); ou escalas globais, que avaliam de forma geral determinadas competências e geralmente são classificações do tipo Likert de cinco pontos.(25)

A escolha da ferramenta deve estar de acordo com o objetivo de aprendizagem e o contexto. As mais utilizadas para avaliação das habilidades técnicas operatórias na cirurgia robótica são: *Robotic assessment of technical skills* (ROSATS) e *Global Evaluative Assessment of Robotic Skills* (GEARS), sendo ambas escalas globais.(26) Como exemplos de ferramentas para avaliação de habilidades não técnicas temos: *Non-Technical Skills for Surgeons* (NOTSS) e *Observational Teamwork Assessment for Surgery* (OTAS).(27)

1.1.4. Evidências de validade

Qualquer currículo de treinamento, antes que possa ser recomendado, deve demonstrar evidências de validade. Apesar disso, segundo a revisão sistemática de Borgersen et al (2018), 93,4% dos estudos de validação em simulação cirúrgica de 2008 a meados de 2017 utilizaram quadros de validade desatualizados ou não especificados, o que prejudica a avaliação de competências/habilidades.(28)

Ao longo dos últimos 20 anos, diferentes tipos de validade (face, conteúdo, constructo, concorrente e preditiva) foram substituídos por um modelo unificado, em que todas as validades são consideradas de constructo. Essa concepção contemporânea de validade, baseada no estudo de Messick (1995), considera a validade como uma aplicação ou interpretação de pontuações de um simulador e não o simulador em si.(29,30) Para se alcançar a validação, são necessárias múltiplas fontes de evidência de validade, que podem ser: conteúdo, respostas, estrutura interna, relação com outras variáveis e consequências.(29) Os poucos estudos de simulação em cirurgia que utilizaram o conceito contemporâneo de validação basicamente forneceram apenas evidências de relações com outras variáveis e negligenciaram as outras fontes de evidência, especialmente as respostas e consequências.(30) Apesar de não ser imprescindível apresentar todas, quanto mais fontes de evidência de validade um programa de treinamento conseguir alcançar, ele terá mais condições de produzir os efeitos dele esperados.

1.2. OBJETIVOS

1.2.1. Objetivo Geral

Desenvolver processo de treinamento em cirurgia robótica com ênfase na aquisição de competências.

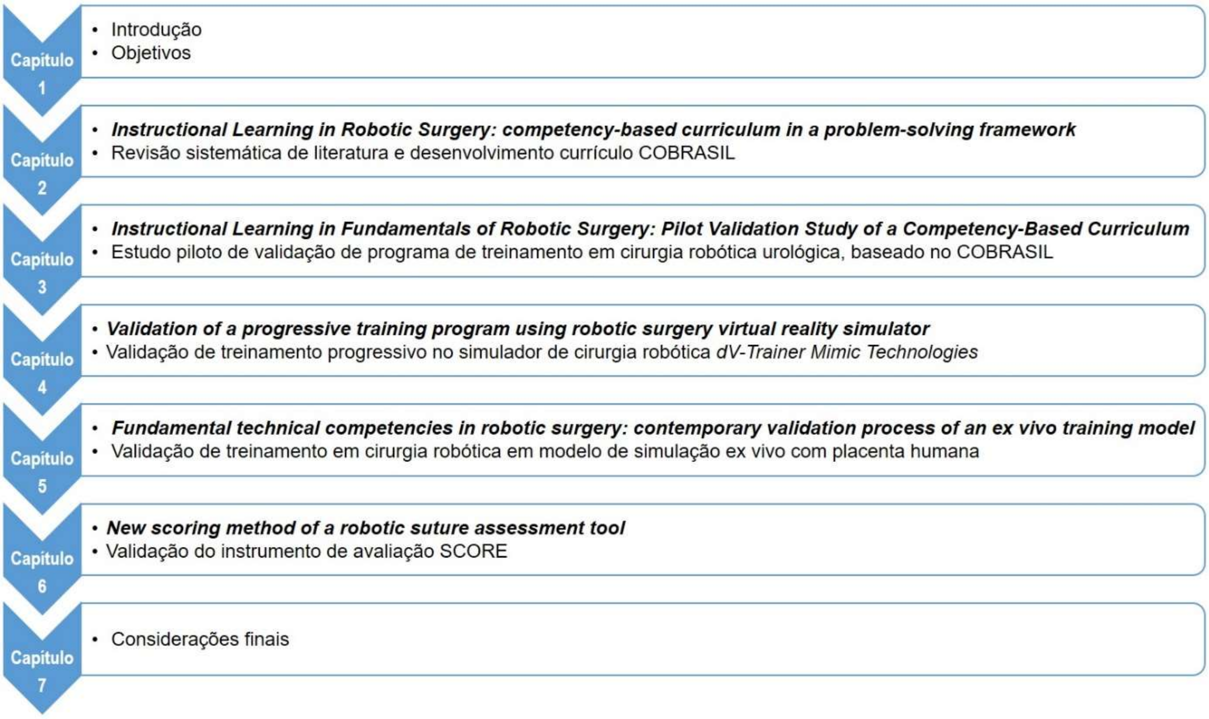
1.2.2. Objetivos Específicos

- Desenvolver currículo de treinamento em cirurgia robótica, baseado em competências;
- Validar programa de treinamento em cirurgia urológica robótica, baseado em competências;
- Validar treinamento progressivo em cirurgia robótica no simulador virtual *Mimic dV-Trainer*;
- Desenvolver e validar treinamento em cirurgia robótica em modelo de simulação ex vivo com placenta humana;
- Desenvolver e validar ferramenta objetiva e estruturada de avaliação de habilidades operatórias de sutura em cirurgia robótica, do tipo *checklist*.

1.3. ESTRUTURA DA TESE

Essa pesquisa iniciou-se em 2019 após aprovação pelo Comitê de Ética em Pesquisa (CEP- parecer Nº CAAE: 0364.0.203.000-11) da Faculdade de Medicina da Universidade Federal de Minas Gerais (FM-UFMG) e da Faculdade de Ciências Médicas de Minas Gerais/FELUMA (FCMMG), Brasil e está organizada em sete capítulos, em ordem cronológica e hierarquizada (figura 1). Todos os participantes consentiram por escrito em participar desse estudo de forma livre e consciente, preservando a voluntariedade da participação e o respeito à dignidade e decisão de cada sujeito da pesquisa.

Figura 1: Estrutura da tese organizada em sete capítulos



Capitulo 1
- Introdução
- Objetivos

Capitulo 2
- ***Instructional Learning in Robotic Surgery: competency-based curriculum in a problem-solving framework***
- Revisão sistemática de literatura e desenvolvimento currículo COBRASIL

Capitulo 3
- ***Instructional Learning in Fundamentals of Robotic Surgery: Pilot Validation Study of a Competency-Based Curriculum***
- Estudo piloto de validação de programa de treinamento em cirurgia robótica urológica, baseado no COBRASIL

Capitulo 4
- ***Validation of a progressive training program using robotic surgery virtual reality simulator***
- Validação de treinamento progressivo no simulador de cirurgia robótica *dV-Trainer Mimic Technologies*

Capitulo 5
- ***Fundamental technical competencies in robotic surgery: contemporary validation process of an ex vivo training model***
- Validação de treinamento em cirurgia robótica em modelo de simulação ex vivo com placenta humana

Capitulo 6
- ***New scoring method of a robotic suture assessment tool***
- Validação do instrumento de avaliação SCORE

Capitulo 7
- Considerações finais

O primeiro capítulo refere-se à introdução e aos objetivos dessa tese. Os próximos cinco capítulos correspondem a cinco artigos escritos em inglês e enviados para publicação em revistas científicas indexadas. Ressalta-se que os estudos tiveram populações com tamanhos e características semelhantes, mas os métodos e amostras de cada artigo são distintos e independentes. No capítulo 2, após revisão sistemática de literatura, desenvolveu-se um currículo de treinamento em cirurgia robótica, baseado em competências, cujo o acrônimo foi COBRASIL. No capítulo 3, foi realizado estudo piloto de validação de programa de treinamento em cirurgia robótica, no contexto urológico, baseado no currículo COBRASIL. No capítulo 4, validou-se um treinamento progressivo no simulador de cirurgia robótica *dV-Trainer Mimic Technologies (Seattle, WA, USA)*. No capítulo 5, desenvolveu-se e validou-se o treinamento em cirurgia robótica em modelo de simulação ex vivo com placenta humana para aquisição de competências em *wet lab*, e, finalmente, no sexto capítulo desenvolveu-se e validou-se o instrumento de avaliação SCORE, uma ferramenta objetiva e estruturada de avaliação de habilidades operatórias de sutura em cirurgia robótica, do tipo *checklist*, que foi utilizada após o treinamento no modelo de simulação ex vivo com placenta humana. No sétimo e último capítulo da tese, foram feitas as considerações finais.

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2. CAPÍTULO 2: Instructional Learning in Robotic Surgery: competency-based curriculum in a problem-solving framework

2.1. ABSTRACT

Introduction: Robot-assisted surgeries (RAS) have grown exponentially in recent years and several training programs have been developed. However, there is a lack of criteria well-structured training curriculum in RAS.

Objective: To develop a structured competency-based training curriculum for robotic assisted surgery by reviewing the literature on RAS training.

Methods: In January 2021 a literature search was conducted on PubMed database in adherence to PRISMA standards using the query (Robotic Surgery OR Robot-Assisted Surgery) AND (Curriculum OR Simulation OR Training OR Education[Mesh] OR Learning[Mesh] OR Teaching[Mesh]) AND (Clinical Competence[Mesh] OR Professional Competence[Mesh] OR Social Skills[Mesh]) AND (Instruction OR Instructional OR Models, Educational[Mesh]). Additional studies were identified by manually searching "similar articles" and reference lists of the studies found through database search. Moreover, content posted on internet and abstract presentations published considered larger curriculum programs by the authors were also used. A total of 190 studies were identified, of which 17 were included in the final analysis. The training modalities and curriculum designs of each study were analyzed and the Competency-Based Robot-Assisted Surgery Instructional Learning (COBRASIL) curriculum was developed in the 5W2H organizational tool.

Results: Training modalities were subcategorized in e-learning, theoretical training, live case observation, virtual reality simulator, skills-laboratory (dry and wet lab), proctoring and assessment. Curriculum designs were subcategorized in knowledge-based training, skill-based simulation training, team-based training, modular-based training and proficiency-based training. The COBRASIL curriculum combined all these training modalities and curriculum designs into a single structured curriculum. The structuring of this curriculum was problem-centered and involved five steps to promote learning: (1) learners should be engaged to solving real-world problems; (2) existing knowledge should be activated as a foundation for new knowledge; (3) new knowledge should be demonstrated to the learner; (4) new knowledge should be applied by the learner; (5) new knowledge should be integrated into the learner's world.

Conclusions: The COBRASIL was planned as a structured competency-based curriculum that can be used in multiple different clinical and technological contexts in robotic surgery.

Key words: Robotic surgery, Curriculum, Simulation training, Education, Clinical competence.

2.2. INTRODUCTION

Since the end of the last century, there has been an exponential increase in the number of minimally invasive surgeries, initially with pure laparoscopic approach and more recently with robot-assisted surgery (RAS).(1) The learning curve in the acquisition of minimally invasive surgical skills requires training outside the operating room (OR). It is believed that the simulation-based training maximizes the competence development of surgeons and, consequently, decreases this curve.(2) Thus, aiming mainly at the safety of patients, simulators have been developed and increasingly used in the training of RAS.(3) However, the current simulators are mainly focused in the development of basic technical skills which are different from surgical competence.(4)

Competence can only be developed in a wet lab or through real operative experience(5); surgical competence is the ability to successfully apply professional knowledge, technical and nontechnical skills, as well as attitudes in different contexts.(6) A competency-based training allows surgical competences to work together in different combinations to produce a desired result. According to the Accreditation Council for Graduate Medical Education (ACGME), there are six domains of clinical medical competence which are: patient care; medical knowledge; practice-based learning and improvement; interpersonal and communication skills; professionalism and systems-based practice.(7) Many authors suggest that the most effective scenarios for development of these competences are those that are problem-centered.(8) Merrill (2002) identified prescriptive principles that are common to various theories and elaborated the following five instructional principles to promote learning: (1) learners should be engaged to solving real-world problems; (2) existing knowledge should be activated as a foundation for new knowledge; (3) new knowledge should be demonstrated to the learner; (4) new knowledge should be applied by the learner; (5) new knowledge should be integrated into the learner's world.(8) Similarly, the evidence of systematic review and meta-analysis by Cook et al (2013) that evaluated the effectiveness of instructional design features supports some best practices for simulation-based education as follows: range of difficulty, repetitive practice, distributed practice, cognitive interactivity, multiple learning strategies, individualized learning, mastery learning, feedback, longer time, and variation in the clinical context.(9) All these learning principles are key to build a successful robotic surgery training program.

However, there is a lack of criteria well-structured training program for board certification in RAS and training programs do not satisfy most of these prerequisites for a validated learning process. The aim of this study was to develop a structured competency-based training curriculum for robotic assisted surgery by reviewing the literature available on RAS training.

2.3. METHODS

2.3.1. Literature search

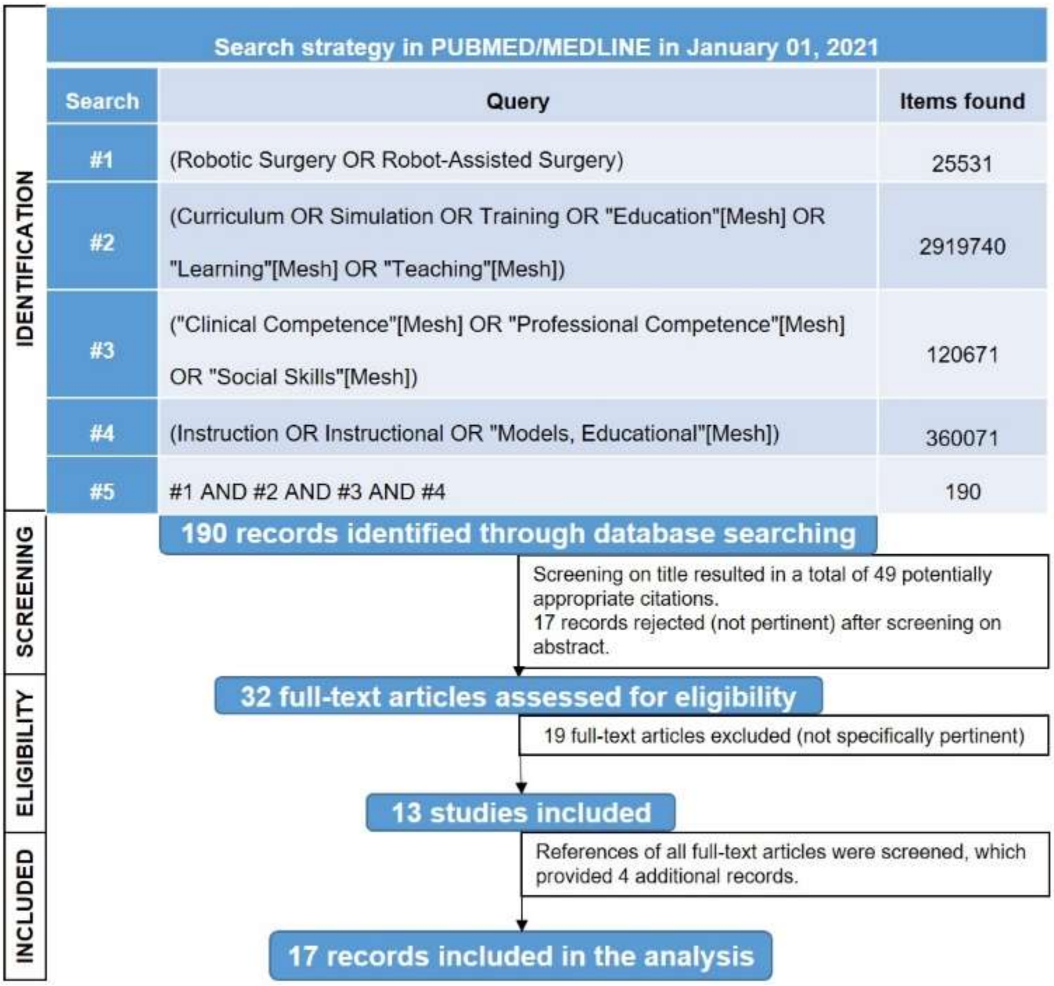
A systematic search of the PUBMED/MEDLINE database was conducted in adherence to PRISMA standards to identify relevant studies, assessing RAS structured training curriculum, in January 01, 2021. The following terms were used: (Robotic Surgery OR Robot-

Assisted Surgery) AND (Curriculum OR Simulation OR Training OR "Education"[Mesh] OR "Learning"[Mesh] OR "Teaching"[Mesh]) AND ("Clinical Competence"[Mesh] OR "Professional Competence"[Mesh] OR "Social Skills"[Mesh]) AND (Instruction OR Instructional OR "Models, Educational"[Mesh]). Additional studies were identified by manually searching the “similar articles” and reference lists of the studies found through database search. Moreover, content posted on internet and abstract presentations published considered larger curriculum programs by the authors were also used. All relevant studies were analyzed by two authors (CMEC and CPR) and the discrepancies were resolved by a third author (CRF).

2.3.2. Study selection

This search produced 190 unique citations (Figure 2.1). The list of generated articles was screened by title and abstract and then relevant full papers were scrutinized. Curriculum was considered to be a description of the training structure and the methods of learning, teaching feedback and supervision. After exclusion of the studies that clearly dealt with an isolated validation study and had no current application to a teaching curriculum, a total of 32 potential articles were gathered. Reviews were excluded and 13 papers that were linked to a larger curriculum programs were selected. Any references to other curricula within these excluded reviews were also screened and provided 4 additional records. A total of 17 relevant records that clearly addressed aspects of the structured training curriculum for RAS in some specialty were found.

Figure 2.1: Systematic search in adherence to PRISMA standards



Search strategy in PUBMED/MEDLINE in January 01, 2021

Search	Query	Items found
#1	(Robotic Surgery OR Robot-Assisted Surgery)	25531
#2	(Curriculum OR Simulation OR Training OR "Education"[Mesh] OR "Learning"[Mesh] OR "Teaching"[Mesh])	2919740
#3	("Clinical Competence"[Mesh] OR "Professional Competence"[Mesh] OR "Social Skills"[Mesh])	120671
#4	(Instruction OR Instructional OR "Models, Educational"[Mesh])	360071
#5	#1 AND #2 AND #3 AND #4	190

190 records identified through database searching

Screening on title resulted in a total of 49 potentially appropriate citations.
17 records rejected (not pertinent) after screening on abstract.

32 full-text articles assessed for eligibility

19 full-text articles excluded (not specifically pertinent)

13 studies included

References of all full-text articles were screened, which provided 4 additional records.

17 records included in the analysis

2.3.3. Curriculum development

Based on the ACGME’s competences, the included articles in this review were categorized into training modalities and curriculum designs. Training modalities were subcategorized in e-learning, theoretical training, live case observation, virtual reality simulator, skills-laboratory (dry-lab and wet-lab), proctoring and assessment. Curriculum designs were subcategorized in knowledge-based training, skill-based simulation training, team-based training, modular-based training and proficiency-based training (Figure 2.2).

Figure 2.2: Definitions of the subcategories of training modalities and curriculum designs

Training modalities	
E-learning	Acquisition of knowledge utilizing electronic technologies to access educational curriculum.
Theoretical training	Acquisition of knowledge to understand the fundamental concepts and know-how about how something works and its mechanism.
Live case observation	Acquisition of knowledge through case observation to collect relevant information and data from a real scenario.
Virtual reality simulator	Acquisition of skills through computer technology to create a simulated environment.
Skills-laboratory (dry-lab and wet-lab)	Acquisition of skills in a well-established simulated learning environment.
Proctoring	Acquisition of skills in a real supervised learning environment.
Assessment	The process of considering all information about a situation or a person in training.
Curriculum designs	
Knowledge-based training	Based on the knowledge that the learner already has and aims to build on it.
Skill-based simulation training	Based on how the learner uses his knowledge and skills, rather than how much knowledge he has acquired.
Team-based training	Based on a collaborative learning and teaching strategy (includes non-technical skills training).
Modular-based training	Based on the construction of skills and knowledge in discrete units with increasing levels of complexity in a real learning environment.
Proficiency-based training	Based on learning the knowledge and skills that learners should have as they progress through their training.

According to Cook (2013), instructional design guidelines should support the development of curricula for learners reach complex learning.(9) Complex learning is the integrated acquisition of knowledge, skills and attitudes and allows the transfer competencies to an increasingly varied set of real-world contexts and settings. An extraction of the components of curricula in this review was used to develop a basic structured competency-based training curriculum for robotic assisted surgery. To organize and facilitate the reproducibility of complex learning promotion, Merril's five instructional principles were used to assemble this curriculum in a 5W2H framework.(8) This framework was developed by the founder of Toyota Industries, Sakichi Toyoda, to elaborate action plans and it is considered one of the most efficient management tools in the world.(10) This problem solving approach consisted of answering seven questions: what will be done to promote learning (what?), why it will be done (why?), who will be responsible for promoting learning (who?), where it will be done (where?), when it will be done (when?), how it will be done (how?) and how much it will cost (how much?).

2.4. RESULTS

The main findings in literature review are listed in Figure 2.3. All of the studies in our sample were published in English language. Only three curricula were developed from consensus after discussions with international panels of experts. However, the study by Veronesi et al (2018) was ongoing project to develop a curriculum in robot-assisted thoracic surgery and has not yet been validated, as well as 5 other studies. The rest were in several stages of validation. Even so, all validated robotic training curricula evaluated in this review used outdated or unspecified validity frameworks, which impairs the assessment of relevant competency/skills.

The training contexts ranged from fundamental principles of robotic surgery to specific procedures in different surgical specialties such as urology surgery, surgery in obstetrics and gynecology, gastrointestinal surgery, cardiac surgery, thoracic surgery, general surgery, otorhinolaryngology surgery and multidisciplinary. Learners included residents, fellows and practicing surgeons. Some curricula took few days (short time program), while others included module or fellowship programs that took several weeks (median time program) or months to complete (long time program).

Studies in this review used multiple training modalities to teach robotic surgery, but few were able to join them in the same curriculum. Although some studies mention the importance of integrating non-technical skills in robotic training, only two used the simulation of complete immersion of Team-Based Training in curriculum design.

Figure 2.3: Main robotic training curriculum findings in literature review

Organization or Authors/ Years	Process of development	Validation	Specialties/ Procedure	Duration/ Type	Training modalities	Curriculum designs
Geller et al (2011)(11)	Not specified / single-centre	No	Gynecology / Fundamentals of robotic surgery	Short time / platform set-up and 4 dry-lab tasks	EL; DL; AS	K; S
Macgregor et al (2012)(12)	Literature review / Society of American Gastrointestinal and Endoscopic Surgeons	No	Multi-specialty / Fundamentals of robotic surgery	Short time / 5 simulated tasks on the dVSS	VR; AS	S
Dulan et al (2012)(13)	Expert opinion / single-centre	Yes	Multi-specialty / Fundamentals of robotic surgery	Median time / platform set-up and 9 dry lab tasks, which are practiced for up to 8 weeks until trainees are proficient	EL; DL; AS	K; S; P
Stegemann et al (2013)(14)	Expert opinion / multi-centre	Yes	Multi-specialty / Fundamentals of robotic surgery	Short time / 16 simulated tasks on the RoSS	VR; AS	S
Foell et al (2013)(15)	Not specified / single-centre	Yes	Urology, Gynecology, Thoracic Surgery / Fundamentals of robotic surgery	Median time / platform set-up (2-hour), dry lab tasks (30min) and three individual 1-hour sessions on the dVSS (at weekly intervals). Retention of skills was assessed at 5 months post-training	EL; TT; VR; DL; AS	K; S; P (1/3 participants)
BAUS (2013)(16)	Not specified / single-centre	Yes	Urology / Fundamentals of robotic surgery	Median time / sessions for technical skills were run for 14 half-days, whereas non-technical skills sessions were conducted as seven full-day programmes	VR; DL; WL; AS	S; T
FRS (2014)(17)	Consensus by multiple institutions / 14 international surgical Societies	Yes	Multi-specialty / Fundamentals of robotic surgery	Short time / ongoing training until the apprentice's learning curve reaches reference values	EL; TT; VR; DL; AS	K; S; T; P
ERUS (2015)(18)	Consensus by multiple institutions / European Association of Urology and Robotic Urology Section	Yes	Urology / Radical Prostatectomy(19,20), Partial Nephrectomy(21) and Radical Cystectomy(22)	Long time / 12-week comprehensive training programme (fellowship-style modular console training)	EL; TT; VR; DL; WL; PT; AS	K; S; M; P
Valdis et al (2015)(23)	Expert opinion / single-centre	Yes	Cardiac surgery / Internal Thoracic Artery dissection and Mitral Valve Annuloplasty	Short time / 9 simulated tasks on the dVSS and final assessment on porcine model	VR; WL; AS	S
TASSL (2015)(24)	Expert opinion / multi-centre	No	Multi-specialty / Not specified	Median time / 7 simulated tasks on the dVSS (ongoing training until the trainee achieves the proficiency benchmarks on 2 consecutive trials), log 5 robotics cases as first assistant, modular console training on porcine model and log 10 robotics cases as console surgeon to be assessed	EL; TT; VR; WL; AS	K; S; P
Walliczek-Dworschak et al (2016)(25)	Not specified / single-centre	No	Otorhinolaryngology / Fundamentals of robotic surgery	Median time / three consecutive repetitions of 5 simulated tasks on the dVSS were performed in a defined order on days 1, 8, 15 and 22. On day 22, one repetition of a previously unpractised more advanced module was also performed	VR; AS	S
Hung et al (2016)(26)	Expert opinion / single-centre	Yes	Urology / Radical Prostatectomy and Partial Nephrectomy	Long time / fellowship-style modular console training	PT; AS	M; P
Tam et al (2017)(27,28)	Not specified / single-centre	Yes	Oncology surgery / Pancreatoduodenectomy	Long time / training module	VR; DL; AS	S
Rusch et al (2018)(29)	Not specified / Society of European Robotic Gynecological Surgery	Yes	Gynecology / Hysterectomy and Pelvic Lymphadenectomy	Long time / fellowship-style modular console training	EL; TT; VR; DL; WL; PT; AS	K; S; M; P
Veronesi et al (2018)(30)	Consensus by multiple institutions / European Society of Thoracic Surgeons and European Association for Cardio-Thoracic Surgery	No	Thoracic surgery / Fundamentals of robotic surgery and Right Upper Lobectomy	Long time / Not specified (recommendation)	EL; TT; VR; DL; WL; PT; AS	K; S; M; P
Moit et al (2019)(31)	Expert opinion / single-centre	Yes	General surgery / Not specified	Long time / fellowship-style modular console training	EL; TT; VR; DL; PT; AS	K; S; M; P
Nacul et al (2020)(32)	Literature review / Brazilian College of Surgeons	No	Multi-specialty / Not specified	Long time / Not specified (recommendation)	EL; TT; VR; DL; WL; PT; AS	K; S; M; P

Training modalities: EL= E-Learning; TT= Theoretical Training; VR= Virtual Reality Simulator; DL= Dry lab; WL= Wet lab; PT= Proctoring and AS= Assessment. **Curriculum designs**: K= Knowledge-Based Training; S= Skill-Based Simulation Training; T= Team-Based Training; M= Modular-Based Training and P= Proficiency-Based Training. **Simulators**: dVSS= da Vinci Surgical Simulator; RoSS= Robotic Surgical Simulator

2.4.1. Development of structured competency-based training

Based on the literature used in this review, the Competency-Based Robot-Assisted Surgery Instructional Learning (COBRASIL) curriculum was developed by combining all training modalities and curriculum designs into a single structured program that can be used in multiple different clinical and technological contexts. The structuring of this curriculum was problem-centered and involved all five steps of instruction of Merrill's principles (Figure 2.4). Although all curriculum designs are present at all five steps of COBRASIL, predominantly the first 3 steps were a knowledge-based training and the step 4 was a skills-based simulation training and team-based training. These steps allowed the development of basic competences in RAS and the consequent qualification of the trainee to operate a real patient with expert surgeon (proctor) supervision. In step 5, modular-based training and proficiency-based training merge to form the integration phase, in which, in addition to the knowledge and technical and non-technical skills, the attitude can be tested, completing the competency-based training for a specific surgery on a specific robotic platform. This final stage in the robotic education process allowed full certification in specific context to perform real surgery without proctor supervision.

2.4.1.1. Step 1

At this stage the learning objectives must be defined. In addition to the basic knowledge of robotic technology, the trainee must understand the fundamentals necessary to performing specific surgical procedures and the type of whole activity that they will learn to complete. Motivation is an active part of the construction of knowledge. In step 1 of COBRASIL, trainees should be responsible for individual preparation for the learning process and instructors should motivate them to engage in solving authentic problems. For this, it was essential to identify learning needs and individualize training due to the variability of previous educational and professional experiences among individuals (i.e. some trainees may have been trained in laparoscopy and others may not). The learner is an integral part of this process and there is constantly an interaction between the new knowledge and that antecedent. Prior to the hands-on training, all trainees can complete step 1 at home by performing a specific e-learning module as available on the website (http://www.davincisurgerycommunity.com), as well as an online pre-training test on the robotic system and a demography questionnaire to identify learning needs.

2.4.1.2. Step 2

This step is responsible for initiating the activation of the previous knowledge. Even in front of a group without any practical experience, the prior activation of questions and concepts promote learning. Thus, previous knowledge incorporated other meanings and strengthened itself, and if it did not exist, it would be presented, which would allow an interpretation of the content itself and the attribution of meaning. Theoretical training promoted by experts in the classroom, using multiple learning strategies (i.e. patient case, worked example, discussion, interactive lectures), can be offered to the learners one day before the hands-on training.

2.4.1.3. Step 3

Demonstrate what is to be learned in step 3 of this curriculum allows reflection on the context in which the task to be learned may be inserted. This phase of training affords the trainee the opportunity to watch video recordings and live surgical broadcasts. The Halstedian model of "see one, do one, teach one" should be remembered, replacing the "see one" by "see as much as possible". Video recording has the advantage that surgeries are selected and edited in advance and the main moments can be discussed in the classroom with the expert before the hands-on training. Live case observation provides a direct interaction with the surgeon in the OR and allows a real experience with the opportunity to trying on the dynamics of the robotic team, docking procedures and troubleshooting of problems.

2.4.1.4. Step 4

In step 4 of COBRASIL, instructors guide learners to apply their new knowledge or skills to solve the problem. For this purpose, different instructional strategies can be used to facilitate learning, such as simulation training with range of difficulty, multiple repetitions, discussion, feedback, intentional sequencing and variation of tasks. During this step, a hands-on portal access, docking/undocking training and a combination of virtual-reality simulation and dry laboratory on the robotic platform should be offered. The wet laboratory should be mandatory as it provides the closest alternative to real surgery, allowing a full-immersion simulation. Thus, team-based learning could also be addressed at this stage with consequent strengthening of non-technical skills, allowing the valorization of the individual responsibility of surgeons towards their work teams. In addition, the actual management of the patient usually involves a great interaction of elements and this complexity experienced by the robotic surgeon can preferably be learned, trained and practiced in a high-fidelity operating room simulation. To lead to skill retention, this phase should spread over a period of time, preferably for more than two days of simulation training. This training time may vary between learners, as ideally the model of mastery learning should be applied. In this model, trainees must achieve a clearly defined performance pattern before qualifying or moving on to the next task. Thus, the concept of proficiency in a certain skill begins to be applied in curriculum. Measuring with assessment tools and setting outcomes for basic certification is critical in this simulation-based mastery learning, to determine when a learner has achieved the desired level of proficiency in a given skill that allows safe surgery in the real world with proctor supervision. As important as the assessment of the learners' performance is the assessment of impact of training to allow the continuous improvement of the curriculum. The most commonly used approach to this measurement is based on the Kirkpatrick's 4-level Model.(33) The first level of model (reaction) includes impacts on learners' satisfaction. In the second level (learning) the knowledge and skills of the learners are measures. At the third level (behavior or performance) the trainees' ability to use their newly learned knowledge or skills in the workplace is evaluated. Finally, in the fourth level (results) the impact that the training had in general is measures, in addition to the changes in clinical processes.

2.4.1.5. Step 5

Simulation training does not replace real-world experience in OR and perhaps step 5 of COBRASIL could be considered the most important in the learning process. At this stage, there is the integration of new knowledge into the learner's world and they become able to demonstrate improvement in skill, to defend their new knowledge. Some authors have demonstrated the superiority of the proficiency-based training method when compared to time and repetition-based training models.(34) Progression from bedside to console with a clinical modular training under proctor supervision prior to an independent operation was mandatory for patient safety. The proficiency learning curve depends on a number of variables within each context and the need for training time at this step is certainly greater than in previous stages. The initial training time planned for the ERUS Curriculum was 3 months and was then updated to 6 months, to allow adequate acquisition of trainees' skills. So what really matters should be ongoing training until the trainees are proficient. At the end of COBRASIL's step 5, the trainee can be evaluated in different contexts by an independent expert who must use recognized assessment tools to complete the certification process in robot-assisted urological surgery.

2.4.2. Cost of training

The costs of this training process are not limited to didactic coursework, surgical materials, acquisition of dual console, VR simulators, models for dry and wet simulation training. There are several indirect costs that can be underestimated such as proctorship programs, training the surgical team and an increased OR time while ascending the learning curve. According to the systematic review by Schreuder et al (2012), the costs associated with learning curve were high and may vary from \$49,613 to \$554,966.(35)

Figure 2.4: Competency-Based Robot-Assisted Surgery Instructional Learning (COBRASIL) curriculum

	Distributed Practice	What?	Why?	Where?	Who?	When?	How?	How much?
BASELINE EVALUATION	**Step 1** **Problem**	Define learning objectives; Motivate learners; Identify learning needs.	Individualization of training	Home	Trainees	24 hours (Until the beginning of the training)	E-learning; Demographic survey; BASELINE KNOWLEDGE TEST	High costs, but quite variable. E.g. of costs of robotic system (±$1,800,000) with the additional 10% per year of fixed service costs and instrument costs (±$700 to $1000 per case) (Schreuder , 2012). E.g. of cost of VR simulators (CHILDS, 2019): dVT- $158,000 dVSS - $89,000 RXM - $137,000 RoSS - $120,000 SEP - $62,000 ProMIS - $35,000
	Step 2 **Activation**	Activate knowledge.	Even in front of a group without any practical experience, the prior activation of questions and concepts promote learning	Classroom	Instructors	Minimum of 04 hours (first day)	Theoretical training (multiple learning strategies)	
	Step 3 **Demonstration**	Demonstrate what is to be learned.	Allows reflection on the context in which the task to be learned may be inserted	Classroom	Instructors	Minimum of 08 hours (first day)	Videos and live surgical broadcasts	
BASIC CERTIFICATION	**Step 4** **Application**	Application new knowledge or skills; Simulation training to consolidate technical and nontechnical skills; Evaluate the performances and impact of the program.	Allows technical and nontechnical skills to be more transferable to the ORs and feedback to the trainee.	Simulation centre	Instructors	Minimum of 24 hours (second and third days)	Combination of dry laboratory, wet laboratory (team-based training) and virtual-reality simulation (range of difficulty, mastery learning, multiple repetitions, task variation, or intentional task sequencing) BASIC EVALUATION: Knowledge (test), Skills (automated performance assessment and by global scales and/or checklists) and Program (Kirkpatrick's 4-level Model)	
FULL CERTIFICATION	**Step 5** **Integration**	Integrate new knowledge into the learner's world and they should be able to demonstrate improvement in skill.	Gain experience with patients.	Operation Room	Proctors	Ongoing training until the trainees are proficient for each procedure (after the basic certification)	Variation in the clinical context: Begin with assisting, and then console operation (modular training) under supervision (with or without dual-console), before independent operation (formal feedback) FINAL EVALUATION Assessment of full operation video by global scales and/or checklists	

2.5. DISCUSSION

Robotic surgery is a rapidly expanding field and simulated training in the competence-based curriculum is mandatory. However, simulation-based medical education is only a complement and does not replace the many existing educational methods and strategies in the traditional clinical environment to ensure that robotic trainees become competent. After the simulation-based learning experience to develop the minimum level of skills for the provision of safe care, trainees need to practice under supervision in real patients.(36) The COBRASIL curriculum took this into account and significant attention was paid to the fundamental robotic principles in the first 4 steps and step 5 involved integration of knowledge, attitudes, and skills from multiple competency domains.

Most of the curricula in this review followed a similar sequence: learners started with preclinical simulation-based training with virtual reality simulators and dry-labs, followed by clinical modular console training in real patients. However, most of them lacked specifics about the questions addressed in the 5W2H framework, not allowing to clearly identify the real problems of trainees and how to solve them.

Despite the wet labs allow the acquisition of technical and non-technical robotic skills, besides being a great way to train the entire surgical team, it was also overlooked in most curricula. The high costs of live animals or human cadavers, in addition to ethical concerns, may have limited their use in robotic surgery training. However, other biological models without these disadvantages, as human placenta, could be used in wet lab to reproduce simulated scenarios close to reality.(37) As important as simulated training is the assessment of skills acquired to enable feedback and be able to help trainees improve their performance.(38) While Geller et al (2011) used only time as a parameter to evaluate the performance of trainees, all other curricula used objective structured assessment tools.

Prospective randomized studies have shown that the application of proficiency-based progression training improves trainee competencies by 40-70% compared to the level reached using a traditional repetition-based training.(39) Objective structured tools that can evaluate acquired competencies are fundamental for the development of curricula that can accredit surgeons as being able to perform a specific robotic procedure. Several of these tools are being developed to evaluate trainees in different contexts.(40) In the urological context, the following tools can be cited as examples: Robotic Anastomosis Competency Evaluation (RACE), Prostatectomy Assessment and Competency Evaluation (PACE), Scoring for Partial Nephrectomy (SPaN), Pelvic Lymphadenectomy Appropriateness and Completion Evaluation (PLACE) and Cystectomy Assessment and Surgical Evaluation (CASE).(36)

Almost all studies in this review focused robotic training in da Vinci Intuitive Surgical System (Sunnyvale, CA, USA), but it is worth noting that several other robotic surgical platforms will soon be available on the market that may change the context and, consequently, require new competencies. The COBRASIL was created with the intention of being device-independent and specialty-independent, in an attempt to standardize training and assist the credentialing process of surgeons for specific robotic surgical procedures on specific robotic platforms. However, before this curriculum can be recommended, it must demonstrate solid evidence of validity using a contemporary validation framework, such as that conceptualized by Messick.(41)

2.6. CONCLUSION

The COBRASIL was planned as a structured competency-based curriculum to guide the training and credentialing process of robotic surgery in different contexts. By using Merril's five instructional principles in the 5W2H framework, this curriculum can be adapted or reconfigured to suit requirements of any robotic surgery training program.

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3. CAPÍTULO 3: Instructional Learning in Fundamentals of Robotic Surgery: Pilot Validation Study of a Competency-Based Curriculum

3.1. ABSTRACT

Introduction: There is an urgent need to develop robotic surgery training programs. However, training programs published in the literature do not satisfy most of the prerequisites for a validated learning process.

Objective: To develop a pilot validation study of a structured competency-based training program in fundamentals of robot-assisted surgery (RAS).

Methods: This training program followed 5 steps. Predominantly the first 3 steps were a knowledge-based training and the step 4 was a skills-based simulation training and team-based training. These steps allowed the development of basic competences in RAS and were inserted in a 3-day course. The 5th step was a supervised modular training robotic urological surgery program, with increasing levels of complexity in a real learning environment of specific urological surgeries. A pilot validation study was carried out to determine the validity of this training program in context of fundamentals of RAS. Validity evidence for this training process were assessed in accordance with Messick's framework of validity which considers five sources of evidence: content, responses, internal structure, relationship to other variables and consequences. A total of 15 participants were enrolled in this training program and divided into two groups: trainee group (attending urologists with no robotic cases performed) and expert group (attending urologists with at least 50 robotic cases performed) whose performances would serve as a benchmark for trainees. The participants' performances were recorded and compared for evidence of validity. At the end of course all participants received individual feedback and filled out a post-training questionnaire based on the Kirkpatrick's Model.

Results: In total, 7 experts and 8 trainees completed the 3-day course, which reached the sources of evidence recommended in the Messick's framework. The differences observed between the groups' performances in theoretical and simulation training were considerably supported by statistical significance tests ($p<0,005$). The modular training in the step 5 was completed by one trainee who reached certification of urological robotic surgery after 1-year supervised program and allowed evidence of validity of consequences. The results of post-training questionnaire indicate an excellent educational impact.

Conclusions: This preliminary study established evidence of validity for a structured competency-based training program in fundamentals of robotic surgery.

Key words: Robotic surgery, Validation study, Simulation training, Education, Clinical competence.

3.2. INTRODUCTION

Simulation is a technique (not a technology) for practice and learning that can be applied to robot-assisted surgery (RAS) as an alternative to error safe environment.(1) Most robotic centers have simulators, but lack well-trained robotic surgeons.(2) This is probably because there is a lack of structured robotic training programs that are critical to improving patient safety and outcomes. Puliatti et al (2020) published a review aimed at identifying training programs currently available in RAS. The literature analysis suggested that there is an urgent need to develop and validate competency-based robotic surgery training programs focused on the learning process.(3)

The systematic review and meta-analysis by Cook et al (2013) evidenced that the instructional design key features should be included during the construction of RAS training programs, as well as the assessment of their impacts on training.(4) However, such training programs should demonstrate evidence of validity. Despite this, according to the systematic review by Borgersen et al (2018), 93.4% of the validation studies in surgical simulation from

2008 to mid-2017 used outdated or unspecified validity frameworks, which impairs the assessment of relevant competency/skills.(5)

The contemporary validity framework, based on Messick, considers validity to be an application or interpretation of simulator scores not for the simulator itself.(6) Our research group previously developed a structured competency-based training curriculum for RAS that could be adapted to meet the requirements of any robotic surgery training program in different contexts. However, before this curriculum can be recommended, it must demonstrate solid evidence of validity using a contemporary validation framework, such as that conceptualized by Messick. The aim of this study was to address this gap by developing a pilot validation study of a structured competency-based training program of fundamentals of robotic surgery.

3.3. MATERIALS AND METHODS

This study received an approval from a certified Ethical Board and was divided into two stages. Firstly, the Competency-Based Robot-Assisted Surgery Instructional Learning (COBRASIL) curriculum was developed by reviewing the literature available on RAS training. Merril's five instructional principles to promote learning were used to assemble this curriculum in a 5W2H framework, which has been described previously.(7) Finally, a pilot validation study was carried out to determine the validity of this curriculum in context of a short full-time program of fundamentals of robotic surgery. Validity evidence for procedural competency in fundamentals of robotic surgery was assessed in accordance with Messick’s framework of validity which considers five sources of evidence: content, responses, internal structure, relationship to other variables and consequences.

3.3.1. Pilot validation study

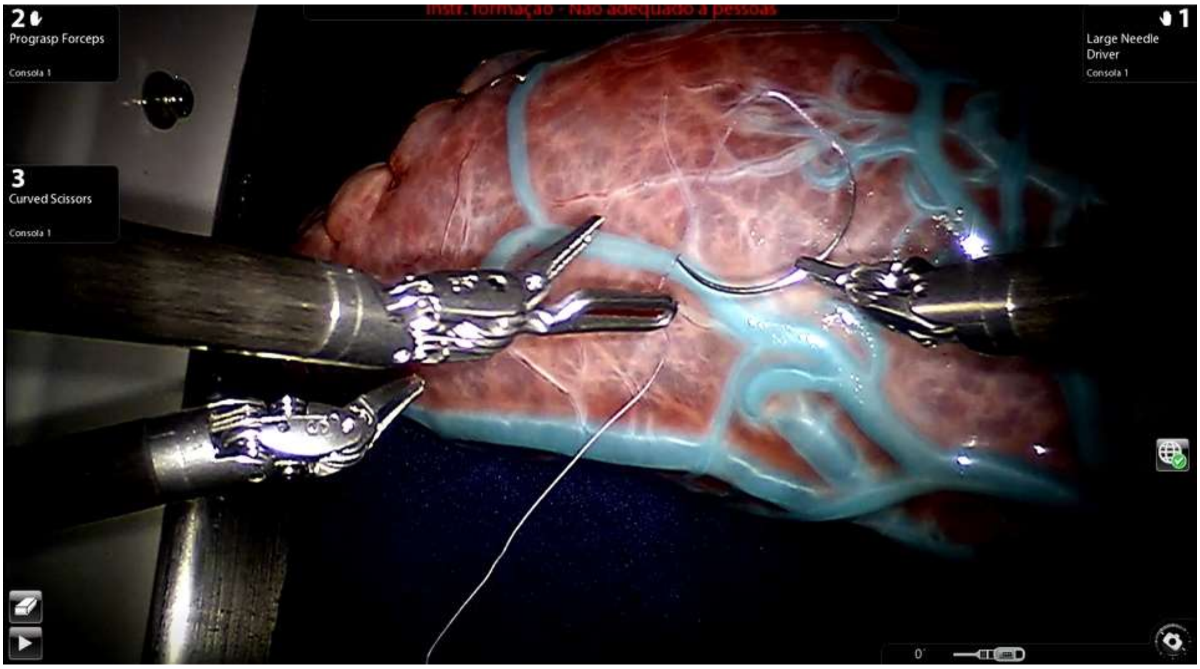
Based on the first 4 steps of COBRASIL Curriculum, a 3-day course (training was distributed for 12 hours per day) for suture skills training of robotic novices was developed. A total of 15 participants were divided into two groups as follows: eight trainees (attending urologists with no robotic cases performed) and seven experts (attending urologists with at least 50 robotic cases performed) whose performances would serve as a benchmark for trainees. Informed consent was given by all participants and they were informed that all data would be de-identified before evaluation by the study investigators.

Prior to the 3-day course all trainees were invited to complete at home a specific e-learning module (http://www.davincisurgerycommunity.com), as well as an online pre-training test on the Intuitive Surgical da Vinci Si robotic system and a questionnaire on demographics (Step 1 of COBRASIL). The step 2 of COBRASIL was interactive lectures based on the "Basic proficiency requirements for the safe use of robotic surgery" developed by Netherlands Institute for Healthcare Research (NIVEL) 4 hours long.(8) The step 3 of this curriculum lasted a total of 8 hours and consisted of video demonstration of the fundamentals of robotic surgery and two live surgical broadcasts (one robot-assisted radical prostatectomy with extended pelvic lymph node dissection and one robot-assisted partial nephrectomy).

During the step 4 of COBRASIL, different instructional strategies were applied to facilitate learning, such as simulation training with multiple repetitions, discussion, feedback, intentional sequencing and variation of tasks. At this stage on the course a hands-on portal access, docking/undocking and a dry lab suture training were carried out on the da Vinci Si platform. Then, all participants performed the training task "Basic Suture Sponge" from the software program of the virtual simulator Mimic's dV-Trainer (dVT) and "Task 3 Railroad Track" from the virtual simulator RobotiX Mentor (RXM). These two types of VR simulators were used to test the progression of trainees' robotic suture skills before and after completing 14 different exercises with range of task difficulty. Benchmark scores based on expert performance offered viable targets for trainees. This stage and the next one lasted 12 hours each.

Still in step 4, a standardized explanation about a robotic hemostatic suture task in a human placental model described by Campos et al (2020)(9,10) was presented to the subjects and then administered a practice round (Figure 3.1). This exercise in wet lab trained camera navigation and clutch, precise needle control, suture placement, square knot tying with proper force and the switching back and forth between a primary instrument and the 4th arm in a coordinated fashion, as well as nontechnical skills. Each training was recorded and a blinded rater would then evaluate the performances using a Global Evaluative Assessment of Robotic Skills (GEARS) tool and a checklist for suturing in RAS. (11,12) The performances of the participants with different levels of experience (experts vs. trainees) and the time needed to complete the tasks were compared for evidence of validity. At that time, training of the operative team was also simulated, with emphasis on the training of the communication skill.

Figure 3.1: Robotic hemostatic suture task in the wet lab with human placental model.



At the end of the 3-day course all participants received individual feedback and filled out a post-training questionnaire. This survey contained a test on the Intuitive Surgical da Vinci Si robotic system and a series of questions to assess the impact of the training based on Kirkpatrick model.(13)

A fellowship-style modular console training was offered to those trainees who successfully completed the 3-day course. This was the 5th step of the COBRASIL training curriculum which was a supervised modular training robotic urological surgery program, with increasing levels of complexity in a real learning environment of specific urological surgeries. Only one trainee completed the step 5. In the first 6 months he participated as beside-assistance, followed by 6 months of console modular clinical training in radical prostatectomies, partial nephrectomies and radical cystectomies. Throughout the 1-year program, the trainee underwent evaluations by an independent specialist and the proctor who used objective evaluation tools to complete his certification process in robot-assisted urological surgery. In this study, only the suture ability was considered in the assessment, since the focus was on the certification of fundamental technical competencies in robotic surgery. For this, the GEARS tool and a checklist for suture in RAS were used by two raters (one of them was independent and the other was the proctor) in the evaluation of three sequential videos of the trainee's robotic suture training in real-world operating theater, which happened in the first modular console trainings. At the end of fellowship program, the trainee answered if he felt prepared to perform robotic urological surgery alone, through a questionnaire presented on a Likert scale from 1 to 5 (1, certainly not; 2, no; 3, maybe; 4, yes; 5, certainly yes).

Stata version 11.0 was used for all data analysis. All tests were two-sided with 95% CI and p-value$\leq$0.05 considered significant. We used Mann-Whitney and chi-square tests to compare continuous and dichotomous measures respectively between the groups. To evaluate the reliability of the performance tests, the intraclass correlation coefficient (ICC) and Cronbach's alpha coefficient were used. To perform the analyses, the percentage values were considered, allowing a single scale for all variables.

3.4. RESULTS

In this pilot validation study, all 15 participants completed the 3-day course, which reached the five sources of evidence recommended in the Messick's framework. The differences observed between the groups' performances in theoretical and simulation training were considerably supported by statistical significance tests (Table 3.1).

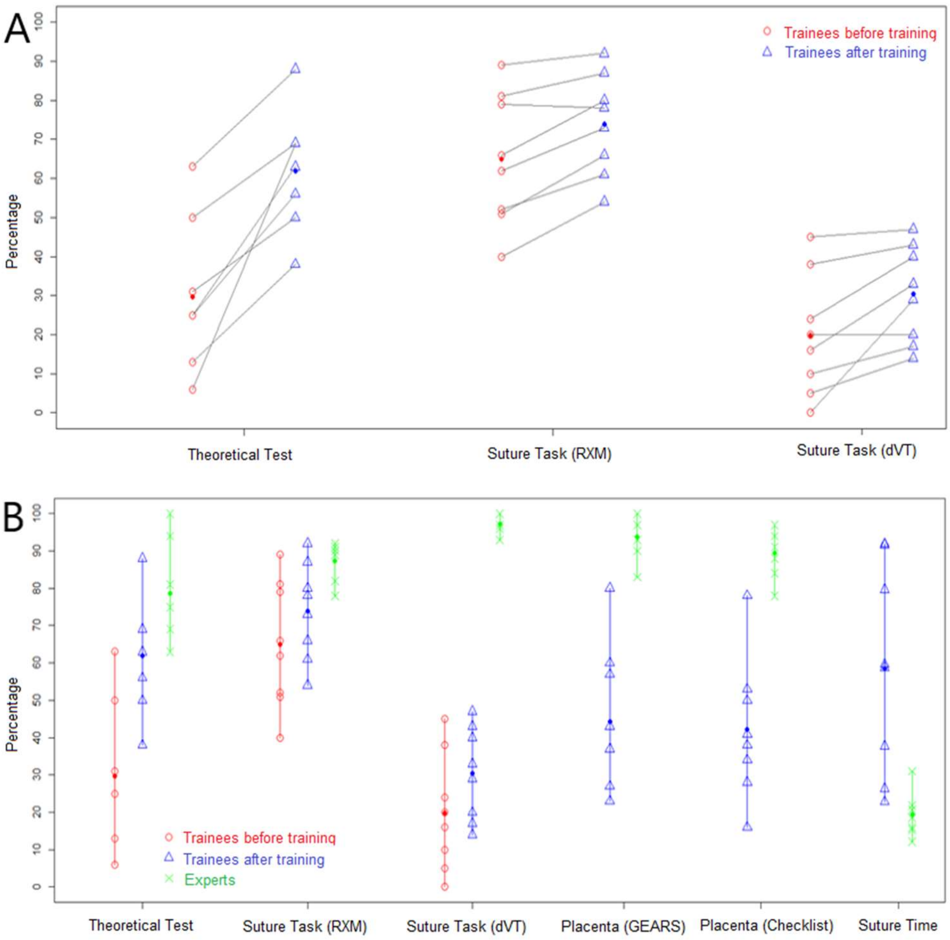
Table 3.1: Difference in the performances of the participants before and after the 3-day course's training and between the groups.

Evaluations	Groups	Performance (Average)	Standard deviation	Comparison between Groups	Test t (p-value)	Mann-Whitney (p-value)
Theoretical Test	TG before training	29,75	18,63	TG (before vs. after)	0,0002	0,0069
	TG after training	62,00	14,79			
	EG	78,71	13,79	TG (after) vs. EG	0,0207	0,0201
Suture Task (RXM)	TG before training	65,00	17,02	TG (before vs. after)	0,0017	0,0103
	TG after training	73,87	12,97			
	EG	87,28	5,21	TG (after) vs. EG	0,0119	0,0211
Suture Task (dVT)	TG before training	19,75	15,61	TG (before vs. after)	0,0082	0,0112
	TG after training	30,37	12,78			
	EG	97,14	2,41	TG (after) vs. EG	0,0000	0,0006
Suture Task Placenta (GEARS)	TG	44,25	19,96	TG vs.EG	0,0000	0,0006
	EG	93,85	5,78			
Suture Task Placenta (Checklist)	TG	42,25	18,64	TG vs.EG	0,0000	0,0008
	EG	89,43	6,63			
Suture Time in the Placenta Model	TG	585,62	277,73	TG vs. EG	0,0024	0,0006
	EG	193,57	60,95			

EG: Experts Group; TG: Trainees Group

In general, the variables showed improvement in trainees’ performances from before to after 3-day course’s training (Graph 3.1). The post-training questionnaire showed the impact of the course. The perception of progress of knowledge and skills of the trainees was 100%. However, only 32.5% of these participants felt prepared to perform robotic surgery at the end of the 3-day course. Even so, the approval of the format and duration of the basic training was 90%. Regarding the program's motivation capacity and its use as a teaching method in robotic surgery, there was a maximum score agreement of 100%. All participants also gave maximum score in the overall evaluation of the proposed curriculum.

Graph 3.1: Individual progressions and comparisons between variables and groups.



A - Comparison between the performances of trainees, before and after training. The lines define each trainee and evidence the individual progression. Solid circles represent their average performances. B - Vertical lines extend from the minimum value to the maximum of the respective variable in each group. Solid circles represent their average performances. Each unit of time represents 10 seconds. Single scale for all variables in percentage values.

The modular training in the step 5 of COBRASIL curriculum was completed by one trainee who reached full certification of urological robotic surgery after 1-year supervised program. His evaluations of suture ability in step 5 using GEARS and suture-checklist, respectively, in the three videos with independent rater (IR) and proctor rater (PR) were: 80% and 56% for IR and 80% and 63% for PR in video 1; 80% and 66% for IR and 80% and 69% for PR in video 2; 80% and 78% for IR and 87% and 81% for PR in video 3. The ICC between the two judges was 0.89, with a CI of 95% between 0.2889 and 0.9881 (p= 0.0024) demonstrating the excellent replicability of the tests. The internal consistency between the tools was also excellent, with a Cronbach's Alpha Coefficient of 0.9719.

Thus, the judges' results were convergent and the trainee achieved performance similar to the experts in the suture task, right at the beginning of his learning curve in the console modular clinical training. During the fellowship program, he participated in approximately 150 robotic surgeries as beside-assistance, 80% in radical prostatectomy, 17% in partial nephrectomy and 3% in radical cystectomies. As a console surgeon he participated in approximately 20 cases, all of them were radical prostatectomy. The trainee felt prepared to perform robotic urological surgery at the end of fellowship program, with grade 5 (certainly yes) on the Likert scale.

3.5. DISCUSSION

This prospective study investigated the performance of novice and expert robotic surgeons from before to after 3-day course's training to gather validity evidence for a structured competency-based training program of RAS. For this study, despite the fact that there are others validity frameworks, the Messick's one was chosen, considering that this is the most widely accepted contemporary validity framework, according to Borgersen et al (2018).

The plan for the 3-day course, described by detailed specifications based on the COBRASIL curriculum, clearly related the content tested by the participants to the domain of the fundamentals of robotic surgery as described by the course learning objectives. The COBRASIL curriculum was able to combine the best practices, according to Cook et al (2013), of all major robotic surgery curricula already validated and developed by expert Delphi Consensus, such as FRS and ERUS curricula.(14-19) This, by itself, has already ensured the validity of content. Borgersen et al (2018) report that all 5 sources of validity evidence do not always need to be addressed in a single study. However, this study presented the other four evidences of Messick's validity, in addition to the evidence of content.

Response process is defined here as the maximum effort taken to minimize bias in the program.(20) For example, in this study in which the program was developed to train the fundamentals of robotic surgery and assess suture skills, the lack of prior experience on how to perform a suture can affect performance scores. In this case, the construction of the suture process itself should be evaluated first before evaluating familiarity with the robotic instruments used in the suture, since novice group may not perform better than experts simply because they do not know how to perform a suture. In this study, all the trainees were attending urologists who mastered the suture technique. Other measures used to minimize bias in the evaluation process were the standardization of instructions and blind raters in wet lab. Automated performance assessments by virtual simulators alone have already avoided a rater bias.

The internal structure can be evaluated statistically and addresses the reliability of scores that intend to measure the same construction. In this study, a high degree of reliability was demonstrated, since the evaluations using both GEARS and the suture-specific checklist allowed a clear discrimination between experts and trainees and the results were consistent from one measurement to another. These differences between the levels of proficiency and experience, in addition to the positive correlation between the performance scores for this ex vivo model and other previously virtual reality simulators also demonstrated evidence of the validity of relationship to other variables. Divergent evidence of suture times among trainees and experts is also considered important for this source of validity.

According to Goldenberg & Lee (2018), evidence of consequences is the most subjective source of validity, but it is essential not only for the trainee and the training program, but also for society.(21) Consequential validity refers to the potential and actual consequences of the interpretation of performance scores and the decisions that result (e.g., certification of fundamental technical competencies in robotic surgery). The evaluations of the suture ability of the trainee during the actual surgeries reached the parameters of the experts. Thus, the 3-day simulation course enabled the transfer of basic robotic skills to real patients and thus allowed them to gradually progress to more complex tasks in real-world operational theater.

The results of post-training questionnaire indicate that the 3-day course had an excellent educational impact. The most commonly used approach to the measurement of the impact of training is based on the Kirkpatrick's 4-level Model as described by Smitd et al (2009). The first level of model (reaction) includes impacts on learners' satisfaction. In the second level (learning) the knowledge and skills of the learners are measures. At the third level (behavior or performance) the participants' ability to use their newly learned knowledge or skills in the workplace is evaluated. Finally, in the fourth level (results) the impact that the training had in general is measures, in addition to the changes in clinical processes. In pilot study, all participants felt that the 3-day course significantly improved their robotic skills. However, the strictly simulated training up to step 4 may have influenced the low rate of trainees who felt prepared to perform real robotic surgery at the end of the program. Simulation training does not replace real-world experience in operation room and perhaps step 5 could be considered the most important in the learning process. The long duration of the fellowship program may have influenced the low-adhering of the participants for this step.

Certification in RAS should be based on demonstration of competences in a given context (specific surgery and specific robotic plataform) rather than caseload. In step 5, the trainee was able to prove his competencies in the fundamentals of robotic surgery, especially the suture. Probably at the end of the fellowship program he would also be able to prove his competencies in robot-assisted radical prostatectomy. However, the context of this study was the suture training on the platform of the da Vinci robot, so only this certification can be proven.

The COBRASIL curriculum was developed to be specialty-independent and device-independent. This competency-based curriculum can be adapted to suit requirements of any surgical training program, including outside the field of robotics. In RAS, progression from bedside to console with modular training under proctor supervision prior to an independent operation, in addition to assessments for each competency, should be considered mandatory for patient safety(22). Although they were not evaluated in this study, non-technical skills should also be considered, including communication and teamwork(23). Further studies are needed to investigate the learning curves of trainees for each context, as well as the time required to achieve proficiency.

Other methodological limitations of this research are the single-center design and small number of participants. Despite this, the sample size was sufficient to detect statistically significant differences between the groups' performances. Thus, given the results of this pilot validation study, the trainees may be able to apply the content learned in his own environment of professional practice after this training process in robotic surgery. Nevertheless, validation studies need to be conducted before large-scale implementation of this curriculum.

3.6. CONCLUSION

This preliminary study established evidence of validity for a structured competency-based training program of fundamentals of robotic surgery. This short full-time course should be incorporated into fellowship-style robotic surgery training so that novice robotic surgeons have achieved optimal training before starting supervised modular training robotic surgery program.

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4. CAPÍTULO 4: Validation of a progressive training program using robotic surgery virtual reality simulator

4.1. ABSTRACT

Introduction: The Mimic's dV Trainer (dVT) is the most validated virtual reality robotic surgery simulator in the literature. Despite this, these validation studies used outdated validity frameworks as face, content and construct validity types. Validity evidence is not for the simulator itself, but for the application or interpretation of the results of the training program that uses it. Most robotic centers have simulators, but lack elements to build a validated training program.

Objective: To validate a progressive training program in dVT.

Methods: This validation study was carried out using the Messick's contemporary validity framework which considers 5 sources of evidence: content, responses, internal structure, relationship to other variables and consequences. Participants were divided into 3 training groups according to their levels of experience in robotic surgery, in addition to a control group. A progressive training for the acquisition of technical skills in robotic surgery was performed using the dVT and the scores were compared between the training groups. After performing the required dVT's exercises, all experts filled out a post-study questionnaire. Then, a suture training task similar to the Sponge Suture 1 from the dVT was proposed in dry lab. Each training was recorded and a blinded rater would then evaluate the performances using an assessment tool. The results of this dry lab's training were correlated with the automated performance assessments in the exercise from dVT. The performances of the training groups (participants who did the progressive training) were compared with control group (participants who trained in the dVT freely without any specific order).

Results: All experts assessed dVT as easy to use and useful as a training tool for the console functionalities of da Vinci robot. The training groups' performances in dVT's exercises showed clear discrimination between experts and novices ($p<0,05$), with the exception of Ring Walk 1 exercise ($p=0.11$). Cronbach's Alpha Coefficient was 0.96. There was a positive Pearson's correlation between the scores in the Sponge Suture 1 and dry lab suture training task ($r= 0,93$; 95% CI between 0.72 and 0.98, with $p = 0.0001$). The training groups had better performances in dry lab suture simulation training than the control group ($p=0.02$).

Conclusions: This progressive training program in dVT established the five sources of validity evidence for the Messick's contemporary validation process.

Key words: Robotic surgery, Validation study, Simulation training, Education, Virtual reality.

4.2. INTRODUCTION

As in aviation, simulation training is essential in the healthcare field. It would be unimaginable to travel on an airplane in which the pilot had not trained for long hours of practice in flight simulators. Simulators offer an excellent opportunity to familiarize with technology and develop skills that will be used in real-world scenarios.(1)

Currently there are a number of virtual reality (VR) simulators available for the acquisition of technical skills in robot-assisted surgery (RAS), as dV Trainer (dVT) Mimic Technologies (Seattle, WA, USA).(2) Validity of these robotic surgery simulators were confirmed in the literature by several studies.(3) Despite this, the vast majority of these validation studies used outdated validity frameworks as face, content, criterion, construct, concurrent and predictive validity types.(4) In the contemporary validity framework, these types of validity have been replaced by a unified model in which the concept of Messick has become the gold standart. This concept consists of five sources of validity evidence: content, responses, internal structure, relationship with other variables and consequences.(5)

Validity evidence is not for the simulator itself, but for the application or interpretation of the results of the training program that uses it.(5) Most robotic centers have simulators, but lack elements to build a training program. Tillou et al (2016) validated a progressive training program using a robotic surgery simulation device.$^{(6)}$ However, they also used outdated validity frameworks which impairs the application of a simulator in a given context. The aim of this study was to perform validation of the progressive training program described by Tillou et al (2016) in a VR robotic simulator, but using Messick validity framework.

4.3. MATERIALS AND METHODS

This validation study was carried out using the Messick's framework (Figure 4.1) and received an approval from a certified Ethical Board. A total of 15 surgeons were enrolled and classified as novice (no robotic surgical training), intermediate (less than five robotic cases) or expert (50 or more robotic cases). Then, three groups (with five members each) were formed according to the level of experience of the participants as follows: novice group (NG), intermediate group (IG) and expert group (EG).

Figure 4.1: Messick's validity framework in relation to this study

Sources of evidence	Question to be answered	Method to get the answer
Content	Does the dVT training program content represent the domain being evaluated or measured?	Only the experts assessed the content of post-study questionnaire on the usefulness of dVT
Response	What efforts have been taken to minimize a rater bias?	Standardization of instructions, automated performance assessments by dVT and blind rater in dry lab
Internal structure	How reliable is the assessment generated by dVT?	The internal consistency of measurement repetition of the simulator scores was assessed by Cronbach's alpha coefficient
Relationship with other variables	Do the dVT assessment scores correlate with external independent measures?	Comparison of scores between groups for each exercise of the dVT and relations between the results for different simulators were analyzed
Consequence	What is the impact of the training program using dVT on the novice robotic operator or patients?	Comparison of dry lab test scores between participants who completed progressive dVT training or not

dVT: robotic surgery's virtual reality simulator dV Trainer Mimic Technologies

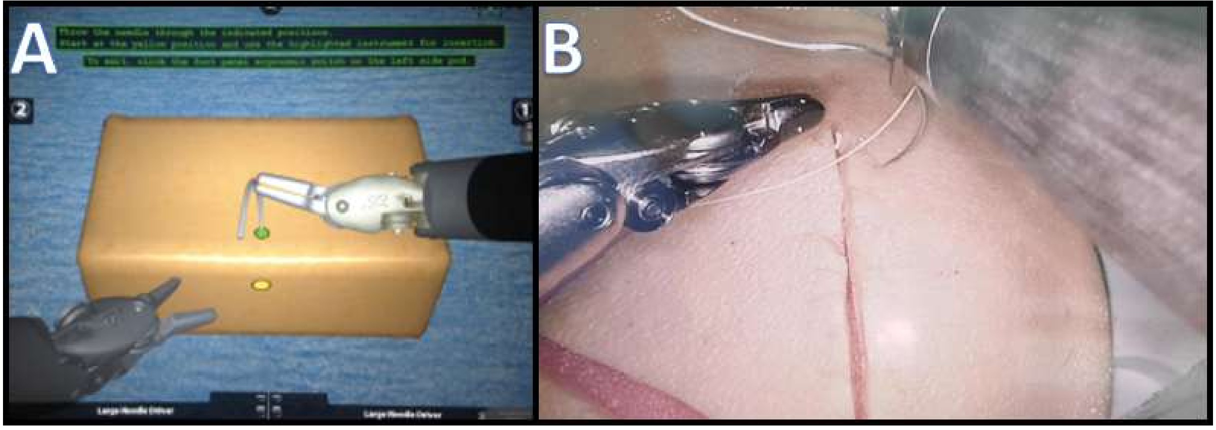
All of the participants answered a demographic questionnaire that addressed age and laparoscopy experience. A standardized explanation about dVT with eight of its simulation training exercises was presented to all participants before starting the practice. As detailed in the article by Tillou et al (2016), these 8 exercises were identified as essential to ensure progressive learning and were divided into four skills trainings: (1) Camera and Clutching (camera targeting 1 and 2); (2) Handling Endowrist (ring walk 1 and 2); (3) Needle Driving (sponge suture 1 and 2); and (4) Energy and Dissection (energy switching 1 and dissection).(6) These skills trainings were the minimum proficiency requirements in order to be able to work with the da Vinci robotic surgery platform (Intuitive Surgical). The trained console functionalities were: camera navigation from the console (how the camera is moved and zoomed in and out); movements of the robotic instruments (Endowrist technology); suturing skills with needle driver; activation of monopolar and bipolar coagulation and dissection skills with scissors and graspers.

The score of each participant in the exercises was evaluated by the device software algorithm. The minimum score of 80% was necessary to advance to the next exercise and the number of repetitions required and the time to achieve this result were unlimited. The "performance index" (PI) of each participant was calculated. This was a ratio in which the sum of the scores for each exercise was divided by the number of repetitions required to achieve at least 80% for each exercise. The results of the PI were compared between the three groups to establish evidence of validity.

After performing the required exercises on dVT, all experts filled out a post-study questionnaire. This survey contained the following two statements: this simulator is easy to use and this simulator is useful for training the console functionalities of da Vinci robot. The survey was presented on a Likert scale of 1 to 5 (1, strongly disagrees; 2, disagrees; 3, does not know; 4, agrees; 5, strongly agrees). In addition, all participants answered the following question: Does this simulator motivate you to train robotic surgery? (yes or no).

At the end of the study all participants of EG and IG were invited to perform a suture training task in dry lab similar to the “Sponge Suture 1” exercise from the dVT (Figure 4.2). Five surgeons with previous experience in dVT, but who did not perform the progressive training proposed by Tillou et al(6) were also invited to perform the suture task in dry lab. Each training was recorded and a blinded rater would then evaluate the performances using the Objective Structured Assessment of Technical Skills (OSATS) tool.(7) The results of this training in dry lab were correlated with the automated performance assessments in the "Sponge Suture 1" exercise by dVT and performances were compared between the participants with different levels of experience.

Figure 4.2 – Suture training task in the different models of robotic surgery simulation



A: “Sponge Suture 1” exercise in dVT; B: suture training task in dry lab

Stata version 11.0 was used for all data analysis. All tests were two-sided with 95% CI and $p \leq 0.05$ considered significant. Kruskal-Wallis nonparametric statistical test and Dunn's method were used to compare ages of the participants and PI between the groups. The G-test was used to compare the previous experience in laparoscopy of the participants. Relations between the results for different simulators were analyzed using Pearson's correlation coefficient (r). To evaluate the reliability of the performance tests, the Cronbach's alpha coefficient was used. Mann-Whitney test was used to compare continuous measures between the participants' performance in dry lab. To perform the analyses, the values reported as percentages were considered to have a single scale for all variables.

4.4. RESULTS

All participants completed the study. The mean age in the EG, IG and NG were, respectively, 50.6 years (45-59); 37.4 years (36-40) and 30.6 years (29-32), p=0.0495. Regarding the variable experience in laparoscopy (procedures/year) there was no difference between the groups (p=0.15).

All experts assessed dVT simulator as easy to use (3 and 2 out of 5 reported likert score of 5 and 4, respectively) and useful as a training tool for the console functionalities of da Vinci robot (5 out of 5 reported likert score 5). All participants considered dVT simulator motivating to train robotic surgery.

The mean PI of all groups in each exercise performed in the dVT showed clear discrimination between experts and novices, with the exception of exercise 3, the "Ring Walk 1" (Table 4.1). All other exercises had the significant test with at least one group statistically dominating the other. In exercises 1, 4 and 5, the difference occurred only between EG and NG. In exercise 2, the difference occurred between EG and NG and between IG and NG. In exercises 6, 7 and 8, the difference occurred between EG and IG and between EG and NG. These results were consistent and demonstrated a high degree of reliability. The internal consistency was excellent, with a Cronbach's Alpha Coefficient of 0.9554.

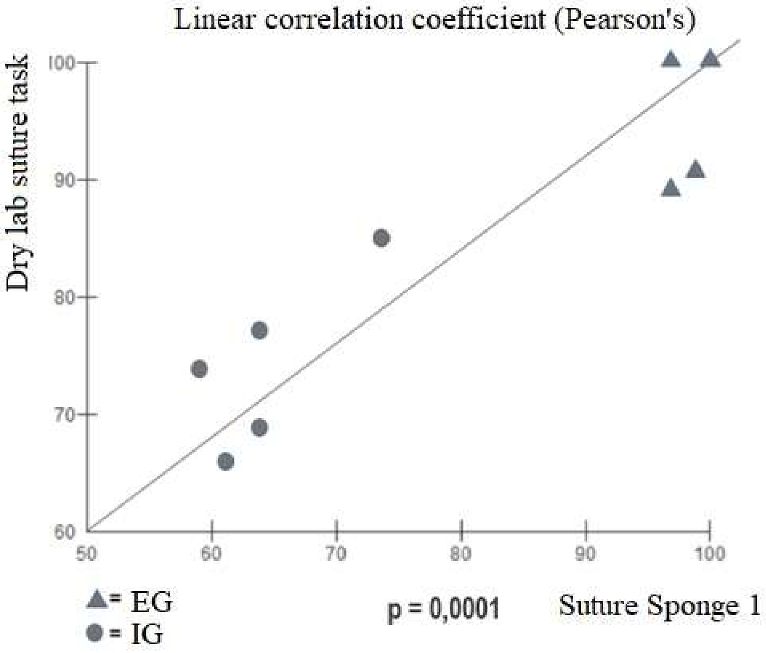
Table 4.1: Average performance indexes of participants in each group according to training in the dVT simulator

Exercises	EG Average PI	IG Average PI	NG Average PI	Global average p-value (Kruskal-Wallis)	Multiple comparisons p-value (Dunn)
1) Camera Targeting 1	91,6 (86-99)	87,2 (84-91)	69,2 (56-83)	0.0073	EG vs. IG: ns EG vs. NG:<0,05 IG vs. NG: ns
2) Camera Targeting 2	89,2 (80-94)	82,2 (75-95)	54,8 (41-73)	0.0009	EG vs. IG: ns EG vs. NG:<0,01 IG vs. NG:<0,01
3) Ring Walk 1	98 (95-100)	93,4 (83-99)	88,8 (80-98)	0.1133	EG vs. IG: - EG vs. NG: - IG vs. NG: -
4) Ring Walk 2	99,4 (98-100)	97,6 (95-100)	69,8 (56-92)	0.0042	EG vs. IG: ns EG vs. NG:<0,05 IG vs. NG: ns
5) Sponge Suture 1	98,6 (97-100)	64,4 (59-74)	51,6 (42-63)	0.0030	EG vs. IG: ns EG vs. NG:<0,05 IG vs. NG: ns
6) Sponge Suture 2	92,2 (82-97)	70,4 (63-86)	62,2 (53-75)	0.0008	EG vs. IG:<0,01 EG vs. NG:<0,01 IG vs. NG: ns
7) Energy Switching	95 (90-99)	79,6 (72-89)	78 (74-85)	0.0001	EG vs. IG:<0,01 EG vs. NG:<0,01 IG vs. NG: ns
8) Dissection	92 (85-100)	82,2 (80-85)	74 (70-85)	0.0024	EG vs. IG:<0,05 EG vs. NG:<0,01 IG vs. NG: ns

NG: novice group; IG: intermediate group; EG: expert group; PI: performance index; ns: not significant

The correlation between the scores of the EG and IG in the "Sponge Suture 1" exercise of dVT and dry lab suture training task is evident in Graph 4.1. A linear correlation coefficient (Pearson's) of 0.9290 was obtained with 95% CI between 0.72 and 0.98, with p = 0.0001.

Graph 4.1: Percentage scores on dVT ("Suture Sponge 1") and the dry lab suture task.



EG: expert group; IG: intermediate group.

Averages performances in dry lab were 74% for IG (n=5) and 49% for surgeons who also had previous experience in dVT, but who did not perform the progressive training (n=5). The difference observed between these participants' performances in dry lab suture simulation training were considerably supported by statistical significance test (p=0.0184).

4.5. DISCUSSION

In this prospective study, the progressive training program proposed by Tillou et al in dVT was investigated and validity evidence regarding content, responses, internal structure, relationship with other variables and consequences were gathered. These are all components of contemporary Messick’s unified validity framework that considers validity as an application or interpretation of scores of a simulator and not the simulator itself.(4,5)

Establishing a fixed number of training hours in virtual reality simulators is a frequent approach in robotic surgery training programs, but one that ignores the variability of learning, age and previous educational and professional experiences among individuals.(8) In this study the EG’s participants were older than the other groups, but the greater experience in robotic surgery was not reflected in greater experience in laparoscopy. Our data support previous assertions in the literature that the robotic surgery requires a different set of skills compared to open and laparoscopic surgery.(9-11) Therefore, this progressive training program based on proficiency respected individual variability in relation to robotic skills acquisition and should be considered a mandatory bridge to the real patient, regardless of the surgeon's previous experience both in laparoscopy and in open surgeries.

Most of the published literature on validation studies in simulation-based training used outdated validity frameworks.(4,12) Tillou et al (2016) validated this training program using "validity types" such as face, content and construct, which is an outdated concept for validation.(6) According to the systematic review by Borgersen et al (2018), 93.4% of the validation studies in surgical simulation used outdated or unspecified validity frameworks.(4) Of these, 41.6% of the studies evaluated the face validity, which is a subjective approach to the realism of the simulator.(4) However, the results are much more important than superficial looks of simulator and face validity contrasts sharply with true scientific validity evidence required to support or refute the meaning and interpretation of assessment scores.(13) Although face validity is not considered as acceptable evidence of validity, the realism of the simulator could affect the motivation of the participants. In the present study, all participants considered dVT simulator motivating to train robotic surgery and motivation is an active part of learning.

In this study, only the experts assessed the content of post-study questionnaire and all of them assessed dVT simulator as easy to use and useful as a training tool for the console functionalities of da Vinci robot. The content and construct validities of the study by Tillou et al were partly transferable to the contemporary framework. However, when evaluating the competence of a trainee, a clear understanding of how validity is established and is determined in each context is mandatory.(14) For example, the simulator can be very useful to train a suture in the da Vinci robot, but little useful to train a knot. Therefore, it is necessary to evaluate the evidence in the specific scenario in which the simulator will be used. In addition, choosing a panel of judges with a high level of content experience is another important step in providing content-related evidence.(14) The console functionalities of da Vinci robot were the competency domain of the present study and the evaluations of only the experts of the dVT simulator were focused on this context. In order to achieve robust evidence of validity to support competency judgments, it is important that the researchers move away from the outdated and limited concept of validity and adopt contemporary taxonomy of validity evidence, where the different "validity types" have been replaced by a unified model, in which validity evidence comes from various source and all are considered construct validity.(12)

The results of this study showed significant differences in performance between the groups, mainly between EG and NG, with a high degree of reliability and internal consistency, demonstrating the evidence of internal structure. Heterogeneous PI among IG's participants brought them closer to NG than EG in some exercises. Brinkman et al (2013) were interested in the learning curve of novice surgeons and concluded that basic robotic skills are learned fairly quickly after the use of simulators. However, ten repetitions were not enough for most novices to move to an expert level.(15) Some dVT exercises helped the surgeon acquire familiarity with the robotic platform, but did not develop the operative skills, as was the case of the "Ring Walk 1" exercise, which was the only one that did not differentiate the groups according to their experience levels. Thus, this exercise could be removed from the progressive training program without prejudice to the development of skills.

The standardization of instructions at all stages, the automated performance assessments by dVT's software algorithm and the blind rater in dry lab used in this study served to minimize the bias in evaluation process and reflected the response process evidence. Although OSATS is a good objective assessment tool in dry lab training, the evaluator's personal opinion still stands out in the face of the instrument, which makes it difficult to apply.(7,16,17) This does not happen in the computerized evaluation of dVT which certainly brings more concordant and reliable feedback. Nevertheless, the validity evidence of relationship to other variables was achieved with the differences between EG and IG and the positive correlation between the performance scores for the "Sponge Suture 1" exercise of dVT and dry lab suture training task.

The intended consequence of training in this simulation-based program was to improve the surgeon's competencies in relation to the console functionalities of da Vinci robot. This goal was achieved at the time when the averages participants' performances of the IG in dry lab suture simulation training were higher than those who did not previously perform the progressive training proposed in this study.

The main methodological limitations of this research are the single-center design and small number of participants. A sample size calculation was not performed, but our results converged with the studies performed in other contexts suggest that our sample was representative. This learning method opens new fields of research that lead to a deepening of the knowledge of the competencies involved in the training of robotic surgeons. The transfer of VR simulation robotic surgical skills to performance in other learning environments such as wet lab and thus allow gradual progression to more complex tasks in other contexts, needs investigation.

4.6. CONCLUSION

The VR simulation training program in which a specific series of exercises in a specific and progressive order to train console functionalities of da Vinci robot enabled the minimum proficiency requirements in robotic surgery. This proficiency-based training established the five sources of validity evidence (content, responses, internal structure, relationship to other variables and consequences) for the Messick's validation process and should be embedded into a competency-based robotic surgical training curriculum.

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5. CAPÍTULO 5: Fundamental technical competencies in robotic surgery: contemporary validation process of an ex vivo training model

5.1. ABSTRACT

Introduction: Live animals or human cadavers are the best simulation models for training robotic surgery. However, high costs and ethical concerns limit their use and availability. In addition, simulated training in a specific context should demonstrate evidence of validity to be recommended.

Objective: To develop an ex vivo simulation model and validate its application in synthesis and hemostasis training in robotic surgery.

Methods: A simulation model for the training of synthesis and hemostasis in robotic surgery was built from human placentas. Then, a validation study was carried out using the Messick's framework. Participants were classified as experts who had at least fifty robotic cases performed and trainees who were attending surgeons with simulation experience but no clinical experience in robotic surgery. A standardized explanation about a hemostatic suture exercise using the robotic platform to control a simulated bleeding was presented to the subjects and then administered a practice round in the simulation model. Each training was recorded and a blinded rater would then evaluate the performances using GEARS tool and checklist for suturing in robotic surgery. Then, we invited all participants to perform a suture exercise similar to the human placental model in virtual reality simulators and dry lab. The results were correlated with the suture exercise in ex vivo model. In the end, all participants received individual feedback and completed a questionnaire to assess the impact of the training, based on Kirkpatrick's model.

Results: In total, seven experts and eight trainees completed the training. All experts assessed ex vivo simulator as realistic and usefulness as a training tool and most participants considered ex vivo simulator more motivating to train robotic surgery than the others simulators. The assessments using objective evaluations tools allowed a clear discrimination between experts and trainees ($p<0,005$) and the results were consistent from one measurement to another (Cronbach’s Alpha Coefficient = 0.9275). There was a positive Pearson’s correlation between the performance scores of this ex vivo model and the other simulators ($p<0,0001$).

Conclusions: This preliminary study suggests that the human placenta simulation model is reliable in training fundamental surgical competencies in robotic surgery. Many sources of evidence had been demonstrated for the validation process in the application of this training model.

Key words: Robotic surgery, Simulation training, Models, Education, Clinical competence.

5.2. INTRODUCTION

Since the use of robot-assisted laparoscopic approach has increased rapidly, it is important to maximize the efficiency of robotic surgical training.(1) Training in the laboratory on simulation models may help providers develop familiarity with robotic platform, as well as cognitive and technical competency in robotic surgery.(2) There are several virtual reality (VR) simulators available for da Vinci robot (dVR) manufactured by Intuitive Surgical Inc., Sunnyvale, CA, USA(3). The use of these simulators is a good strategy to shorten the learning curve without compromising patient safety. The other option for developing robotic technical skills is to use the dVR in a dry or wet lab settings. When comparing these options it should be noted that technical skills differ from surgical competence which can only be developed in a wet lab or through real operative experience.(4) Therefore, while VR simulators can replace a dry lab, they cannot replace the experience in a wet lab.(5)

Robotic wet laboratories provide the closest alternative to real surgery. While live animals or human cadavers are the best simulated scenarios, high costs, availability and ethical concerns limit their use in robotic surgery training.(6) Some authors described embalmed body parts and other models of wet lab as training materials to learn vascular identification and robotic dissection.(7) However, before they could be recommended, such simulation models should demonstrate evidence of validity. Most validation studies in surgical simulation have been using outdated or unspecified validity frameworks, which impairs the assessment of relevant competency/skills.(8)

Over the past 20 years, different types of validity (face, content, construct, criterion, and concurrent) have been replaced by a unified model, where all validity is construct validity. This contemporary validity framework, based on Messick,(8) considers validity to be an application or interpretation of simulator scores not for the simulator itself and requires multiple sources of evidence: content, responses, internal structure, relationship to other variables and consequences.(9) Unfortunately, the few studies that used this modern concept of validation provided only evidence of relationships to other variables and neglected other sources of evidence, especially the responses and consequences.(8) Furthermore, to our knowledge there are no validation studies reporting a high fidelity ex vivo simulation model that allows the joint development of two fundamental technical competencies for any robotic procedure: synthesis and hemostasis. The purpose of this study was to address this gap by developing such a model and evaluating the sources of evidence for the validation process.

5.3. MATERIALS AND METHODS

This prospective observational study received an approval from a certified Ethical Board and 15 human placentas were collected. The expectant mothers underwent prenatal infectious evaluation and signed consent for donation of placenta for practice in surgical techniques.

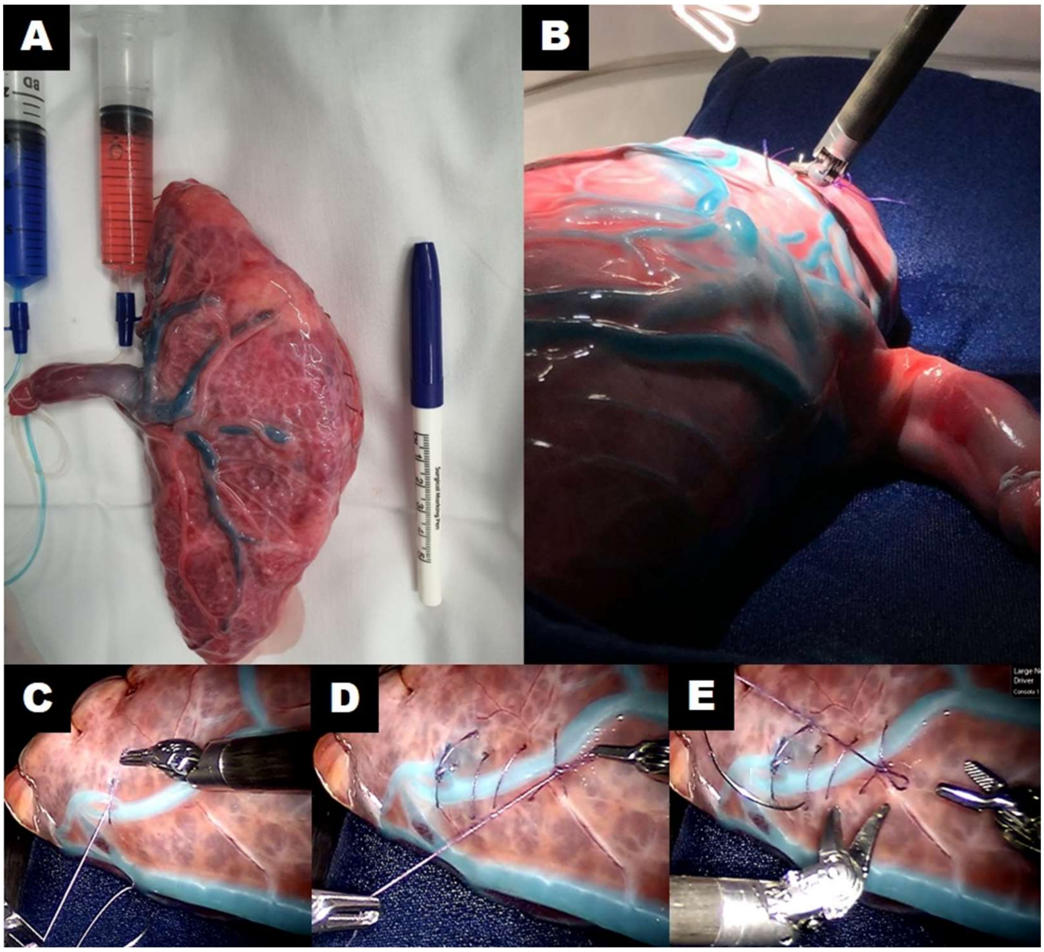
Participants were classified as experts (at least 50 robotic cases performed) and trainees (attending surgeons with simulation experience but no clinical experience in robotic surgery). We divided 15 subjects into two groups as follows: seven experts, Expert Group (EG) and eight trainees, Trainee Group (TG).

The study was divided into two stages. Firstly, a simulation model for the training of synthesis and hemostasis in robotic surgery was built. Then, a validation study was carried out using the Messick's framework to justify the use of this training model.(10)

5.3.1. Human placental simulation model

The characteristics and preparation of the human placenta were described in our earlier paper.(11) However, in this study some minor adaptations were made, with the following three steps to simulate a bleeding kidney. In step one, placenta was spread over the operative table with the fetal surface facing upward. It was folded inwards and was sutured using a 3-0 Vycril to simulate a kidney. In the second step, the main artery and vein were cannulated with a 6 French gauge urinary catheter and continuous infusion of colored saline solution (red for artery and blue for vein – Gouache 1:10 saline) was started to simulate blood (Figure 5.1A). Since the placenta vascular tree has just one flow direction, the infused fluid flowed out through the placenta stroma into a bowl connected to a drainage system. Simulated bleeding was performed by sticking with a needle into a blood vessel of the placenta in the third step.

Figure 5.1: Robotic hemostatic suture exercise in the human placental model simulating a kidney.



A: Human placental model simulating a kidney for exercise that included the following tasks: B - perform a suture on the simulated blood vessel; C - tie a surgeon's knot to stop the simulated bleeding; D - back up the knot with a square knot (two throws); perform continuous suture along the vessel (three point of entry); tie a surgeon's knot to stop the suture; back up the knot with a square knot (two throws); E - use 4th arm with robotic scissors to cut the thread.

5.3.2. Validation study

A standardized explanation about a hemostatic suture exercise using the dVR to control a simulated bleeding was presented to the subjects and then administered a practice round in the simulation model (Figure 5.1B, C, D and E). This exercise trained camera navigation and clutch, precise needle control, suture placement, square knot tying with proper force and the switching back and forth between a primary instrument and the 4th arm in a coordinated fashion. Each training was recorded and a blinded rater would then evaluate the performances using a Global Evaluative Assessment of Robotic Skills (GEARS) tool and a checklist for suturing in robotic surgery.(12,13) The performances of the participants with different levels of experience (experts vs. trainees) and the time needed to complete the tasks were compared for evidence of validity. At the end of the study all participants received feedback on their performances in the human placenta simulation model.

To evaluate the convergent validity evidence, we invited all participants to perform the training task “Basic Suture Sponge” from the software program of the dV-Trainer (dVT), designed by Mimic Technologies, Inc and “Task 3 Railroad Track” from the RobotiX Mentor (RXM), designed by Simbionix, Ltd (Figure 5.2). In addition, we prepared a suture exercise similar to the human placental model for dry lab in dVR. The participants’ performances were recorded and the results were correlated with the hemostatic suture exercise to control a simulated bleeding in wet lab using ex vivo model.

Figure 5.2: Suture tasks in the different models of robotic surgery simulation

A – Human placental model (wet lab); B- Inanimate model (dry lab); C - Task 3 Railroad Track” from RXM (VR simulator); D - Basic Suture Sponge from Mimic’s dVT (VR simulator).

After performing the required tasks on simulation models, all experts filled out a post-study survey. This contained a series of descriptions of the models including the following two statements: this ex vivo model is a realistic simulator and this ex vivo simulator is useful for robotic surgery training. In addition, all participants answered the following statement: this ex vivo simulator motivates you to train robotic surgery more than the VR simulators or dry lab.

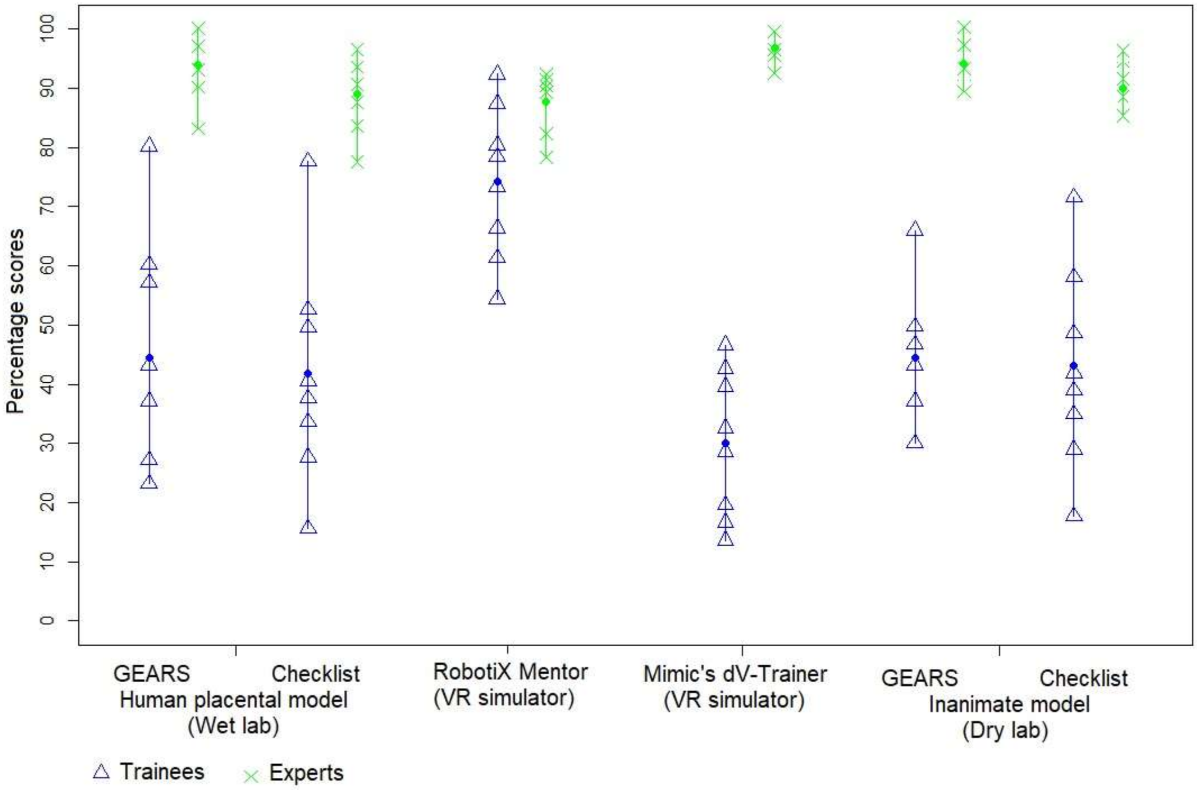
The surveys were presented on a Likert scale of 1 to 5 (1, strongly disagrees; 2, disagrees; 3, does not know; 4, agrees; 5, strongly agrees).

Stata version 11.0 was used for all data analysis. All tests were two-sided with 95% CI and $p \leq 0.05$ considered significant. We used Mann-Whitney and chi-square tests to compare continuous and dichotomous measures respectively between the groups. The internal consistency of the performance tests was assessed using Cronbach's alpha coefficient. Correlations between the results for different simulation models were analyzed using Pearson's correlation coefficient matrix. Pearson's coefficient (r) can range from -1 to +1, and the closer to these values, the stronger the association of variables under examination.

5.4. RESULTS

All 15 participants completed the study. Average performance in ex vivo model was 94% for experts (n=7) and 44% for trainees (n=8) with GEARS and was 89% for experts (n=7) and 42% for trainees (n=8) with checklist for suturing in robotic surgery ($p=0.004$ and $p=0.005$ respectively) (Graph 5.1).

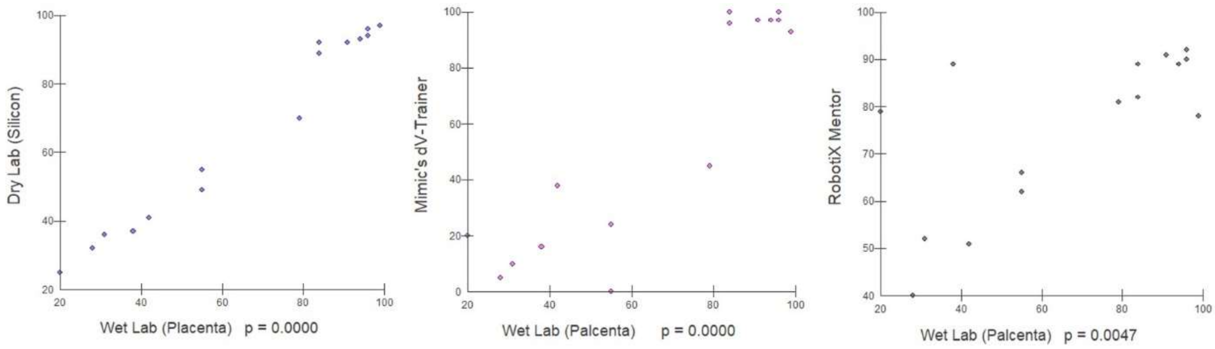
Graph 5.1: Comparisons between variables and groups.



Vertical lines extend from the minimum to the maximum value of the respective variable in each group. Solid circles represent their average performances. Single scale for all variables in percentage values.

The mean time required to complete the training of robotic suture in wet lab was significantly shorter for experts compared to novices (194 vs. 586 seconds, p=0.006). The internal consistency of the performance tests was excellent, with a Cronbach's Alpha Coefficient of 0.9275. The performance scores for wet and dry lab as well as the VR simulators showed high degree of correlation with Pearson's correlation coefficient matrix (Graph 5.2). In descending order, the strength of association of the results of the human placenta model was stronger in relation to the results of the inanimate model (r=0.9878, p<0.0001), Mimic's dV-Trainer (r=0.9032, p<0.0001) and RobotiX Mentor (r=0.6865, p=0.0047).

Graph 5.2: Pearson's correlation between the results for different simulation models.



Performance scores in wet lab (human placenta) and dry lab (silicon): r=0.9878, p<0.0001; performance scores in wet lab (human placenta) and Mimic's dV-Trainer: r=0.9032, p<0.0001; performance scores in wet lab (human placenta) and RobotiX Mentor: r=0.6865, p=0.0047.

All experts assessed ex vivo simulator as realistic (7 out of 7 reported likert score 5) and usefulness as a training tool (7 out of 7 reported likert score 5). Most participants considered ex vivo simulator more motivating to train robotic surgery than the VR simulators and dry lab (ten, two and three out of 15 reported likert scores of 5, 4 and 3 respectively).

5.5. DISCUSSION

Usage of robotic surgery has increased exponentially in recent years making the development of simulators for training increasingly important.(14) To our knowledge this is the first application of ex vivo model for robotic surgery training of all the simulation options available published in the literature. Moreover, unlike the vast majority, this study used the contemporary Messick's framework to achieve evidence of validation. Like this, the results showed that the human placental model provides an alternative to error safe environment for robotic surgeons to develop their technical competencies.

Despite the Messick validity framework was formally adopted by American Educational Research Association, American Psychological Association, and National Council on Measurement in Education in 1999, according to the systematic review by Borgersen et al (2018), 93.4% of the studies still use outdated or unspecified validity frameworks. Some of them had components that were transferable to the new framework, such as construct and content validities, while others used less relevant techniques such as face validity. In the old validity concept, face validity was a subjective approach to the realism of the simulator. Although Messick (1995) does not consider face validity as acceptable evidence of validity, he suggested that realism could affect the cooperation and motivation of participants which is why we chose to use it in this study.(15) In the present study, the human placental model was rated highly by experts for its realism.

The results of this study have also showed that ex vivo model is more motivating than other types of simulators. The real motivation for trainees is learning and many authors suggest that the most effective learning environments are those that are problem-centered.(16) The Merril's first principle of instruction is "*learning is promoted when learners are engaged in solving real-world problems*". In this work, the problem to be solved was a bleeding kidney. Although VR simulators can reproduce synthesis training and hemostasis, all of them are still limited by the lack of realistic visual and physical responses during suturing.(17,18) This human placental model reproduced with high fidelity a bleeding kidney and approached much more of a real-world problem.

The high score and concordance between the experts in the assessment of this model as being useful as a robotic training tool support the content validity. This requires a panel of judges with a high level of content expertise. Deciding who is an expert can be an arbitrary process.(19) As in competence, the domain of content may vary according to the context and, consequently, modify the panel of judges.(20)

The standardization of instructions and the blind rater used in this study served to minimize the bias in evaluation process and reflected the response process evidence. In addition, the assessment scores of the participants with different levels of experience reflected their performances in the exercise. The intended constructions were the achievement of hemostasis using sutures and the improvement of the robotic skills. Thus, the speed and quality of the suturing were also well considered by the blind rater.

The internal structure evidence was achieved with a high degree of reliability and internal consistency, since the assessments using both GEARS and the suture-specific checklist allowed a clear discrimination between experts and trainees and the results were consistent from one measurement to another. According to the systematic review published by Ilgen et al (2015), checklist inter-rater reliability and trainee discrimination were more favorable than a global rating scale. However, a global rating scale like GEARS may better capture nuanced elements of expertise.(21) The use of appropriate measures aligned with the intended objectives of the simulation is fundamental for achieving validity.(22) Moreover, according to Campos et al (2020), the main role of performance evaluation tools is to give individual feedback to the trainee.(23) The feedback given to participants at the end of this study could help them improve their skills.

The systematic review by Kwong et al (2019) showed that non-technical skills are a critical component of robotic surgery training and their evaluation tools should be improved.(24) The focus of this study was only the acquisition of suture technical skills (synthesis and hemostasis) and only these were evaluated. Although no non-technical skills assessment tool has been utilized, this wet laboratory may also allow the acquisition of skills such as situation awareness, decision-making, coordination, cooperation, leadership, teamwork and communication.

The validity evidence of relationship to other variables was proven with the differences between experts and trainees and the positive correlation between the performance scores for this ex vivo model and other previously validated simulators. Many complex surgical procedures require sutures to stop bleeding. Thus, this basic operative skill is fundamental and must be mastered by a robotic surgeon. In this validation study, with this context and these participants, the robotic simulation training in this wet lab allowed the development of the following technical competencies: hemostasis and synthesis. In addition, this model may also allow the training of other competencies, in different contexts, degrees of complexities and levels of experience of the surgeons. For example, this model could be used for experienced urologists to train and develop new techniques for robotic partial nephrectomy. In this case, the tumor could be simulated by injecting silicone in the placenta stroma followed by a catalyst to solidify it and the umbilical cord would simulate the kidney vessels.

Consequences evidence is the most subjective source of validity evidence.(25) The intended consequence of training in this high fidelity ex vivo simulation model was to improve the surgeon's fundamental robotic technical competencies and thus allow them to progress gradually to more complex tasks. In the study by Mills et al (2017), there was no correlation between attending surgeons' simulator performance and expert ratings of intraoperative videos based on the GEARS scale.(26) However, these results were based on the comparison of the performances of expert surgeons in a virtual simulator with a real surgery. Given the artificial nature of VR simulators, it is possible that the increase in the score in these simulators does not correlate with increases in intraoperative performance, because they primarily provide familiarity with robotic equipment rather than develop specific skills. The context of Mills' work was different from that featured in this present study which had a scenario much closer to reality. So even if the simulation doesn't replace the real experience, training in wet lab may be helpful when performed before facing the real-world operating theater.

The main methodological limitations of this research are the single-center design and small number of experienced surgeons. In our institution only seven surgeons had already performed more than 50 robotic cases and only one had surpassed 500 cases. A larger number of experts would need to be assessed to further confirm validity in the application of this training model. However, this can only be achieved through the use of multicenter studies, due to the limited ability to recruit surgeons with extensive robotic experience in individual institutions.

Furthermore, an intermediate group was not created in this study which would reinforce the ability of this model to differentiate surgeons with different degrees of experience. Even so, this human placenta simulation model demonstrated construct validation and consequently may become a reliable training tool in robotic surgery.

5.6. CONCLUSION

This preliminary study suggests that the human placenta simulation model is reliable in training fundamental robotic such surgical technical competencies as synthesis and hemostasis. Many sources of evidence (content, responses, internal structure, relationship to other variables and consequences) had been demonstrated for the validation process in the application of this training model.

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6. CAPÍTULO 6: New scoring method of a robotic suture assessment tool

6.1. ABSTRACT

Introduction: Robotic surgeons' competency evaluations are often performed based on case records that only measure the operational experience and use subjective criteria with low reliability. Objective assessments tools such as checklists and global rating scales are required to adequately assess robotic surgical skills and enable learning feedback. The choice of assessment tool depends on the purpose and especially the context. Although most robotic surgical procedures require suture there are only one published study on suture evaluation in robot-assisted surgery (RAS).

Objective: To develop a new scoring method for suture assessment in robotic surgery.

Methods: This prospective study aimed to construct the Suture Checklist of Objective Robotic Evaluation (SCORE) tool by a panel of experts in RAS and medical education, based on two validated assessments: Guni' Suture Checklist (SC) and Global Evaluative Assessment of Robotic Surgery (GEARS). Then, a validation study was carried out using the Messick's framework. A total of 15 participants were divided into trainee and expert groups and practiced a suture task in an ex vivo simulation model and in real-world theater on the robotic platform. The videos of suture tasks were evaluated by blinded raters using SC, GEARS and SCORE. The tools were correlated and the performances were compared using STATA®.

Results: The assessments using objective evaluations tools allowed a clear discrimination between experts and trainees ($p<0,005$) and the results were consistent from one measurement to another (Cronbach's Alpha Coefficient = 0.8410). The Pearson's correlation coefficient (r) between GEARS and SCORE was 0.9840, with a CI of 95% between 0.95 and 0.99 ($p< 0.0001$); and r between SC and SCORE was 0.5839, with a CI of 95% between 0.10 and 0.84 ($p= 0.0222$). The Intraclass Correlation Coefficient between the judges in SCORE was 0.91, ($p< 0.0001$) demonstrating the excellent replicability of this test.

Conclusions: The SCORE tool is an objective and structured assessment tool that can cover all steps in the context of a robotic suture and provides feedback to trainees about their performances.

Key words: Robotic surgery, Assessment, Simulation training, Education, Suture techniques.

6.2. INTRODUCTION

Oliver Holmes, an American physician, said “the great thing in the world is not so much where we stand, as in what direction we are moving”. Simulation is the way forward as one of the best methods of surgical education, especially in robotic surgery. Certainly, the assessment of acquired skills is part of this path.(1)

Validated simulation-based assessment tools must be developed in order to evaluate accurately skills acquired by the trainees and their track progression. These include checklists and global rating scales (GRS) and the relative advantages and disadvantages of these two types of tool have long been debated.(2) Global Evaluative Assessment of Robotic Surgery (GEARS) is one of the most used tools to assess robotic skills. This GRS using a five-point Likert scale across six domains: depth perception, bimanual dexterity, efficiency, force sensitivity, autonomy, and robotic control.(3) GEARS asks raters to judge participants’ overall performance while checklists are limited to defining whether or not the task has completed.

Although most robotic surgical procedures require suture there are only one published study on suture evaluation in robotic surgery.(4) Guni et al (2018) developed a technical checklist for the assessment of suturing in robotic surgery and established evidence of the validity of this tool by comparing it with GEARS as standard.(4) Checklists reducing the risks of variations in interpretation between raters. However, evidence suggests that this format may result in a loss of information when compared to GRS.(2) The purpose of this study was to developed a new scoring method, the Suture Checklist of Objective Robotic Evaluation

(SCORE), which was modified from both Guni' suture checklist (SC) and GEARS in evaluation of robotic suture in an ex vivo simulation model and real-world theater.

6.3. MATERIALS AND METHODS

This study received an approval from a certified Ethical Board and involved an ex vivo simulation model built using human placenta for robotic surgery training. The characteristics and preparation of the human placenta were described in our earlier paper.(5) The expectant mothers underwent prenatal infectious evaluation and signed consent for donation of placenta for practice in surgical techniques. Validity evidence was assessed in accordance with Messick's framework of validity which considers five sources of evidence: content, responses, relationship to other variables, internal structure and consequences.(6)

The SCORE tool, described by detailed specifications based on the two validated assessments (GEARS e SC), was developed by a panel of experts in robotic surgery and medical education, reaching the source of evidence of content validity. In the creation of SCORE, the six domains of GEARS were expanded to 10 and the 23 domains/subdomains of SC were reduced also to 10, covering global robotic surgery and exclusive suture technique features. Assessment of each SCORE domain is done by scoring on binary scale (not performed/done incorrectly = 0 or completed correctly = 1). Thus, the maximum total score was 20 as shown in Figure 6.1.

Figure 6.1: Suture Checklist of Objective Robotic Evaluation (SCORE)

ITEMS	GLOBAL	NOT DONE	DONE
1	Efficient time/motion, remains focused on the goal	0	1
2	Continuity/no hesitation, with progression	0	1
3	Proper handling of tissues, without injuries	0	1
4	Stabilization of tissue, without excessive force	0	1
5	Competent use of both hands	0	1
6	No collisions of instruments	0	1
7	No instruments out of view	0	1
8	Camera view centered	0	1
9	Camera view with a good distance from the target	0	1
10	Able to complete the task	0	1
ITEMS	**SUTURE**	**NOT DONE**	**DONE**
11	Needle loaded at 1/2 to 1/3 from need driver tip	0	1
12	Needle inserted at 90° to point of entry	0	1
13	Needle driven through in one movement to the point of entry	0	1
14	Needle pulled out along its curve	0	1
15	Equidistant suture placement	0	1
16	Instruments positioned with correct C or reverse C loop	0	1
17	Thread wrapped around needle driver (once or twice according to technique)	0	1
18	Short tail of thread is pulled completely through loop in one smooth motion	0	1
19	All throws squared	0	1
20	Complete the task without breaking the suture	0	1
TOTAL SCORE			
TIME NEEDED TO COMPLETE		**SECONDS**	

A total of 15 participants were divided into two groups as follows: trainee group (TG), eight attending surgeons with simulation experience but no clinical experience in robotic surgery, and expert group (EG), seven attending surgeons with at least 50 robotic cases performed. To achieve the evidence of responses, all participants received standardized instructions on training and they were informed that all data would be de-identified before evaluation by the study investigators. So, all of them performed a suture on the simulated blood vessel, tied a surgeon’s knot, backed up the knot with a square knot (three throws) and used 4th arm to cut the thread. This task trained camera navigation, precise needle control, suture placement, square knot tying and the switching back and forth between a primary instrument and the 4th arm in a coordinated fashion. Each training was recorded and a blinded rater would then evaluate the performances using SCORE, in addition to GEARS and SC. The performances of the participants with different levels of experience (experts vs. trainees) and the time needed to complete the tasks were compared for evidence of relationship to other variables. The intended consequence of this training was to improve a surgeon's robotic suture skills and this evidence was demonstrated using objectives tools during the certification process in robotic surgery for one trainee. After simulation-based training, one novice operator performed three sequential suture tasks in a real-world surgeries and the procedures were recorded. The videos of suture tasks were evaluated by four independent blinded raters (two of EG and two of TG) using GEARS, SC and SCORE to verify the convergent validity evidence and internal structure. All raters received standardized instructions on the use of the tools. The novice operator also performed a self-assessment of his procedures using the three tools.

Stata version 11.0 was used for all data analysis. All tests were two-sided with 95% CI and $p \leq 0.05$ considered significant. We used Mann-Whitney and chi-square tests to compare continuous and dichotomous measures respectively between the groups. Correlations between the results for performance scores with the different tools were analyzed using Pearson’s correlation coefficient (r). To evaluate the reliability of the performance tests, the intraclass correlation coefficient (ICC) and Cronbach's alpha coefficient were used. To perform the analyses, the values reported as percentages were considered to have a single scale for all variables.

6.4. RESULTS

All participants completed the study and their performances for the suture task in the ex vivo simulation model were measured in each assessment tool. The results of the performance averages and standard deviations were, respectively: 93.85% (5.78) for EG and 44.25% (19.96) for TG with GEARS; 89.83% (6.63) for EG and 42.25% (18.64) for TG with SC; 87.86% (6.36) for EG and 44.38% (18.60) for TG with SCORE; and for the variable time was evidenced 193.57 seconds (60.95) for EG and 585.62 seconds (277.73). In addition to the total scores of the participants' performances in each tool, Table 6.1 shows the partial scores (GLOBAL and SUTURE) of the SCORE tool.

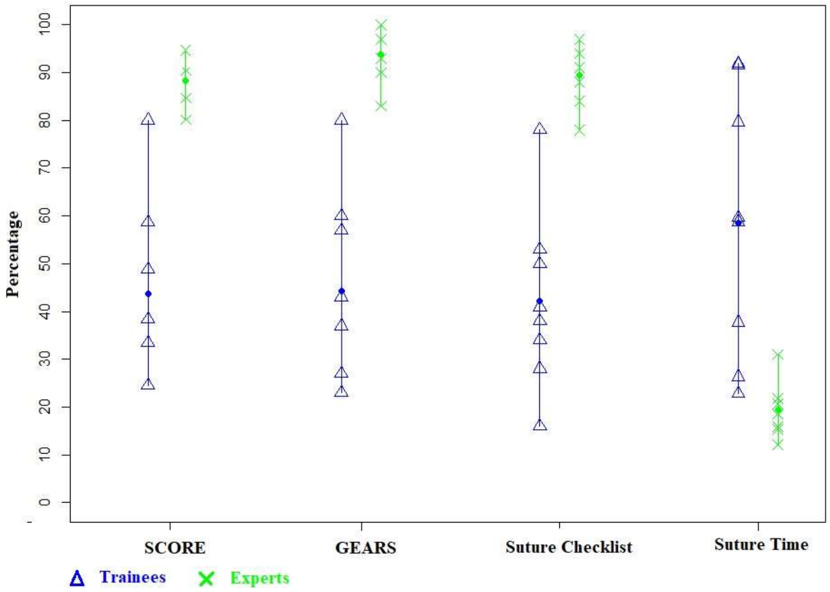
Table 6.1: Participants' performances measured with different skills assessment tools

GROUPS	*TIME (Seconds)*	*GEARS (MaxTS=30)*	*SUTURE CHECKLIST (MaxTS=32)*	*SCORE (MaxTS=20)*		
				GLOBAL (MaxPS=10)	**SUTURE (MaxPS=10)**	**TOTAL**
Expert 1	122	30 (100%)	31 (97%)	9 (90%)	10 (100%)	19 (95%)
Expert 2	218	25 (83%)	27 (84%)	7 (70%)	10 (100%)	17 (85%)
Expert 3	185	29 (97%)	30 (94%)	9 (90%)	9 (90%)	18 (90%)
Expert 4	159	29 (97%)	30 (94%)	8 (80%)	10 (100%)	18 (90%)
Expert 5	310	28 (93%)	28 (88%)	8 (80%)	8 (80%)	16 (80%)
Expert 6	207	29 (97%)	29 (91%)	9 (90%)	10 (100%)	19 (95%)
Expert 7	154	27 (90%)	25 (78%)	9 (90%)	7 (70%)	16 (80%)
Trainee 1	377	13 (43%)	13 (41%)	4 (40%)	4 (40%)	8 (40%)
Trainee 2	264	17 (57%)	17 (53%)	7 (70%)	5 (50%)	12 (60%)
Trainee 3	797	7 (23%)	5 (16%)	2 (20%)	3 (30%)	5 (25%)
Trainee 4	588	8 (27%)	11 (34%)	2 (20%)	5 (50%)	7 (35%)
Trainee 5	919	8 (27%)	9 (28%)	2 (20%)	3 (30%)	5 (25%)
Trainee 6	916	11 (37%)	12 (38%)	5 (50%)	3 (30%)	8 (40%)
Trainee 7	228	24 (80%)	25 (78%)	8 (80%)	8 (80%)	16 (80%)
Trainee 8	596	18 (60%)	16 (50%)	6 (60%)	4 (40%)	10 (50%)

MaxTS: maximum total score; MaxPS: maximum partial score

The differences observed between the groups' performances in simulation training were considerably supported by statistical significance tests (Mann-Whitney test and T test, respectively) according to the following results: p=0.0006 and p=0.0000 with GEARS; p=0.0008 and p=0.0000 with SC; p=0.0009 and p=0.0001 with SCORE. The mean time required to complete the training of robotic suture in wet lab was significantly shorter for experts compared to novices (p=0.006 for Mann-Whitney test and p=0.0024 for T test) (Graph 6.1).

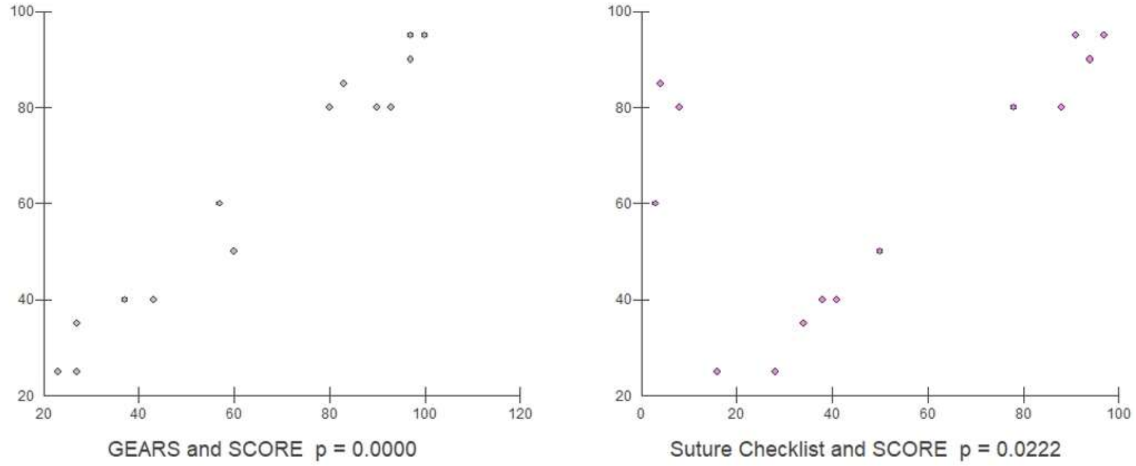
Graph 6.1: Comparisons between variables and groups



Vertical lines extend from the minimum value to the maximum of the respective variable in each group. Solid circles represent their average performances. Each unit of time represents 10 seconds.

In addition to the difference in performance between experience levels, the scores achieved with the evaluation tools showed a high degree of correlation, evidencing a relationship between the variables (Graph 6.2). The Pearson's correlation coefficient (r) between GEARS and SCORE was 0.9840, with a CI of 95% between 0.95 and 0.99 ($p< 0.0001$); and r between Suture Checklist and SCORE was 0.5839, with a CI of 95% between 0.10 and 0.84 ($p= 0.0222$).

Graph 6.2: Pearson’s correlation between the results for performance scores with the different tools



GEARS and SCORE p = 0.0000

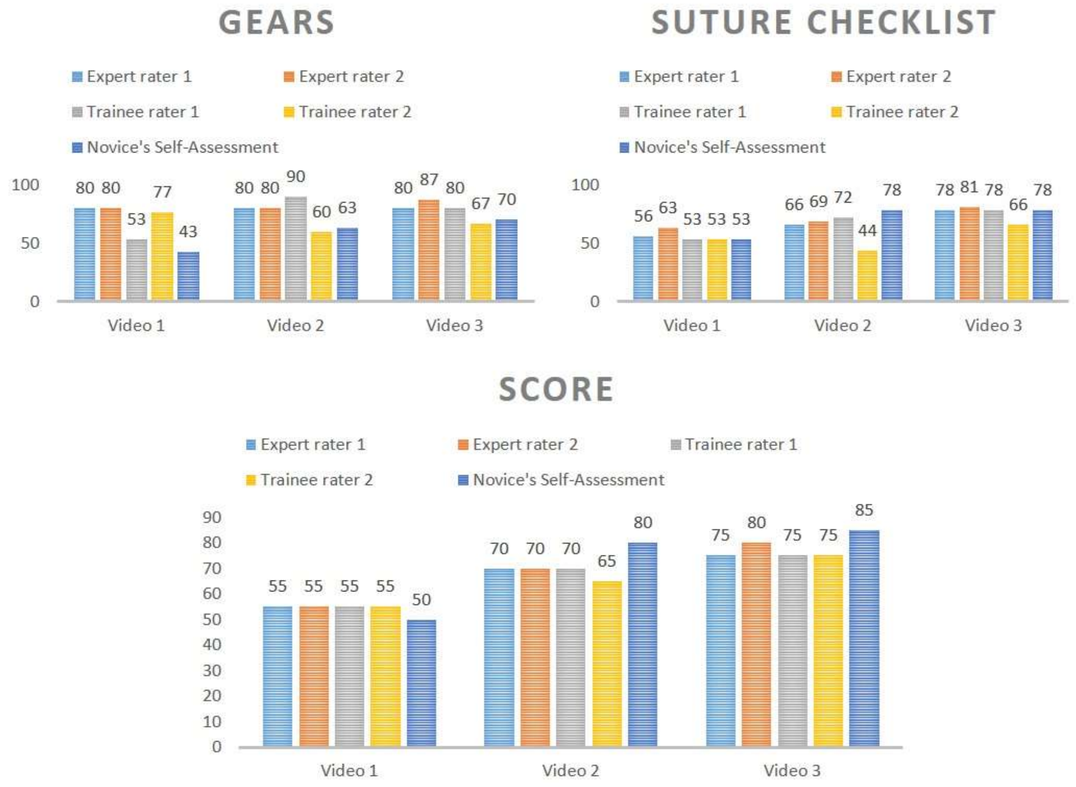
Suture Checklist and SCORE p = 0.0222

Pearson’s correlation between GEARS and SCORE: r = 0.9840, with a CI of 95% between 0.95 and 0.99 ($p < 0.0001$); Pearson’s correlation between Suture Checklist and SCORE: r = 0.5839, with a CI of 95% between 0.10 and 0.84 (p= 0.0222).

The novice operator in the process of certification achieved performance similar to the EG in the suture task, right at the beginning of his learning curve in the real-world theater. The comparison between the performances of novice evaluated by different tools showed that the SCORE measurement instrument was better able to reproduce the results of the judges consistently than GEARS and Suture Checklist (figure 6.2). The ICC between the judges in GEARS and Suture Checklist were 0.00 (p= 0.5350) and 0.50 (p= 0.0155) demonstrating a poor and medium replicability of the tests, respectively. Meanwhile, the ICC between the judges in SCORE was 0.91, ($p < 0.0001$) demonstrating the excellent replicability of this test. The internal consistency between the tools was acceptable, with a Cronbach’s Alpha Coefficient of 0.8410.

Figure 6.2: Suture tasks novice's perfomance scores with the different tools by four independent blinded raters and self-assessment.

	Evaluation Tools	Expert rater 1	Expert rater 2	Trainee rater 1	Trainee rater 2	Novice's Self-Assessment
Novice's performance VIDEO 1	GEARS	80%	80%	53%	77%	43%
	Suture Checklist	56%	63%	53%	53%	53%
	SCORE	55%	55%	55%	55%	50%
Novice's performance VIDEO 2	GEARS	80%	80%	90%	60%	63%
	Suture Checklist	66%	69%	72%	44%	78%
	SCORE	70%	70%	70%	65%	80%
Novice's performance VIDEO 3	GEARS	80%	87%	80%	67%	70%
	Suture Checklist	78%	81%	78%	66%	78%
	SCORE	75%	80%	75%	75%	85%



Comparison between the performances of novice (in percentages) by different judges and evaluation tools.

6.5. DISCUSSION

Evaluation tools such as checklists and GRS have been developed for the assessment of skills in robotic surgery.(3,4) The choice of the evaluation tool depends on the purpose, simulation, context, and practical constraints.(7) This prospective study aimed to construct the SCORE tool, which consisted of a checklist for suture in robotic surgery, which included the global rating items and respected the appropriate psychometric properties. The SCORE items were identical/similar to the checklists/GRS already established and validated(3,4), adapted to be arranged in a clear and practical sequence that facilitates the assessment. Thus, SCORE tool is a broad instrument that can cover all the steps in the context of a robotic suture and provides feedback to trainees about their performances.

All assessments have to meet some requirements such as validity and reliability to fulfill their purposes. The main technical quality criterion of an assessment is validity.(7) Validity can be defined as the degree to which all accumulated evidence corroborates the intended interpretation of the scores of a test for the proposed purposes.(8) According to Standards for Educational and Psychological Testing, there are five major sources of evidence described by Messick that can be used to support a validity argument: evidence based on content, response processes, internal structure, relations to other variables, and consequences of testing.(6,8) The application of the SCORE tool in this study reached all five of these evidences of validity, as described below.

- Evidence based on content: the checklist items of this study based on the two validated assessments were formulated by a panel of experts and the contents of the test is representative in the context of robotic suture. This did not depend on the interpretation of the meaning of the participants' performances.
- Evidence based on response processes: the standardization of the instructions and the blind raters minimized a rater bias. This was important for the validity of interpretation of the meaning of the participants' performances.

- Evidence based on internal structure: the internal consistency of the results showed that the various assessments in this study could be reliably distinguished based on examinee performance.
- Evidence based on relations to other variables: the comparison of examinee performance between groups with different tools and the correlations with other measures thought to be related also provided support for the validity argument.
- Evidence based on consequences of testing: in this study, the training of robotic surgery in a human placenta simulation model and the consistent results of the SCORE tool applied in the real-world theater had consequences for the novice operator, especially since it was used in its certification process.

Reliability concerns the consistency of measurement.(7) The systematic review by Ilgen et al (2015) evidenced that the inter-rater reliability was similar between checklists and global rating scales.(2) In the present study, the Suture Checklist proved to be more reliable than the GEARS. In addition, the SCORE measurement instrument was even more able to reproduce the judges' results consistently than GEARS and Suture Checklist. Ilgen et al (2015) published that the content evidence for GRSs usually referenced previously reported instruments, whereas content evidence for checklists usually described expert consensus.(2) The SCORE tool was constructed using both strategies with consensus of experts based on previously validated instruments. The systematic review by Ilgen et al (2015) also showed that content Checklists and GRS usually had similar evidence for relations to other variables.(2) Despite being tools of different scales, in the present study the correlation between them is also satisfactory. Thus, the SCORE tool presented a high degree of reliability and validity in its application in the suture tasks in both the simulated and real scenarios.

In the assessment process it should be possible to identify the trainee's progress in the acquisition of skills. It is necessary to identify and reinforce the strengths and learning gaps of each trainee to establish corrective strategies and improvements in the teaching-learning process and stimulate self-assessment capacity. Task-specific checklists and GRS are both recommended assessment tools to provide constructive feedback on surgical performance.(9,10) The assessment of skills should be seen as something constructive by trainees, with the aim of maximizing their performance during the robotic training and professional life within a necessary education process permanent. Feedback are key point of the learning process.(9,10) According to Nazari et al (2021), a task-specific feedback is more effective in improving surgical skills in terms of time and path length in novices compared to a global rating scale.(11) In this sense, the use of checklists that direct the feedback are interesting tools. The higher the number of items on the checklist, the greater the complexity and requirement for the rater. In this study, very specific skills were evaluated in the context of robotic suture, so the construction of a tool with fewer items was considered, but that contemplated all the domains of competence to be evaluated. The binary model of the SCORE tool demonstrated greater reliability among raters and can be considered easier to reproduce.

The main methodological limitations of this research are the single-center design and small number of participants. Despite this, the sample size was sufficient to meet the fundamental requirements of an assessment tool, which are: validity and reliability. Nevertheless, external validation studies need to be conducted before large-scale implementation of this evaluation tool in a robotic training curriculum.

6.6. CONCLUSION

This preliminary study suggests that the Suture Checklist of Objective Robotic Evaluation was reliable and established evidence of validity for a robotic suture in an ex vivo simulation model and real-world theater. Thus, this evaluation tool can be incorporated into robotic surgery training curricula.

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7. CAPÍTULO 7: Considerações Finais

Nessa tese, desenvolveu-se um processo de treinamento em cirurgia robótica com ênfase na aquisição de competências. Ao longo dos anos vem acontecendo uma mudança nos paradigmas da educação cirúrgica, com aumento crescente do ensino por simulação para o desenvolvimento de competências técnicas operatórias.(1,2) A segurança do paciente deve sempre ser a prioridade. Nessa direção, o treinamento baseado em simulação permite a prática em diferentes contextos de situações reais, porém em um ambiente que não traz riscos aos pacientes.(3,4) Embora a simulação seja fundamental no processo de aprendizagem, ela certamente não substitui a experiência real. Assim, no ensino da cirurgia não se pode abdicar completamente do clássico método Halstediano, em que a cirurgia supervisionada no paciente real é considerada peça chave.(5,6)

Paralelamente à propagação mundial da simulação como método de ensino médico, a cirurgia robótica cresceu exponencialmente nas últimas décadas e requer competências e treinamentos específicos.(7) Para otimizar a capacitação na cirurgia robótica, desenhos instrucionais de promoção da aprendizagem, com cenários simulados focados na resolução de problemas reais, foram recomendados nesse estudo, dentro de uma estruturação organizacional factível e confiável. Os cinco capítulos compostos de artigos apresentados nessa tese podem ser percebidos como tendo uma conexão hierárquica, em que os resultados finais dependem de bons resultados em cada um dos níveis iniciais.

No primeiro artigo, desenvolveu-se o currículo de treinamento em cirurgia robótica, baseado em competências, após uma revisão sistemática da literatura sobre o assunto. Os achados dessa revisão forneceram elementos que apoiaram a construção do currículo COBRASIL que envolveu múltiplas estratégias de ensino, *feedback*, repetição da prática, variação de dificuldades, complexidade crescente, prática distribuída, interação cognitiva, individualização da aprendizagem, variação de contexto clínico e integração do conhecimento.(8) Além disso, a negligência dos princípios de Merrill (2002) (1-motivação; 2-ativação; 3-demonstração; 4- aplicação; e 5-integração) verificada nos currículos publicados anteriormente justificou o desenvolvimento do currículo dessa pesquisa.(9) No entanto, como descrito no segundo artigo, qualquer currículo de treinamento, antes que possa ser implementado em larga escala, deve demonstrar evidências de validade. O estudo preliminar de validação do currículo COBRASIL demonstrou múltiplas fontes contemporâneas de evidência de validade (conteúdo, respostas, estrutura interna, relação com outras variáveis e consequências), que reforçou ainda mais a relevância do processo de treinamento em cirurgia robótica descrito nessa tese.(10-12)

O treinamento fora da sala operatória na plataforma robótica deve anteceder a cirurgia no paciente real que deve ser supervisionada até a completa capacitação do cirurgião.(13) Para isso, o uso de simuladores virtuais *dry-lab* e *wet-lab* é imprescindível para o desenvolvimento de competências técnicas e não técnicas em cirurgia robótica. Conforme descrito no artigo 3, os simuladores virtuais utilizados dentro do programa validado de treinamento progressivo, baseado em proficiência, permitiram o máximo proveito na capacitação inicial. O modelo ex vivo com placenta humana descrito no artigo 4 substituiu modelos animais, que possuem custos e preocupações éticas limitantes ao seu uso rotineiro, e forneceram a alternativa de simulação mais próxima da cirurgia real dentro desse processo de treinamento em cirurgia robótica. Ressalta-se que a integração dos novos conhecimentos ao mundo real é uma das etapas mais importantes para aprendizagem, e, para isso, a presença do tutor para auxiliar o aprendiz no momento de necessidade é fundamental, assim como a avaliação das competências adquiridas. Dessa forma, o artigo 5 validou o instrumento de avaliação SCORE, uma ferramenta objetiva e estruturada de avaliação de habilidades operatórias de sutura em cirurgia robótica, do tipo *checklist*, que permitiu avaliar essa competência cirúrgica fundamental em vários contextos, diferentemente dos critérios subjetivos e baseados em registros de casos, que medem apenas a experiência operacional, utilizados em outros currículos.(13) Assim, esse processo de treinamento permitiu a aquisição e aperfeiçoamento de novas competências, além do *feedback* das deficiências identificadas durante as cirurgias robóticas, tornando possível a certificação.

Da mesma forma que não se deve basear a certificação de cirurgiões robóticos na quantidade de casos operados, não se deve utilizar um único instrumento de avaliação nesse processo, pois a competência sofre influência direta do contexto. Vale enfatizar que, na literatura, outras ferramentas objetivas e estruturadas estão sendo desenvolvidas para avaliações de competências operatórias nos mais diversos contextos.(14) No contexto urológico, por exemplo, pode-se citar as ferramentas RACE (*Robotic Anastomosis Competency Evaluation*) e PACE (*Prostatectomy Assessment and Competency Evaluation*) para avaliações de competências na prostatovesiculectomia radical robótica; a ferramenta SPaN (*Scoring for Partial Nephrectomy*) para nefrectomia parcial robótica; a PLACE (*Pelvic Lymphadenectomy Appropriateness and Completion Evaluation*) para linfadenectomia pélvica robótica e a CASE (*Cystectomy Assessment and Surgical Evaluation*) para cistectomia radical robótica.(13) Embora o uso dessas ferramentas seja fundamental no processo de certificação robótica para cada procedimento específico, até o momento, nenhum estudo avaliou sua correlação com os desfechos clínicos.

As principais limitações do presente estudo foram os tamanhos reduzidos das amostras de cada artigo e a falta de validação externa desse processo de treinamento em cirurgia robótica. As amostragens utilizadas foram de conveniência, devido aos custos envolvidos no treinamento em cirurgia robótica em nosso meio e o tempo necessário para se certificar um cirurgião. Além disso, em março de 2020, a Organização Mundial de Saúde declarou pandemia de uma nova doença infecciosa, denominada *coronavirus disease 19* (COVID-19), cujo isolamento social foi uma das principais medidas de prevenção.(15) Diante disso, as autoridades mundiais de saúde recomendaram que fossem evitadas as cirurgias eletivas, com o intuito de reduzir a sobrecarga dos sistemas de saúde causada pela COVID-19, ao reduzir a exposição das equipes médicas e dos pacientes a uma potencial contaminação, o que também impactou diretamente no ensino e na capacitação dos cirurgiões robóticos.

De qualquer forma, em relação aos dados quantitativos, os resultados estatísticos sugeriram que as amostras foram representativas. Em geral, quanto maior o tamanho da amostra, maior a relevância estatística dela, ou seja, menor é a chance de os resultados serem apenas coincidência. Apesar dos números reduzidos de participantes nos artigos dessa tese, os modelos de pesquisa permitiram respostas valiosas e funcionaram como um pré-teste, uma vez que se pode considerar o comportamento dos investigados como a estimativa populacional. A estratégia utilizada de se observar um mesmo indivíduo em diferentes momentos (estudo longitudinal) também reduziu a necessidade numérica amostral para a detecção de um fenômeno. Além disso, nessa tese foram desenvolvidas pesquisas qualitativas em que o tamanho amostral não tem relevância na compreensão da complexidade e dos detalhes das informações obtidas.

Assim, diante dos resultados desse estudo, o currículo COBRASIL foi estruturado, treinamentos simulados e instrumento de avaliação foram desenvolvidos, permitindo que os aprendizes se tornem aptos a aplicar o conteúdo aprendido nos seus próprios ambientes de prática profissional após esse processo de treinamento em cirurgia robótica, com ênfase na aquisição de competências. No entanto, as conclusões das pesquisas dessa tese são generalizáveis apenas às populações amostradas, sendo possível que a repetição desse estudo em outros centros possa apresentar resultados diferentes que expresse a realidade da nova população pesquisada. Portanto, estudos de validação externa, utilizando diversas plataformas robóticas, precisam ser realizados para se confirmar a reprodutibilidade e confiabilidade do processo de treinamento em cirurgia robótica desenvolvido nessa tese.

Cada vez mais, os avanços tecnológicos permitem que a cirurgia robótica seja adotada em todo o mundo. Além do robô *da Vinci* da *Intuitive Surgical* (Sunnyvale, CA, EUA), outras plataformas robóticas ficarão disponíveis no mercado em breve, como: *Medtronic system* (Minneapolis, MN, EUA), *VERB surgical system* da *Johnson & Johnson* e *Google* (Mountain View, CA, EUA), *Senhance surgical system* da *Transenterix* (Morrisville, NC, EUA), *Medicaroid* (Chuo-ku, Kobe, Japão) e *Titan Medical SPORT* (Toronto, Canadá).(16) É essencial que os cirurgiões estejam capacitados nos diversos contextos com o objetivo de garantir a segurança dos pacientes e os melhores resultados operatórios.

O processo de capacitação dessa tese visou a garantia da assistência de qualidade para que os cirurgiões possam continuar exercendo sua profissão de forma adequada e segura mesmo diante do avanço da tecnologia. Salienta-se que as estratégias de aprendizagem e estrutura organizacional utilizadas nesse trabalho abrem novos campos de pesquisa que levam a um aprofundamento no conhecimento das competências envolvidas na capacitação dos cirurgiões.

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ANEXO A

Escala de classificação global do *Objective Structured Assessment of Technical Skills* (OSATS)

GLOBAL RATING SCALE OF OPERATIVE PERFORMANCE **Please rate the participant's performance on the following scale:**				
Respect for Tissue:				
1 Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments.	2	3 Careful handling of tissue but occasionally caused inadvertent damage.	4	5 Consistently handled tissue appropriately with minimal damage.
Time and Motion:				
1 Many unnecessary move.	2	3 Efficient time/motion but some unnecessary moves.	4	5 Clear economy of movement and maximum efficiency.
Instrument Handling:				
1 Repeatedly makes tentative or awkward moves with instruments by inappropriate use of instruments.	2	3 Competent use of instruments although occasionally appeared stiff or awkward.	4	5 Fluid moves with instruments and no awkwardness.
Knowledge of Instruments:				
1 Frequently asked for the wrong instrument or used an inappropriate instrument.	2	3 Knew the names of most instruments and used appropriate instrument for the task.	4	5 Obviously familiar with the instruments required and their names.
Flow of Operation and Forward Planning:				
1 Frequently stopped operating and seemed unsure of next move.	2	3 Demonstrated some forward planning with reasonable progression of procedure.	4	5 Obviously planned course of operation with effortless flow from one move to the next.
Use of Assistants:				
1 Consistently placed assistants poorly or failed to use assistants.	2	3 Good use of assistants most of the time.	4	5 Strategically used assistants to the best advantage at all time.
Knowledge of Specific Procedure:				
1 Deficient knowledge. Needed specific instruction at most operative steps.	2	3 Knew all important steps of the operation.	4	5 Demonstrated familiarity with all aspects of the operation.

Fonte: MARTIN, 1997, p.276

ANEXO B

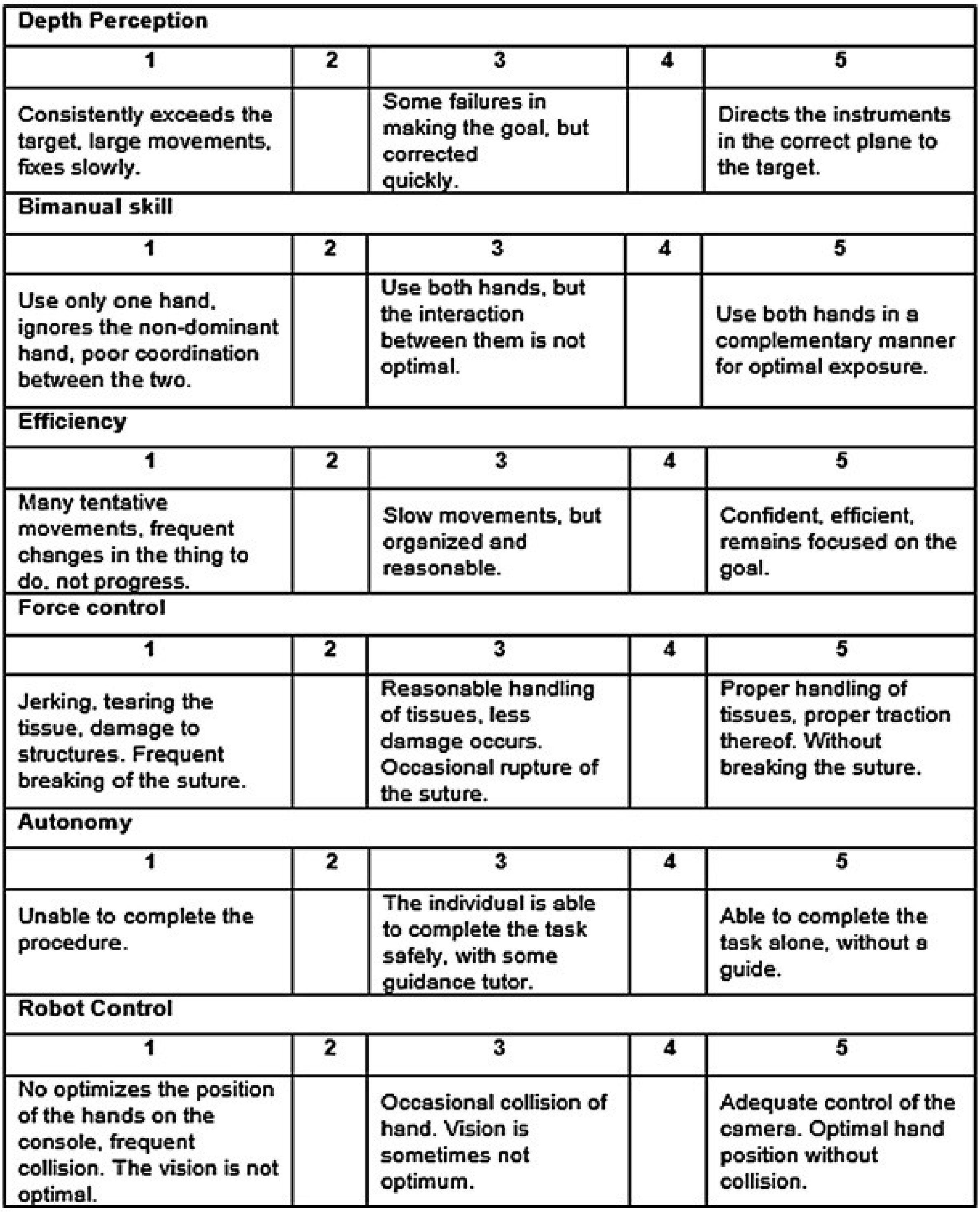
Escala de classificação global do *Objective Structured Assessment of Technical Skills* (OSATS), adaptada transculturalmente ao português-brasileiro

Escala de Classificação Global de Instrumento de Avaliação Objetiva e Estruturada de Habilidades Técnicas Operatórias (*Global Rating Scale of Objective Structured Assessment of Technical Skills*)					
Cuidados com o Tecido (*Respect for tissue*)	1 **Utilizou frequentemente de força desnecessária sobre o tecido ou causou danos ao mesmo pelo uso inapropriado dos instrumentos.** (*Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments.*)	2	3 **Manipulou cuidadosamente o tecido, mas ocasionalmente, causou danos inadvertidos.** (*Careful handling of tissue but occasionally caused inadvertent damage.*)	4	5 **Consistentemente manipulou o tecido de forma apropriada, causando danos mínimos.** (*Consistently handled tissues appropriately with minimal damage.*)
Economia de Tempo e Movimentos (*Time and motion*)	1 **Muitos movimentos desnecessários.** (*Many unnecessary moves.*)	2	3 **Movimentos eficientes, mas alguns desnecessários.** (*Efficient time/motion but some unnecessary moves*)	4	5 **Evidente economia de movimentos e máxima eficiência.** (*Economy of movement and maximum efficiency.*)
Manuseio dos Instrumentos (*Instrument handling*)	1 **Constantemente faz movimentos hesitantes ou desajeitados com os instrumentos.** (*Repeatedly makes tentative or awkward moves with instruments.*)	2	3 **Uso competente dos instrumentos, embora, ocasionalmente, apresenta-se travado ou desajeitado.** (*Competent use of instruments although occasionally appeared stiff or awkward.*)	4	5 **Movimentos ajustados e fluidos com os instrumentos.** (*Fluid moves with instruments and no awkwardness.)*
Conhecimento dos Instrumentos (Knowledge of instruments)	1 **Frequentemente usou ou solicitou instrumentos inapropriados.** *(Frequently asked for the wrong instrument or used an inappropriate instrument.)*	2	3 **Conhecia o nome da maioria dos instrumentos e os utilizou adequadamente para a tarefa.** *(knew the names of most instruments and use appropriate instrument for the task.)*	4	5 **Evidentemente familiarizado com os instrumentos requisitados e com os seus respectivos nomes.** *(Obviously familiar with the instruments required and their names.)*
Fluxo operatório e antecipação no planejamento cirúrgico (Flow of operation and forward planning)	1 **Frequentemente interrompeu o procedimento operatório ou necessitou discutir sobre o próximo passo.** *(Frequently stopped operating or needed to discuss next move.)*	2	3 **Demonstrou capacidade de antecipação no planejamento operatório com progressão contínua do procedimento.** *(Demonstrate ability for forward planning with steady progression of operative procedure.)*	4	5 **Evidentemente planejou o curso da operação, sem esforços para avançar no passo a passo da cirurgia.** *(Obviously planned course of operation with effortless flow from one move to the next.)*
Uso de Auxiliares (Use of assistants)	1 **Consistentemente alocou mal os auxiliares ou falhou ao utilizá-los.** *(Consistently placed assistants poorly or failed to use assistants.)*	2	3 **Bom uso dos auxiliares na maior parte do tempo.** *(Good use of assistants most of the time.)*	4	5 **Utilizou os auxiliares estrategicamente, com o máximo proveito durante todo o tempo.** *(Strategically used assistant to the best advantage at all times.)*
Conhecimento do Procedimento Operatório Específico (Knowledge of specific procedure)	1 **Conhecimento deficiente. Necessitou de instrução específica na maioria dos passos operatórios.** *(Deficient knowledge. Needed specific instruction at most operative steps.)*	2	3 **Conhecia todos os aspectos importantes da operação.** *(Knew all important aspects of the operation.)*	4	5 **Demonstrou familiaridade em todos os aspectos da operação.** *(Demonstrate familiarity with all aspects of the operation.)*

Fonte: CAMPOS, 2020, p.330

ANEXO C

Escala de classificação global do *Global Evaluative Assessment of Robotic Surgery* (GEARS)



Depth Perception

1	2	3	4	5
Consistently exceeds the target. large movements. fixes slowly.		Some failures in making the goal. but corrected quickly.		Directs the instruments in the correct plane to the target.

Bimanual skill

1	2	3	4	5
Use only one hand. ignores the non-dominant hand. poor coordination between the two.		Use both hands. but the interaction between them is not optimal.		Use both hands in a complementary manner for optimal exposure.

Efficiency

1	2	3	4	5
Many tentative movements. frequent changes in the thing to do. not progress.		Slow movements. but organized and reasonable.		Confident. efficient. remains focused on the goal.

Force control

1	2	3	4	5
Jerking. tearing the tissue. damage to structures. Frequent breaking of the suture.		Reasonable handling of tissues. less damage occurs. Occasional rupture of the suture.		Proper handling of tissues. proper traction thereof. Without breaking the suture.

Autonomy

1	2	3	4	5
Unable to complete the procedure.		The individual is able to complete the task safely. with some guidance tutor.		Able to complete the task alone. without a guide.

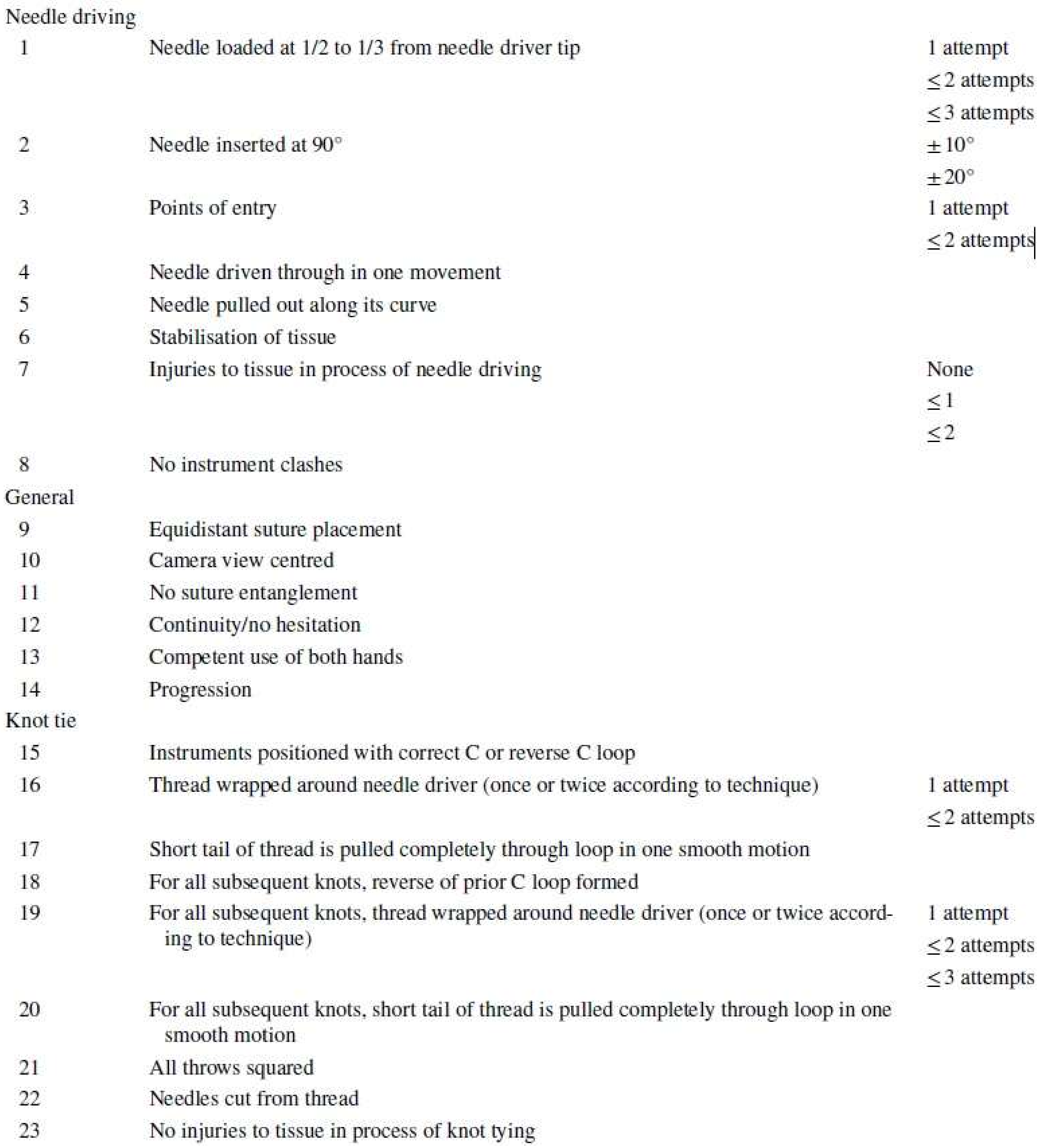
Robot Control

1	2	3	4	5
No optimizes the position of the hands on the console. frequent collision. The vision is not optimal.		Occasional collision of hand. Vision is sometimes not optimum.		Adequate control of the camera. Optimal hand position without collision.

Fonte: SÁNCHEZ, 2016, p.229

ANEXO D

Checklist específico de Sutura desenvolvido por Guni et al (2018)

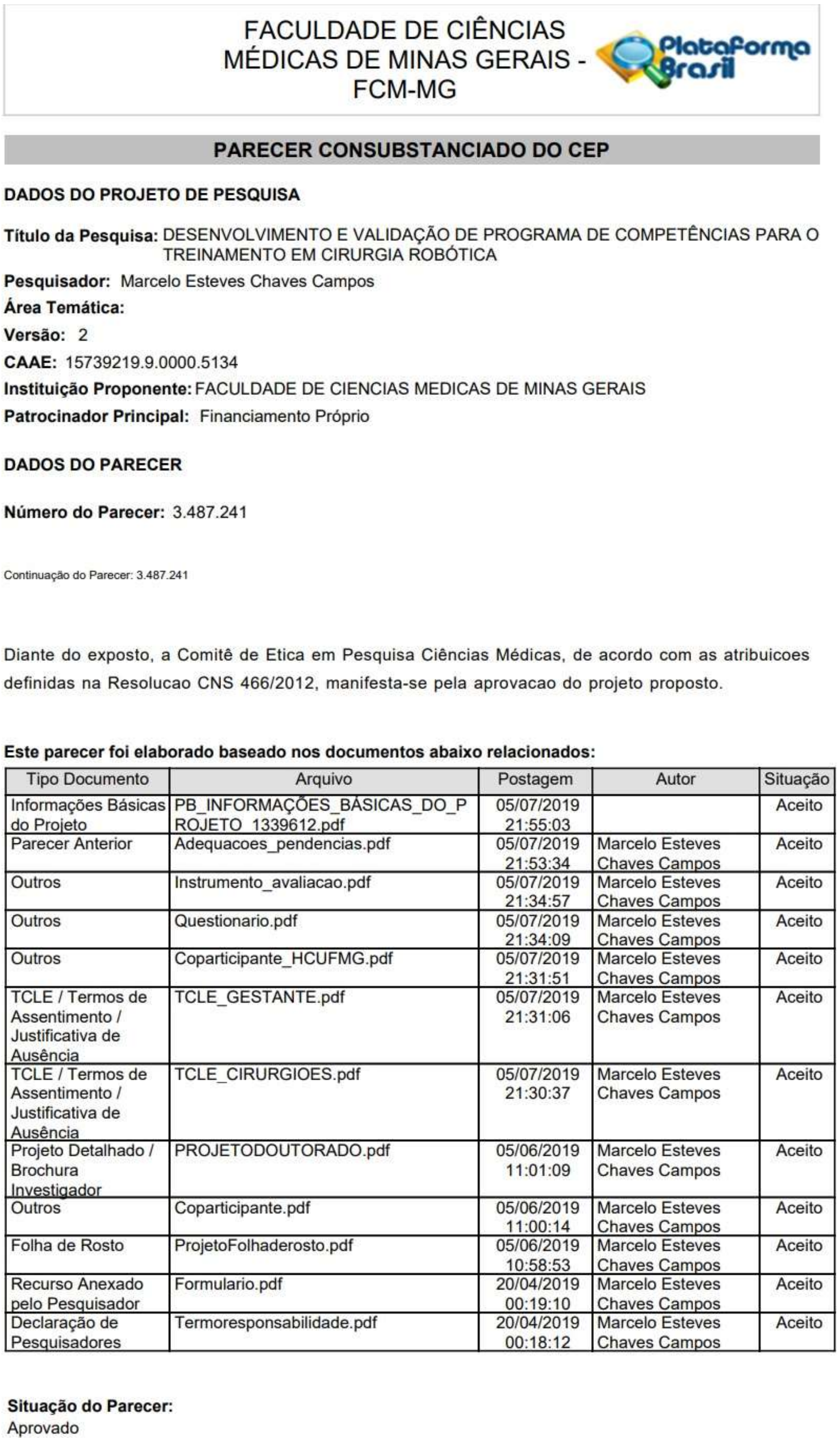


Needle driving		
1	Needle loaded at 1/2 to 1/3 from needle driver tip	1 attempt ≤ 2 attempts ≤ 3 attempts
2	Needle inserted at 90°	± 10° ± 20°
3	Points of entry	1 attempt ≤ 2 attempts
4	Needle driven through in one movement	
5	Needle pulled out along its curve	
6	Stabilisation of tissue	
7	Injuries to tissue in process of needle driving	None ≤ 1 ≤ 2
8	No instrument clashes	
General		
9	Equidistant suture placement	
10	Camera view centred	
11	No suture entanglement	
12	Continuity/no hesitation	
13	Competent use of both hands	
14	Progression	
Knot tie		
15	Instruments positioned with correct C or reverse C loop	
16	Thread wrapped around needle driver (once or twice according to technique)	1 attempt ≤ 2 attempts
17	Short tail of thread is pulled completely through loop in one smooth motion	
18	For all subsequent knots, reverse of prior C loop formed	
19	For all subsequent knots, thread wrapped around needle driver (once or twice according to technique)	1 attempt ≤ 2 attempts ≤ 3 attempts
20	For all subsequent knots, short tail of thread is pulled completely through loop in one smooth motion	
21	All throws squared	
22	Needles cut from thread	
23	No injuries to tissue in process of knot tying	

Fonte: GUNI, 2018, p.4405

APÊNDICE A

APROVAÇÃO NO CEP – NÚMERO DO PARECER 3.487.241



FACULDADE DE CIÊNCIAS
MÉDICAS DE MINAS GERAIS -
FCM-MG

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: DESENVOLVIMENTO E VALIDAÇÃO DE PROGRAMA DE COMPETÊNCIAS PARA O TREINAMENTO EM CIRURGIA ROBÓTICA

Pesquisador: Marcelo Esteves Chaves Campos

Área Temática:

Versão: 2

CAAE: 15739219.9.0000.5134

Instituição Proponente: FACULDADE DE CIENCIAS MEDICAS DE MINAS GERAIS

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.487.241

Continuação do Parecer: 3.487.241

Diante do exposto, a Comitê de Etica em Pesquisa Ciências Médicas, de acordo com as atribuicoes definidas na Resolucao CNS 466/2012, manifesta-se pela aprovacao do projeto proposto.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1339612.pdf	05/07/2019 21:55:03		Aceito
Parecer Anterior	Adequacoes_pendencias.pdf	05/07/2019 21:53:34	Marcelo Esteves Chaves Campos	Aceito
Outros	Instrumento_avaliacao.pdf	05/07/2019 21:34:57	Marcelo Esteves Chaves Campos	Aceito
Outros	Questionario.pdf	05/07/2019 21:34:09	Marcelo Esteves Chaves Campos	Aceito
Outros	Coparticipante_HCUFMG.pdf	05/07/2019 21:31:51	Marcelo Esteves Chaves Campos	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_GESTANTE.pdf	05/07/2019 21:31:06	Marcelo Esteves Chaves Campos	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_CIRURGIOES.pdf	05/07/2019 21:30:37	Marcelo Esteves Chaves Campos	Aceito
Projeto Detalhado / Brochura Investigador	PROJETODOUTORADO.pdf	05/06/2019 11:01:09	Marcelo Esteves Chaves Campos	Aceito
Outros	Coparticipante.pdf	05/06/2019 11:00:14	Marcelo Esteves Chaves Campos	Aceito
Folha de Rosto	ProjetoFolhaderosto.pdf	05/06/2019 10:58:53	Marcelo Esteves Chaves Campos	Aceito
Recurso Anexado pelo Pesquisador	Formulario.pdf	20/04/2019 00:19:10	Marcelo Esteves Chaves Campos	Aceito
Declaração de Pesquisadores	Termoresponsabilidade.pdf	20/04/2019 00:18:12	Marcelo Esteves Chaves Campos	Aceito

Situação do Parecer:
Aprovado

APÊNDICE B

TERMO DE CONSENTIMENTO LIVRE ESCLARECIDO (TCLE) ÀS GESTANTES
DESENVOLVIMENTO E VALIDAÇÃO DE PROGRAMA DE COMPETÊNCIAS PARA O TREINAMENTO EM CIRURGIA ROBÓTICA

Nome dos Responsável: Dr. Marcelo Esteves Chaves Campos

Nós estamos convidando você para participar como voluntário da pesquisa **DESENVOLVIMENTO E VALIDAÇÃO DE PROGRAMA DE COMPETÊNCIAS PARA O TREINAMENTO EM CIRURGIA ROBÓTICA.**

Este documento tem o objetivo de lhe dar informações sobre a pesquisa e de assegurar seus direitos como participante da pesquisa. Por favor, antes de decidir participar da pesquisa, leia este Termo com calma e atenção, use o tempo que precisar. Se você tiver dúvidas pode perguntar a qualquer momento. Se preferir, pode levar este Termo para casa e consultar seus familiares, amigos ou outras pessoas antes de decidir participar da pesquisa.

Primeiro nós queremos que você saiba que sua participação nesta pesquisa é opcional. Você pode decidir não participar da pesquisa ou, caso decida participar, você pode sair dela a qualquer momento, sem penalização ou prejuízo para você. Você pode fazer perguntas a qualquer momento.

Depois que você entender a pesquisa e concordar em participar, nós iremos te pedir para assinar ou colocar a sua impressão digital neste documento. Este documento será elaborado em duas vias, uma será dada para você guardar e outra via será arquivada pelo pesquisador. As duas vias serão assinadas por você e pelo responsável da pesquisa.

JUSTIFICATIVA E OBJETIVOS

Por que estamos fazendo esta pesquisa?

O motivo que nos leva realizar esta pesquisa é porque o treinamento e aprendizado de técnicas cirúrgicas estão evoluindo para o largo uso de simuladores antes de se realizar procedimento operatório em paciente. Justifica-se a existência de laboratórios e centros de treinamento onde os residentes e especialistas possam praticar os diversos procedimentos cirúrgicos. A cirurgia robótica é uma técnica cirúrgica que requer habilidade e treinamento especifico. Diversos modelos de simulação têm sido propostos para o treinamento da cirurgia robótica, incluindo modelos virtuais, inanimados e em animais. Todos têm suas vantagens e desvantagens. Os modelos em cadáveres e em animais vivos são os que mais se aproximam do cenário cirúrgico, mas, devido restrições éticas e financeiras, não são usados de forma sistemática. Modelos biológicos de placentas humanas reproduzem condições anatômicas encontradas durante operações reais, mas nunca foram utilizados na simulação de cirurgias robóticas. O objetivo da pesquisa é desenvolver e validar um programa de competências para o treinamento em cirurgia robótica. Para isso, é necessário validar um simulador virtual de cirurgia robótica e um modelo de treinamento utilizando placentas humanas para simular as condições anatômicas encontradas durante a cirurgia robótica, sem expor os pacientes aos riscos associados.

Por que estamos convidando você para fazer parte desta pesquisa?

Todas as placentas utilizadas na pesquisa serão oriundas de gestantes que tiveram acompanhamento completo no período pré-natal, e não apresentaram nenhuma doença infecto contagiosa investigada segundo normas do Ministério da Saúde do Brasil. A gestante durante o processo de parto está em uma situação de fragilidade, dessa forma esse TCLE deverá ser obtido anteriormente no pré-natal. As placentas humanas doadas para pesquisa, antes de serem descartadas como àquelas não doadas, serão utilizadas como modelo de simulação para o treinamento de cirurgia robótica, sem causar nenhum prejuízo a gestante. O treinamento dos cirurgiões participantes permitirá a validação dos simuladores em relação as validades de face, de conteúdo, de constructo e concorrente. O treino da cirurgia fora da sala operatória é fundamental na educação médica, em especial na cirurgia robótica.

PROCEDIMENTOS

Como será sua participação nesta pesquisa?

As gestantes que concordarem em participar dessa pesquisa doarão as suas placentas para o uso exclusivo no treinamento de técnicas cirúrgicas por médicos cirurgiões, antes de descarte completo das placentas humanas. As placentas serão devolvidas em sua totalidade ao Departamento de Patologia da UFMG cinco dias após a obtenção para o descarte completo do material, sendo proibido o uso total ou parcial desta estrutura biológica para outros fins.

O procedimento de coleta dos dados será realizado através de respostas dos cirurgiões participantes a questionário simples, com perguntas objetivas, após a realização do treinamento proposto no modelo descrito. As cirurgias simuladas serão filmadas para avaliação posterior por peritos em educação cirúrgica.

Os pesquisadores irão tratar a sua identidade com padrões profissionais de sigilo. Os resultados da pesquisa permanecerão confidenciais. Seu nome ou o material que indique a sua participação não será liberado sem a sua permissão. Você não será identificado (a) em nenhuma publicação que possa resultar desse estudo.

DESCONFORTOS, RISCOS E BENEFÍCIOS

Existe algum desconforto ou risco para você por participar desta pesquisa?

Para as gestantes não haverá nenhum risco e prejuízo, uma vez que as placentas doadas e não doadas serão descartadas da mesma forma. Como riscos aos participantes cirurgiões, podemos citar a preocupação com relação à contaminação. Todas as placentas utilizadas em nosso trabalho serão oriundas de gestantes que tiveram acompanhamento completo no período pré-natal e não apresentaram nenhuma doença infecto contagiosa investigada segundo normas do Ministério da Saúde do Brasil. Cada cirurgião deverá usar equipamentos de proteção individuais, que serão fornecidos pelo pesquisador, como: luvas cirúrgicas, óculos de proteção, gorro cirúrgico, máscara facial e capote cirúrgico.

Existe algum benefício para você por participar desta pesquisa?

O uso de simuladores maximiza o desenvolvimento das habilidades operatórias e permite uma reciclagem dos cirurgiões, beneficiando, além dos participantes, os seus pacientes.

ACOMPANHAMENTO E ASSISTÊNCIA

Você será esclarecido (a) sobre a pesquisa em qualquer aspecto que desejar. Você é livre para recusar-se a participar, retirar seu consentimento ou interromper a participação a qualquer momento. A sua participação é voluntária e a recusa em participar não irá acarretar qualquer penalidade ou perda de benefícios.

RESSARCIMENTO E INDENIZAÇÃO

Você receberá pagamento por participar desta pesquisa?

Você não receberá nenhum pagamento, em dinheiro ou em outra forma, por participar desta pesquisa.

Você terá algum custo participando desta pesquisa?

A sua participação nesta pesquisa não acarretará custos a você.

O que acontece se eu tiver algum dano por causa desta pesquisa?

Não há como você sofrer algum dano **decorrente** desta pesquisa, pois as placentas doadas serão descartadas como àquelas não doadas. Mesmo assim, se considerar que teve algum dano, você tem direito à assistência integral e gratuita sem qualquer restrição ou condicionante, assim como o direito de procurar obter indenização.

GARANTIA DE SIGILO E PRIVACIDADE

Seus dados e suas informações serão mantidos em segredo?

Você tem a garantia de que sua identidade será mantida em sigilo e que nenhuma informação será dada a outras pessoas que não façam parte da equipe de pesquisadores. Seu nome ou o material que indique a sua participação não será liberado sem a sua permissão. Na divulgação dos resultados dessa pesquisa, seu nome não será citado.

CONTATO

Quem você poderá contatar se tiver perguntas?

Você pode fazer perguntas ou solicitar novas informações em qualquer momento da pesquisa.

PARA ESCLARECER DÚVIDAS SOBRE A PESQUISA você deve entrar em contato com o pesquisador e sua equipe.

Pesquisador Principal: Marcelo Esteves Chaves Campos (cel: 31 99196-7784)

Outro membro da equipe: Augusto Barbosa Reis (cel: 31 98897-4776)

Endereço: Hospital das Clínicas da UFMG. Avenida Alfredo Balena, 110, nono andar, ala sul.

PARA ESCLARECER DÚVIDAS SOBRE OS SEUS DIREITOS COMO PARTICIPANTE DA PESQUISA você deve entrar em contato com o **Comitê de Ética em Pesquisa das Ciências Médicas (CEPCM-MG).** O Comitê de Ética em Pesquisa (CEP) é um colegiado composto por pessoas voluntárias, com o objetivo de defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos. O CEPCM-MG é diretamente vinculado à Faculdade de Ciências Médicas de Minas Gerais e outros institutos mantidos pela Fundação Educacional Lucas Machado. Você também pode fazer denúncias ou reclamações sobre sua participação e sobre questões éticas do estudo.

Comitê de Ética em Pesquisa das Ciências Médicas (CEPCM-MG):
Endereço: Alameda Ezequiel Dias, nº 275, Bairro Centro. CEP: 30130-110 - Belo Horizonte /MG
Telefone: (31) 3248-7155
Horário de funcionamento: 08:00 às 17:00
E-mail: cep@feluma.org.br

CONSENTIMENTO LIVRE E ESCLARECIDO

Após ter lido, discutido e entendido este Termo de Consentimento; após ter recebido esclarecimentos sobre o motivo da pesquisa, seus objetivos, procedimentos, benefício, potenciais riscos e incômodos que esta possa acarretar a você; após todas as suas dúvidas serem esclarecidas, se aceitar participar da pesquisa, por gentileza, preencha os campos abaixo.

Será fornecido a você uma via original deste documento assinada pelo pesquisador e por você, tendo todas as folhas por nós rubricadas.

Nome Legível do participante: ____
Nome Legível do responsável legal do participante, quando necessário:
____
____
Contato telefônico: ____ E-mail (opcional):
____

____ Data: ____/_____/______.
Assinatura do participante ou responsável legal

RESPONSABILIDADE DO PESQUISADOR

Asseguro ter cumprido as exigências da resolução 466/2012 do CNS/MS e complementares na elaboração do protocolo e na obtenção deste Termo de Consentimento Livre e Esclarecido. Asseguro ter sanado todas as dúvidas do participante da pesquisa. Declaro ter fornecido uma via original deste documento assinada pelo participante e por mim, tendo todas as folhas por nós rubricadas. Informo que o estudo foi aprovado pelo CEPCM-MG. Comprometo-me a utilizar o material e os dados obtidos nesta pesquisa exclusivamente para as finalidades previstas neste documento ou conforme o consentimento dado pelo participante.

____ Data: ____/_____/______.
Assinatura do pesquisador
Marcelo Esteves Chaves Campos

APÊNDICE C

HOSPITAL DAS CLÍNICAS DA UNIVERSIDADE FEREDERAL DE MINAS GERAIS

CENTRO DE TREINAMENTO E EDUCAÇÃO CIRÚRGICA

TERMO DE DOAÇÃO DE PLACENTA HUMANA

Eu, ____, portadora do RG______________________________, após ter sido informada e ter minhas dúvidas suficientemente esclarecidas, concordo em doar de forma voluntária a placenta humana ao Centro de Treinamento e Educação Cirúrgica do Hospital das Clínicas da Universidade Federal de Minas Gerais (CETEC HC-UFMG) para treinamentos de técnicas operatórias em modelos de simulação. Fui informada que o treino da cirurgia fora da sala operatória com modelos de placentas humanas simulam as condições anatômicas encontradas durante as cirurgias, contribuindo à educação médica, sem expor os pacientes aos riscos associados.

Estou ciente que as placentas doadas ao CETEC HC-UFMG serão para o uso exclusivo nos treinamentos de técnicas operatórias por profissionais de áreas cirúrgicas e depois serão devolvidas em sua totalidade ao Departamento de Ginecologia da UFMG para o descarte completo do material, sendo proibido o uso total ou parcial desta estrutura biológica para outros fins. Também estou ciente que minha identidade será tratada com padrões profissionais de sigilo e confidencialidade.

Belo Horizonte, _____________ de ________________________ de 20____.

____

Assinatura **da doadora ou do responsável legal**

APÊNDICE D

TERMO DE CONSENTIMENTO LIVRE ESCLARECIDO (TCLE) AOS CIRURGIÕES DESENVOLVIMENTO E VALIDAÇÃO DE PROGRAMA DE COMPETÊNCIAS PARA O TREINAMENTO EM CIRURGIA ROBÓTICA

Nome dos Responsáveis: Dr. Marcelo Esteves Chaves Campos e Dr. Augusto Barbosa Reis

Nós estamos convidando você para participar como voluntário da pesquisa **DESENVOLVIMENTO E VALIDAÇÃO DE PROGRAMA DE COMPETÊNCIAS PARA O TREINAMENTO EM CIRURGIA ROBÓTICA.**

Este documento tem o objetivo de lhe dar informações sobre a pesquisa e de assegurar seus direitos como participante da pesquisa. Por favor, antes de decidir participar da pesquisa, leia este Termo com calma e atenção, use o tempo que precisar. Se você tiver dúvidas pode perguntar a qualquer momento. Se preferir, pode levar este Termo para casa e consultar seus familiares, amigos ou outras pessoas antes de decidir participar da pesquisa.

Primeiro nós queremos que você saiba que sua participação nesta pesquisa é opcional. Você pode decidir não participar da pesquisa ou, caso decida participar, você pode sair dela a qualquer momento, sem penalização ou prejuízo para você. Você pode fazer perguntas a qualquer momento.

Depois que você entender a pesquisa e concordar em participar, nós iremos te pedir para assinar ou colocar a sua impressão digital neste documento. Este documento será elaborado em duas vias, uma será dada para você guardar e outra via será arquivada pelo pesquisador. As duas vias serão assinadas por você e pelo responsável da pesquisa.

JUSTIFICATIVA E OBJETIVOS

Por que estamos fazendo esta pesquisa?

O motivo que nos leva realizar esta pesquisa é porque o treinamento e aprendizado de técnicas cirúrgicas estão evoluindo para o largo uso de simuladores antes de se realizar procedimento operatório em paciente. Justifica-se a existência de laboratórios e centros de treinamento onde os residentes e especialistas possam praticar os diversos procedimentos cirúrgicos. A cirurgia robótica é uma técnica cirúrgica que requer habilidade e treinamento especifico. Diversos modelos de simulação têm sido propostos para o treinamento da cirurgia robótica, incluindo modelos virtuais, inanimados e em animais. Todos têm suas vantagens e desvantagens. Os modelos em cadáveres e em animais vivos são os que mais se aproximam do cenário cirúrgico, mas, devido restrições éticas e financeiras, não são usados de forma sistemática. Modelos biológicos de placentas humanas reproduzem condições anatômicas encontradas durante operações reais, mas nunca foram utilizados na simulação de cirurgias robóticas. O objetivo da pesquisa é desenvolver e validar um programa de competências para o treinamento em cirurgia robótica. Para isso, é necessário validar um simulador virtual de cirurgia robótica e um modelo de treinamento utilizando placentas humanas para simular as condições anatômicas encontradas durante a cirurgia robótica, sem expor os pacientes aos riscos associados.

Por que estamos convidando você para fazer parte desta pesquisa?

Todas as placentas utilizadas na pesquisa serão oriundas de gestantes que tiveram acompanhamento completo no período pré-natal, e não apresentaram nenhuma doença infecto contagiosa investigada segundo normas do Ministério da Saúde do Brasil. A gestante durante o processo de parto está em uma situação de fragilidade, dessa forma esse TCLE deverá ser obtido anteriormente no pré-natal. As placentas humanas doadas para pesquisa, antes de serem descartadas como àquelas não doadas, serão utilizadas como modelo de simulação para o treinamento de cirurgia robótica, sem causar nenhum prejuízo a gestante. O treinamento dos cirurgiões participantes permitirá a validação dos simuladores em relação as validades de face, de conteúdo, de constructo e concorrente. O treino da cirurgia fora da sala operatória é fundamental na educação médica, em especial na cirurgia robótica.

PROCEDIMENTOS

Como será sua participação nesta pesquisa?

As gestantes que concordarem em participar dessa pesquisa doarão as suas placentas para o uso exclusivo no treinamento de técnicas cirúrgicas por médicos cirurgiões, antes de descarte completo das placentas humanas. As placentas serão devolvidas em sua totalidade ao Departamento de Patologia da UFMG cinco dias após a obtenção para o descarte completo do material, sendo proibido o uso total ou parcial desta estrutura biológica para outros fins.

O procedimento de coleta dos dados será realizado através de respostas dos cirurgiões participantes a questionário simples, com perguntas objetivas, após a realização do treinamento proposto no modelo descrito. As cirurgias simuladas serão filmadas para avaliação posterior por peritos em educação cirúrgica.

Os pesquisadores irão tratar a sua identidade com padrões profissionais de sigilo. Os resultados da pesquisa permanecerão confidenciais. Seu nome ou o material que indique a sua participação não será liberado sem a sua permissão. Você não será identificado (a) em nenhuma publicação que possa resultar desse estudo.

DESCONFORTOS, RISCOS E BENEFÍCIOS

Existe algum desconforto ou risco para você por participar desta pesquisa?

Para as gestantes não haverá nenhum risco e prejuízo, uma vez que as placentas doadas e não doadas serão descartadas da mesma forma. Como riscos aos participantes cirurgiões, podemos citar a preocupação com relação à contaminação. Todas as placentas utilizadas em nosso trabalho serão oriundas de gestantes que tiveram acompanhamento completo no período pré-natal e não apresentaram nenhuma doença infecto contagiosa investigada segundo normas do Ministério da Saúde do Brasil. Cada cirurgião deverá usar equipamentos de proteção individuais, que serão fornecidos pelo pesquisador, como: luvas cirúrgicas, óculos de proteção, gorro cirúrgico, máscara facial e capote cirúrgico.

Existe algum benefício para você por participar desta pesquisa?

O uso de simuladores maximiza o desenvolvimento das habilidades operatórias e permite uma reciclagem dos cirurgiões, beneficiando, além dos participantes, os seus pacientes.

ACOMPANHAMENTO E ASSISTÊNCIA

Você será esclarecido (a) sobre a pesquisa em qualquer aspecto que desejar. Você é livre para recusar-se a participar, retirar seu consentimento ou interromper a participação a qualquer momento. A sua participação é voluntária e a recusa em participar não irá acarretar qualquer penalidade ou perda de benefícios.

RESSARCIMENTO E INDENIZAÇÃO

Você receberá pagamento por participar desta pesquisa?

Você não receberá nenhum pagamento, em dinheiro ou em outra forma, por participar desta pesquisa.

Você terá algum custo participando desta pesquisa?

A sua participação nesta pesquisa não acarretará custos a você.

O que acontece se eu tiver algum dano por causa desta pesquisa?

Se você sofrer algum dano **decorrente** desta pesquisa, você tem direito à assistência integral e gratuita sem qualquer restrição ou condicionante, assim como o direito a indenização.

GARANTIA DE SIGILO E PRIVACIDADE

Seus dados e suas informações serão mantidos em segredo?

Você tem a garantia de que sua identidade será mantida em sigilo e que nenhuma informação será dada a outras pessoas que não façam parte da equipe de pesquisadores. Seu nome ou o material que indique a sua participação não será liberado sem a sua permissão. Na divulgação dos resultados dessa pesquisa, seu nome não será citado.

CONTATO

Quem você poderá contatar se tiver perguntas?

Você pode fazer perguntas ou solicitar novas informações em qualquer momento da pesquisa.

PARA ESCLARECER DÚVIDAS SOBRE A PESQUISA você deve entrar em contato com o pesquisador e sua equipe.

Pesquisador Principal: Marcelo Esteves Chaves Campos (cel: 31 99196-7784)
Outro membro da equipe: Augusto Barbosa Reis (cel: 31 98897-4776)
Endereço: Hospital das Clínicas da UFMG. Avenida Alfredo Balena, 110, nono andar, ala sul.

PARA ESCLARECER DÚVIDAS SOBRE OS SEUS DIREITOS COMO PARTICIPANTE DA PESQUISA você deve entrar em contato com o **Comitê de Ética em Pesquisa das Ciências Médicas (CEPCM-MG).** O Comitê de Ética em Pesquisa (CEP) é um colegiado composto por pessoas voluntárias, com o objetivo de defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos. O CEPCM-MG é diretamente vinculado à Faculdade de Ciências Médicas de Minas Gerais e outros institutos mantidos pela Fundação Educacional Lucas Machado. Você também pode fazer denúncias ou reclamações sobre sua participação e sobre questões éticas do estudo.

Comitê de Ética em Pesquisa das Ciências Médicas (CEPCM-MG):
Endereço: Alameda Ezequiel Dias, nº 275, Bairro Centro. CEP: 30130-110 - Belo Horizonte /MG
Telefone: (31) 3248-7155
Horário de funcionamento: 08:00 às 17:00
E-mail: cep@feluma.org.br

CONSENTIMENTO LIVRE E ESCLARECIDO

Após ter lido, discutido e entendido este Termo de Consentimento; após ter recebido esclarecimentos sobre o motivo da pesquisa, seus objetivos, procedimentos, benefício, potenciais riscos e incômodos que esta possa acarretar a você; após todas as suas dúvidas serem esclarecidas, se aceitar participar da pesquisa, por gentileza, preencha os campos abaixo.

Será fornecido a você uma via original deste documento assinada pelo pesquisador e por você, tendo todas as folhas por nós rubricadas.

Nome Legível do participante: ____
Nome Legível do responsável legal do participante, quando necessário:
____
____
Contato telefônico: ____ E-mail (opcional):
____

____ Data: ____/_____/______.
Assinatura do participante ou responsável legal

RESPONSABILIDADE DO PESQUISADOR

Asseguro ter cumprido as exigências da resolução 466/2012 do CNS/MS e complementares na elaboração do protocolo e na obtenção deste Termo de Consentimento Livre e Esclarecido. Asseguro ter sanado todas as dúvidas do participante da pesquisa. Declaro ter fornecido uma via original deste documento assinada pelo participante e por mim, tendo todas as folhas por nós rubricadas. Informo que o estudo foi aprovado pelo CEPCM-MG. Comprometo-me a utilizar o material e os dados obtidos nesta pesquisa exclusivamente para as finalidades previstas neste documento ou conforme o consentimento dado pelo participante.

____ Data: ____/_____/______.
Assinatura do pesquisador
Marcelo Esteves Chaves Campos