UNIVERSIDADE FEDERAL DE PELOTAS
Programa de Pós-Graduação em Odontologia
Área de Biomateriais e Biologia Oral - Inovação Tecnológica

Tese

Vídeo laringoscópio Anatômico confeccionado por Manufatura Aditiva:
Revisão de Escopo, Prospecção Tecnológica e Validação de um Protótipo

Ana Cristina B. Kraemer Moraes

Pelotas, 2025

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Orientador: Prof. Dr. Rafael Guerra Lund

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Pelotas, 2025

Universidade Federal de Pelotas / Sistema de Bibliotecas
Catalogação da Publicação

M827v Moraes, Ana Cristina Beitia Kraemer

Vídeo laringoscópico anatômico confeccionado por manufatura aditiva [recurso eletrônico] : revisão de escopo, prospecção tecnológica e validação de um protótipo / Ana Cristina Beitia Kraemer Moraes ; Rafael Guerra Lund, orientador ; Chiara das Dores do Nascimento, coorientadora. — Pelotas, 2025.
181 f. : il.

Tese (Doutorado) — Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia, Universidade Federal de Pelotas, 2025.

1. Dispositivo médico. 2. Laringoscópio. 3. Revisão sistemática. 4. Tecnologia biomédica. 5. Usabilidade. I. Lund, Rafael Guerra, orient. II. Nascimento, Chiara das Dores do, coorient. III. Título.

Black D151

Elaborada por Fabiano Domingues Malheiro CRB: 10/1955

NOTAS PRELIMINARES

O presente projeto foi redigido segundo o Manual de Normas para Dissertações, Teses e Trabalhos Científicos da Universidade Federal de Pelotas (2019), adotando o Nível de Descrição em Artigos[1].

Ana Cristina Beitia Kraemer Moraes

[1] Disponível em: https://wp.ufpel.edu.br/sisbi/files/2019/06/Manual.pdf. Acesso em: 24 Jan. 2025.

VÍDEO LARINGOSCÓPIO ANATÔMICO CONFECCIONADO EM MANUFATURA ADITIVA: REVISÃO DE ESCOPO, PROSPECÇÃO TECNOLÓGICA E VALIDAÇÃO DE UM PROTÓTIPO

Tese apresentada ao Programa de Pós-Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal de Pelotas como requisito parcial para obtenção do título de Doutora em Odontologia, na área de concentração em Biomateriais e Biologia Oral, com ênfase em Inovação Tecnológica.

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Dedico esta tese às minhas filhas, Gabriela e Manuela,

por serem minha maior inspiração e motivação,

e ao meu esposo, Mauricio,

pelo apoio incondicional em cada etapa desta jornada.

Vocês são minha base, minha força e minha razão de ser.

AGRADECIMENTOS

A Deus, por guiar meus passos, fortalecer minha jornada e permitir que este momento se concretizasse.

Às minhas filhas, Gabriela e Manuela, e ao meu esposo, Mauricio, por sua paciência, resiliência e apoio incondicional. Vocês foram minha força nos momentos em que precisei priorizar este trabalho, e, sem vocês, esta caminhada não teria sido possível. À minha sogra e ao meu sogro (*in memoriam*), pelo incentivo constante e pelo carinho que sempre me dedicaram.

À minha mãe, que me ensinou o valor da ciência, do conhecimento e do estudo, inspirando-me a nunca parar de aprender. Aos meus irmãos, fonte de inspiração, incentivo e superação, pelo amor incondicional que sempre nos uniu e fortaleceu, meu eterno agradecimento.

Ao meu orientador, Prof. Rafael Guerra Lund, e à minha coorientadora, Chiara das Dores do Nascimento, minha profunda gratidão por sua dedicação incansável a este trabalho, pela orientação cuidadosa e por serem incentivadores essenciais nesta jornada. Minha gratidão também ao Prof. Everton Granemann Souza, cujo apoio foi fundamental para a construção deste estudo.

À minha equipe de trabalho**:** Inês Hirdes, Tássia Felin, Larissa Daneluz, Cíntia Protzen e Marcel Basso**,** por toda a dedicação, auxílio e parceria ao longo desta trajetória de pesquisa. Às alunas que, com empenho e entusiasmo, me acompanharam e compartilharam comigo o aprendizado da pesquisa.

À Universidade Federal de Pelotas e ao Programa de Pós-Graduação em Odontologia, assim como ao seu corpo docente, coordenação e colaboradores, por me proporcionarem acesso a uma formação de excelência, contribuindo de maneira significativa para minha trajetória acadêmica e profissional.

À Universidade Católica de Pelotas, meu reconhecimento e gratidão pela confiança e apoio. Sou imensamente grata por este ser meu local de trabalho, um espaço onde posso aplicar o conhecimento científico para desenvolver projetos de ensino, pesquisa e extensão que impactam e transformam vidas.

A todos que, direta ou indiretamente, fizeram parte deste caminho, meu mais sincero muito obrigada!

"Sempre parece impossível até que seja feito."

Nelson Mandela

PREFÁCIO

Ao longo da história, grandes avanços foram conquistados por aqueles que ousaram desafiar o impossível. Nelson Mandela, um dos maiores símbolos da luta pela justiça e igualdade, enfrentou desafios que pareciam intransponíveis.

Preso por quase três décadas, ele jamais abandonou sua crença em um futuro melhor. Quando finalmente foi libertado, não apenas superou as adversidades, mas liderou uma transformação que mudou o curso da história da África do Sul e do mundo.

Mandela resumiu essa jornada de superação em uma frase emblemática:

"Sempre parece impossível até que seja feito."

No contexto científico e tecnológico, essa mensagem ressoa profundamente. A inovação na medicina é marcada por desafios que, à primeira vista, podem parecer insuperáveis. O desenvolvimento, validação e avaliação de dispositivos médicos exigem rigor, persistência e visão de futuro. Muitos avanços que hoje salvam vidas — como próteses inteligentes, inteligência artificial aplicada à saúde e novos métodos de diagnóstico — foram inicialmente recebidos com ceticismo, mas tornaram-se realidade graças à dedicação de cientistas, engenheiros e profissionais da saúde.

Esta tese se insere nesse mesmo espírito de superação. Ao abordar os desafios e as soluções para a avaliação e validação de dispositivos médicos, reforça a importância da pesquisa e do desenvolvimento na construção de um futuro em que a tecnologia e a ciência caminham juntas para melhorar a vida das pessoas.

Seja na luta por justiça social ou na busca pelo avanço científico, o impossível só existe até que alguém o torne realidade.

RESUMO

MORAES, ANA CRISTINA B. KRAEMER. *Vídeo laringoscópio anatômico em manufatura aditiva: revisão sistemática, prospecção tecnológica e validação de um protótipo.* 2024. 194 folhas. Tese (Doutorado em Odontologia, Área de Concentração em Biomateriais e Biologia Oral com Ênfase em Inovação Tecnológica) – Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia, Universidade Federal de Pelotas, Pelotas, 2024.

No processo de criação de um produto ou equipamento, variáveis de usabilidade e experiência do usuário (UX) devem ser consideradas. A partir da impressão tridimensional (3D) utilizando manufatura aditiva, foi criado um vídeo laringoscópio (VLP) com o objetivo de desenvolver um instrumento para visualização indireta da laringe em uma tela de dispositivo móvel ou tablet, utilizando uma câmera com software próprio. Este estudo teve como objetivo revisar sistematicamente as evidências disponíveis na literatura e realizar uma prospecção tecnológica em bases de dados de patentes sobre a confecção do VLP por meio da tecnologia de manufatura aditiva. Adicionalmente, buscou investigar os métodos de validação de tecnologias em saúde e avaliar a usabilidade de um protótipo desenvolvido por esta doutoranda a partir da experiência do usuário. Para a avaliação da interação e percepção do usuário, foram aplicados os métodos de avaliação de usabilidade conforme as normativas ABNT IEC NBR 62366-1 e ABNT IEC NBR 62366-2, juntamente com o questionário SUS (*System Usability Scale*). O estudo foi dividido em três etapas: (1) revisão sistemática e prospecção tecnológica do dispositivo, (2) revisão sistemática de métodos de usabilidade para equipamentos médicos e (3) avaliação da usabilidade de um vídeo laringoscópio confeccionado por manufatura aditiva. Os dados foram tabulados e submetidos à análise estatística, considerando um poder estatístico de 95% e um nível de significância de 5%. As análises estatísticas (Teste de Shapiro-Wilk, teste de Kruskal-Wallis e regressão logística) foram realizadas no software PSPP Data editor (2024), e a meta-análise pelo RevMan 5.4. O risco de viés foi avaliado por meio do ROBINS-I e do GRADE. O projeto foi aprovado pelo Comitê de Ética em Pesquisa da Universidade Católica de Pelotas (4.780.560/CAAE 47947921.3.0000.5339). A avaliação de tecnologias para equipamentos médicos é fundamental no contexto do acesso e disponibilidade de inovações nos serviços de saúde, sendo considerada uma ferramenta auxiliar nos processos de gestão desses serviços. O estudo demonstrou que o videolaringoscópio impresso em 3D é promissor, mas ainda requer ajustes para otimização clínica. As melhorias sugeridas serão implementadas e testadas em uma nova rodada de avaliação, refinando o design do dispositivo para obter melhor aceitação e eficiência. A consideração desses fatores desde as etapas iniciais do design contribui significativamente para a viabilidade e sucesso do equipamento na prática clínica, destacando a importância de uma abordagem centrada no usuário na criação de novas tecnologias médicas.

Palavras-chave: dispositivo médico; laringoscópio; revisão sistemática; tecnologia biomédica; usabilidade.

ABSTRACT

MORAES, ANA CRISTINA B. KRAEMER. *Anatomical Videolaryngoscope Manufactured by Additive Manufacturing: Systematic Review, Technological Prospecting, and Prototype Validation.* 2024. 194 pages. Thesis (Doctorate in Dentistry, Concentration Area in Biomaterials and Oral Biology with an Emphasis on Technological Innovation) – Graduate Program in Dentistry, Federal University of Pelotas, Pelotas, 2024.

The development of medical devices necessitates a thorough consideration of usability and user experience (UX) factors. Utilizing three-dimensional (3D) printing through additive manufacturing, a Videolaryngoscope (VLP) was designed to facilitate indirect visualization of the larynx on a mobile device or television screen via a camera integrated with proprietary software. This study aims to systematically review the existing body of literature, conduct a technological prospecting analysis in patent databases regarding the development of VLPs using additive manufacturing technology, explore validation methodologies for healthcare technologies, and assess usability aspects related to the prototype. Usability assessment will be conducted in accordance with ABNT IEC NBR 62366-1 and ABNT IEC NBR 62366-2 standards, in conjunction with the System Usability Scale (SUS) questionnaire**.** The study comprises three phases: (1) systematic review and technological prospecting of the device, (2) systematic review of usability assessment methodologies for medical equipment, and (3**)** usability evaluation of a Videolaryngoscope fabricated via additive manufacturing**.** The data will be tabulated and subjected to statistical analysis, considering a statistical power of 95% and a significance level of 5%. The analyses will be conducted using the PSPP Data Editor software (2024), Shapiro-Wilk test, Kruskal-Wallis test, logistic regression, and meta-analysis (RevMan 5.4). The risk of bias will be assessed using ROBINS-I and GRADE. The project will be submitted to the Research Ethics Committee of the Catholic University of Pelotas (4.780.560/CAAE 47947921.3.0000.5339). The study demonstrated that the 3D-print video laryngoscope is promising but still requires adjustments for clinical optimization. Thus, development process proved essential for its effectiveness and acceptance. Considering these factors from the early design stages significantly contributes to the feasibility and success of the device in clinical practice, highlighting the importance of a user-centered approach in the creation of new medical technologies.

Keywords: medical device; laryngoscope systematic review; biomedical technology; usability.

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ABS	**Acrilonitrila Butadieno Estireno**
ASA	***American Society of Anesthesiology***
ATS	**Avaliação das Tecnologias em Saúde**
FDM	**Modelagem por Deposição Fundida**
INPI	**Instituto Nacional de Propriedade Intelectual**
ISO	***International Organization for Standardization***
MA	**Manufatura Aditiva**
MVP	***Minimum Viable Product***
PLA	**Ácido Polilático**
SUS	***System Usability Scale***
UX	**Experiência do Usuário**
VLP	**Vídeo laringoscópio**

Sumário

1. INTRODUÇÃO

A inovação em equipamentos médicos caracteriza-se pela intensa colaboração do usuário final (user innovation) na concepção, desenvolvimento e validação de novos dispositivos. A fabricação de equipamentos com materiais alternativos aos tradicionalmente utilizados no setor industrial tem se consolidado como uma estratégia relevante no campo médico-hospitalar, viabilizando soluções personalizadas, de menor custo e com maior flexibilidade de design. Para que esse processo ocorra de forma eficaz, é essencial a construção de vínculos entre a indústria, a academia e os serviços de saúde, formando um ciclo interativo de inovação que abrange desde a ideação e prototipagem até as fases de validação, distribuição e acompanhamento pós-venda.

Apesar da crescente importância da inovação centrada no usuário, ainda são evidentes as lacunas metodológicas na literatura quanto à avaliação da usabilidade e da experiência do usuário (UX) no contexto de dispositivos médicos (LANDIM et al., 2013). Nesse sentido, a Avaliação de Tecnologias em Saúde (ATS) surge como uma ferramenta fundamental para subsidiar decisões gerenciais e políticas públicas, oferecendo critérios para analisar a efetividade, o custo-benefício e o impacto socioeconômico das tecnologias em desenvolvimento. A adoção da ATS permite incorporar a perspectiva do usuário como elemento-chave na validação de novos dispositivos, especialmente no que se refere à sua aceitabilidade, segurança e aplicabilidade clínica.

Embora análises econômicas frequentemente orientem a decisão sobre a incorporação de tecnologias, é imprescindível que os profissionais de saúde diretamente envolvidos com seu uso participem ativamente dos testes e processos de validação. O engajamento desses profissionais amplia a compreensão das reais necessidades do contexto clínico e contribui significativamente para a qualificação das soluções tecnológicas propostas (ALMEIDA, 2019).

A experiência do usuário (User Experience – UX) está diretamente relacionada à interação do indivíduo com o produto e às percepções cognitivas, emocionais

e comportamentais que emergem dessa interação. De acordo com Tulis e Albert (2008), a UX não se restringe à funcionalidade do dispositivo, mas inclui fatores como segurança, usabilidade e eficiência durante o manuseio. Conforme a ISO 9241-210 (International Organization for Standardization), a experiência do usuário engloba múltiplos aspectos que influenciam sua percepção sobre um produto ou serviço, como a qualidade do design, a facilidade de uso, a imagem institucional e os impactos emocionais gerados pela tecnologia (BORGES; GIEBERTONI, 2018).

Nesse contexto, a usabilidade é um dos pilares para o desenvolvimento de dispositivos médicos eficazes, uma vez que influencia diretamente sua aceitação, aplicação e segurança clínica. A interação entre o usuário e o produto pode ser avaliada por meio de cinco dimensões fundamentais: facilidade de aprendizado, eficiência, memorização, ocorrência de erros e grau de satisfação (DAVIDS et al., 2014). Diferentes métodos têm sido utilizados para avaliar a usabilidade de equipamentos médicos, incluindo a identificação das principais tarefas do dispositivo, a análise do ambiente de uso e o mapeamento de dificuldades operacionais (BORGES; GIEBERTONI, 2018). A recomendação é que essa avaliação ocorra em ambientes controlados, como simulações clínicas, permitindo ajustes no protótipo antes de sua aplicação em pacientes reais (PAGER et al., 2020).

Entre os instrumentos disponíveis para mensurar a usabilidade, destaca-se o System Usability Scale (SUS), criado por John Brooke em 1986. Trata-se de uma ferramenta amplamente reconhecida por sua simplicidade e robustez estatística, capaz de avaliar aspectos como eficácia, eficiência e satisfação, traduzindo a percepção do usuário em um índice quantitativo interpretável (ROMA, 2016; ANDRADE, 2019). Sua utilização no contexto de dispositivos médicos tem contribuído significativamente para identificar deficiências de projeto e orientar melhorias com base na experiência real de uso.

Com o avanço da manufatura aditiva (MA), tecnologias como a modelagem por deposição fundida (Fused Deposition Modeling – FDM) têm possibilitado a criação de dispositivos personalizados e de baixo custo, abrindo novas possibilidades para inovação no setor de saúde (MATOZINHOS et al., 2017). Além da flexibilidade no design e da economia de recursos, destaca-se também

o potencial sustentável da matéria-prima utilizada, como o ácido polilático (PLA) e suas variações com adição de carbono ou propriedades antivirais. Trata-se de um polímero biodegradável, biocompatível e derivado de fontes renováveis, o que o torna ambientalmente mais adequado em comparação a plásticos convencionais (SUBRAMANIAN, 2019). Assim, o uso do PLA no desenvolvimento de dispositivos médicos como o videolaringoscópio 3D (VLP-3D) representa uma alternativa alinhada aos Objetivos de Desenvolvimento Sustentável (ODS), ao mesmo tempo em que mantém propriedades técnicas compatíveis com aplicações clínicas. Um exemplo desse avanço é o desenvolvimento do videolaringoscópio 3D (VLP-3D), dispositivo voltado ao manejo da via aérea, especialmente útil em contextos de treinamento e situações de emergência com recursos limitados (SIN, 2013).

O termo “dispositivo médico” compreende uma ampla gama de produtos destinados à prevenção, diagnóstico, monitoramento e tratamento de condições clínicas. O processo de desenvolvimento de um novo dispositivo inicia-se com a identificação de uma necessidade não atendida ou de uma oportunidade de aprimoramento de tecnologias já existentes. Essa fase de concepção, frequentemente conduzida por meio de brainstormings multidisciplinares, busca aproveitar a experiência e sensibilidade dos profissionais envolvidos para gerar soluções inovadoras (LEÃO, 2024; PETRACCA, 2021).

A concepção do VLP-3D foi guiada pelos princípios do Design Thinking, metodologia estruturada que transforma ideias em soluções práticas por meio de quatro fases principais: preparação, incubação, elucidação e verificação (SANTOS, 2011). Inicialmente, identifica-se o problema com base na empatia e na escuta ativa do usuário; em seguida, desenvolvem-se ideias e protótipos para então submetê-los a testes progressivos, com ciclos contínuos de ajustes até que o produto atinja sua versão final.

As fases de validação do VLP-3D foram conduzidas conforme as diretrizes regulatórias da ANVISA, ISO e FDA, garantindo aderência aos critérios de segurança, eficácia e aplicabilidade. A validação de usabilidade, etapa obrigatória segundo as normas NBR IEC 62366-1 e 62366-2, inclui desde simulações realísticas até ensaios com usuários finais. Neste estudo, o VLP-3D

foi testado em manequins de via aérea em ambiente controlado, aproximando-se das condições reais de uso clínico (LAMBERT et al., 2020).

Durante a pandemia da COVID-19, o videolaringoscópio produzido por manufatura aditiva destacou-se como uma alternativa viável devido à sua rápida prototipagem**,** baixo custo e uso de materiais biocompatíveis, tornando-se um recurso acessível para treinamento e prática clínica. A crescente demanda por esse tipo de equipamento, aliada à expansão das tecnologias da Indústria 4.0, impulsionou pesquisas e avanços no desenvolvimento do videolaringoscópio impresso em 3D, resultando em uma solução inovadora, eficiente e economicamente viável para os serviços de saúde (Paiva; Nogueira, 2021).

Além disso, com o aumento dos casos de insuficiência respiratória, o videolaringoscópio consolidou-se como padrão-ouro no manejo da via aérea durante a pandemia. No entanto, a alta demanda e os custos elevados dos modelos comerciais restringiram seu acesso, tornando essencial o desenvolvimento de alternativas mais acessíveis. Nesse cenário, a fabricação de um modelo de baixo custo por manufatura aditiva surgiu como uma solução estratégica, permitindo maior democratização da tecnologia e suprindo as necessidades do mercado**.**

1.1 JUSTIFICATIVA

A fabricação do videolaringoscópio (VLP) por manufatura aditiva e sua inserção no mercado da saúde são inovações recentes, impulsionadas pelo advento da pandemia de COVID-19. A necessidade de disponibilizar dispositivos com essas características está diretamente relacionada a benefícios como baixo custo, facilidade de fabricação, acessibilidade para profissionais de saúde e adequação das propriedades físicas e mecânicas do dispositivo. Tais aspectos contribuem não apenas para a segurança do paciente, mas também para a otimização da gestão dos serviços de saúde, especialmente em economias subdesenvolvidas (RODRIGUES, 2020).

Diante desse cenário, a realização de um mapeamento tecnológico sobre o videolaringoscópio produzido por manufatura aditiva e a identificação das evidências científicas disponíveis justificam a primeira etapa do projeto. Além

disso, a validação da usabilidade e da experiência do usuário configura-se como um elemento crítico no processo de desenvolvimento de dispositivos médicos.

A usabilidade do VLP-3D deve ser avaliada com base na interação de profissionais de saúde com o protótipo, garantindo que o equipamento atenda aos requisitos de eficácia, eficiência, segurança e satisfação no contexto real de uso. Dessa forma, compreender a viabilidade da aplicação dessa tecnologia na prática clínica por meio da avaliação do usuário na etapa final de desenvolvimento contribui para aprimoramentos técnicos, maior aceitação do produto e, consequentemente, para ampliar seu potencial de adoção nos serviços de saúde.

A importância deste estudo reside na possibilidade de disponibilizar um dispositivo inovador e acessível, cujo impacto pode refletir-se tanto na melhoria da qualidade dos procedimentos de intubação orotraqueal quanto na redução de custos para instituições de saúde. O avanço da manufatura aditiva na produção de dispositivos médico-hospitalares representa uma oportunidade para a introdução de tecnologias mais versáteis e adaptáveis, favorecendo a inovação contínua e a democratização do acesso a equipamentos médicos de ponta.

1.2 OBJETIVOS

1.2.1 Objetivo Geral

Este estudo teve como objetivo realizar uma revisão integrada da literatura científica e de registros de patentes para mapear as evidências técnicas e aplicações relacionadas ao desenvolvimento de videolaringoscópios (VLP) fabricados por meio de impressão 3D. Além disso, buscou-se conduzir uma revisão sistemática dos métodos de avaliação de usabilidade, com o intuito de analisar a experiência do usuário na utilização de um protótipo de VLP desenvolvido pela doutoranda em manequins de simulação realística, com a participação de profissionais de saúde, visando validar sua usabilidade e aplicabilidade clínica (Macedo, 2014).

1.2.2 Objetivos Específicos

- Realizar uma prospecção tecnológica em bases de dados de patentes e literatura científica, identificando tendências e inovações no desenvolvimento de videolaringoscópios fabricados por manufatura aditiva.
- Identificar e analisar as metodologias mais adequadas para a avaliação da experiência do usuário e da usabilidade em dispositivos médico-hospitalares, com ênfase nos equipamentos endoscópicos, considerando as diretrizes normativas aplicáveis.
- Avaliar a percepção do usuário em relação ao uso do videolaringoscópio (VLP) produzido por manufatura aditiva, a partir de testes em manequins de simulação realística, considerando aspectos ergonômicos, técnicos e de segurança.
- Examinar a usabilidade do VLP no contexto de procedimentos de intubação orotraqueal, comparando seu desempenho com dispositivos comerciais de referência, com base em indicadores de eficiência, eficácia e experiência do usuário.
- Investigar a viabilidade da aplicação clínica do VLP-3D desenvolvido, considerando aspectos regulatórios, de fabricação e de aceitação por profissionais de saúde, para avaliar seu potencial de incorporação ao mercado de dispositivos médicos.
- Realizar uma análise estatística dos dados coletados, verificando a confiabilidade dos resultados obtidos na avaliação da usabilidade e percepção do usuário, utilizando testes estatísticos adequados à natureza dos dados.
- Verificar a conformidade do VLP-3D com normas e recomendações técnicas internacionais, incluindo requisitos de segurança, desempenho e ergonomia definidos por órgãos reguladores da área da saúde.

1.3 HIPÓTESES

1.3.1 Hipótese Nula (H_0): Não há diferença estatisticamente significativa entre os grupos VLP-C (dispositivo comercial) e VLP-3D (protótipo produzido por manufatura aditiva) para as variáveis analisadas;

1.3.2 Hipótese Alternativa (H_1): Existe uma diferença estatisticamente significativa entre as médias dos grupos VLP-C e VLP-3D para as variáveis analisadas.

2. PROJETO DE PESQUISA

2.1 METODOLOGIA

O presente estudo será estruturado em três fases principais, com o objetivo de analisar o estado da arte e as evidências disponíveis sobre manufatura aditiva aplicada a videolaringoscópios (VLPs), métodos de avaliação de usabilidade e experiência do usuário.

Na primeira fase (Fase I), será realizada uma revisão de escopo da literatura, visando mapear o conhecimento científico e tecnológico relacionado ao desenvolvimento de videolaringoscópios por manufatura aditiva. A segunda fase (FASE II) consistirá em uma revisão sistemática para identificar e descrever os principais métodos de avaliação de usabilidade aplicáveis a dispositivos médicos. Por fim, na terceira fase (FASE III), será conduzido um estudo experimental, comparando a usabilidade e a experiência do usuário na utilização de um videolaringoscópio produzido por manufatura aditiva, comparando-o a um dispositivo comercial de referência.

A análise estatística será realizada na terceira fase, com o objetivo de comparar os resultados de usabilidade, adotando um nível de confiança de 95% e um nível de significância de 5% ($p < 0,05$). Os dados serão tabulados e submetidos à análise estatística, considerando um poder estatístico de 95%. As análises serão conduzidas no software PSPP Data Editor (2024), utilizando os seguintes testes estatísticos: Shapiro-Wilk, Kruskal-Wallis, regressão logística, e a meta-análise no RevMan 5.4. Além disso, o risco de viés deverá ser avaliado por meio das ferramentas ROBINS-I e GRADE, garantindo a robustez metodológica e a confiabilidade dos achados.

O projeto foi aprovado pelo Comitê de Ética em Pesquisa da Universidade Católica de Pelotas (4.780.560/CAAE 47947921.3.0000.5339).

2.1.2 Revisão de Escopo (Fase 1)

A revisão de escopo utilizada como referencial teórico neste estudo será conduzida por meio de um processo sistemático de busca e seleção de estudos, seguindo as diretrizes do *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* – PRISMA 2020 (BMJ, 2021). O checklist do PRISMA será adaptado para atender às especificidades da pesquisa, assegurando transparência, reprodutibilidade e rigor metodológico na seleção das evidências.

2.1.3 Descritores e Bases De Dados

A identificação da literatura relevante utilizará descritores controlados e não controlados extraídos das bases: MeSH (*Medical Subject Headings*), Emtree terms (*Embase Subject Headings*) e DeCS (*Descritores em Ciências da Saúde*). A combinação dos termos ocorrerá por meio dos operadores booleanos “AND” e “OR”, com o objetivo de otimizar a busca e ampliar a sensibilidade dos resultados.

As bases de dados consultadas para a obtenção de estudos científicos indexados serão: PubMed, *Web of Science*, Scopus, *Cochrane Library*, SciELO, Embase, LILACS e Bibliotecas Virtuais em Saúde (BVS)**.** Além disso, serão incluídos estudos encontrados por meio de buscas no Google Scholar, considerando a relevância de trabalhos não indexados em bases tradicionais.

2.1.4 Critérios de Elegibilidade

Os critérios de elegibilidade estabelecidos permitirão selecionar estudos relevantes sobre a fabricação de videolaringoscópios por manufatura aditiva. A inclusão de estudos que abordem o desenvolvimento e a fabricação do videolaringoscópio por manufatura aditiva, seja para o dispositivo completo ou para componentes estruturais do equipamento, será considerada. Ainda, trabalhos que investiguem a associação do videolaringoscópio fabricado por manufatura aditiva a microcâmeras ou boroscópios, visando à visualização indireta da laringe. Também serão incluídos estudos comparativos entre videolaringoscópios comerciais e aqueles produzidos por manufatura aditiva,

especialmente aqueles voltados para a avaliação de usabilidade e desempenho técnico. Ensaios clínicos conduzidos em manequins de simulação realística, com o propósito de comparar eficácia, ergonomia e aplicabilidade clínica, também farão parte do escopo da pesquisa.

Os estudos excluídos serão os que descrevem exclusivamente a fabricação de acessórios para videolaringoscópios comerciais ou laringoscópios convencionais, bem como aqueles voltados para o desenvolvimento de videolaringoscópios de uso veterinário ou que utilizem modelos animais. Estudos que não apresentem dados experimentais ou validação técnica, como artigos de opinião, comentários editoriais e resumos de conferências sem análise metodológica detalhada, também serão descartados.

2.1.5 Estratégia de Extração

A extração dos estudos selecionados deverá seguir uma abordagem sistemática e rigorosa. A primeira etapa consiste na triagem inicial dos estudos, com base na análise dos títulos dos artigos, permitindo a exclusão daqueles que não atendam aos critérios de elegibilidade. Os artigos considerados relevantes serão importados e organizados no Mendeley Reference Manager, assegurando a padronização das referências bibliográficas. Após essa etapa, os estudos duplicados identificados deverão ser removidos, evitando redundâncias na análise. Em seguida, será realizada uma segunda triagem, baseada na leitura dos resumos e palavras-chave dos artigos, permitindo o refinamento da seleção dos estudos mais pertinentes à pesquisa.

Posteriormente, os artigos que permanecerem na análise passarão por leitura integral, e aqueles que não preencham integralmente os critérios de elegibilidade serão excluídos. Para assegurar uma análise completa dos textos, os artigos publicados em inglês e espanhol traduzidos para o português quando necessário.

O rigor metodológico empregado no processo de busca, seleção e extração de dados garante que este estudo seja fundamentado em evidências científicas consistentes e atualizadas, contribuindo para a avaliação crítica do uso da manufatura aditiva na fabricação de videolaringoscópios e suas implicações na prática clínica. A adoção de estratégias sistemáticas para a

revisão de literatura permite uma compreensão aprofundada do estado da arte na área, fornecendo subsídios relevantes para a discussão dos resultados e futuras aplicações da tecnologia na área da saúde.

2.1.6 Prospecção Tecnológica

A prospecção tecnológica deverá ser conduzida em bases de dados eletrônicas de patentes, incluindo: EPO/Espacenet, Derwent Innovations Index, USPTO, PATENTSCOPE, INPI, CAPES e Google Patents**,** permitindo a identificação de inovações e registros recentes na área de videolaringoscopia por manufatura aditiva. Nenhum filtro de idioma, período de publicação ou tipo de estudo foi aplicado, garantindo uma análise abrangente e detalhada da produção científica e tecnológica sobre o tema. A extração dos estudos selecionados deverá seguir uma abordagem sistemática e rigorosa.

2.2 Revisão sistemática (Fase II)

2.2.1 Descritores e Bases De Dados

Uma revisão da literatura baseada no processo de busca e seleção dos estudos seguirá as recomendações e o checklist adaptado do PRISMA 2020 (PAIGE; FAIRBANKS; GABA, 2018). Para a estratégia de elaboração da pergunta utilizaremos o acrônimo PICO, sendo a pergunta principal: Quais são os métodos de avaliação da experiência do usuário e usabilidade para dispositivos médicos? Para o levantamento da pesquisa serão identificados descritores do MeSH, Emtreeterms e DeCS, utilizando operadores Booleanos "OR" e "AND". As bases de dados utilizadas serão as do PubMed, Cochrane, Web of Science, Scielo, Embase, Lilacs e Bibliotecas Virtuais em Saúde (BVS) e Google Scholar. A extração dos estudos selecionados deverá seguir uma abordagem sistemática e rigorosa.

2.2.2 Critérios de Elegibilidade

A população-alvo incluirá profissionais de saúde, com ou sem envolvimento de pacientes, enquanto a intervenção se concentrará em metodologias de avaliação da usabilidade. Ensaios clínicos serão o principal desenho de estudo de interesse. Além das buscas em bases de dados, dados suplementares serão obtidos nos sites oficiais de órgãos reguladores internacionais responsáveis por normas e diretrizes para dispositivos médicos.

Serão considerados elegíveis os estudos que investigaram dispositivos, equipamentos ou implantes classificados como dispositivos médicos segundo normas regulatórias internacionais, especificamente para uso em ambientes hospitalares ou serviços de saúde.

2.2.3 Estratégia de Extração

Um rigoroso processo de triagem em três fases será implementado para garantir a **relevância e qualidade** dos estudos incluídos nesta revisão. Três revisores independentes participarão das diferentes etapas da seleção, aumentando a confiabilidade e reduzindo possíveis vieses.

Na fase inicial, dois revisores examinarão independentemente os títulos, e os estudos elegíveis serão organizados no Mendeley Reference Manager. Registros duplicados serão sistematicamente removidos utilizando a ferramenta Rayyan Systematic Review. Na segunda fase, os mesmos revisores analisarão criticamente os resumos, excluindo estudos que não atendam aos critérios de inclusão. A última fase consistirá em uma revisão completa do texto para confirmar a elegibilidade dos estudos para a análise final.

2.2.4 Análise do Risco de Viés

A análise do risco de viés será realizada utilizando o framework GRADE, com o estudo registrado na plataforma GRADEpro via Cochrane (*GRADEpro GDT: Guideline Development Tool [Software], McMaster University and Evidence Prime, 2024*).

2.3 Estudo pré-clínico (Fase III)

Este estudo combinará uma abordagem comparativa (caso-controle) com uma fase de validação pré-clínica em manequins de simulação, avaliando a eficácia do videolaringoscópio desenvolvido em relação a um dispositivo padrão-ouro. Além disso, permitirá a validação de suas funcionalidades inovadoras em ambientes simulados e reais.

A avaliação da usabilidade incluirá métricas objetivas, como tempo de visualização da laringe, tempo de inserção do tubo e taxa de sucesso da intubação, fornecendo dados quantitativos de desempenho. A Escala de Usabilidade do Sistema (SUS), na versão validada para o português, será utilizada para comparar o videolaringoscópio comercial (VLP-C) e o protótipo impresso em 3D (VLP-3D), com pontuações calculadas via *SUS Calculator*. Serão empregadas escalas Likert (1 a 5) para avaliar tarefas críticas e experiência do usuário, com estatísticas descritivas (desvio padrão e mediana) para comparar os dispositivos (MARGOLIS; PROVIDÊNCIA, 2021).

A análise estatística utilizará dados binomiais, estabelecendo significância em $p < 0,005$. O processamento dos dados será realizado no software PSPP 2.0.0 (GNU Project, 2024), garantindo rigor metodológico e reprodutibilidade. A consistência interna será avaliada pelo alfa de Cronbach, e a correlação de Spearman será aplicada para examinar a relação entre pontuações do SUS, satisfação do usuário e percepção da usabilidade.

Para avaliação da normalidade dos dados, será aplicado o teste de Shapiro-Wilk, enquanto comparações entre grupos não paramétricos utilizarão o teste de Kruskal-Wallis. Uma análise de regressão logística investigará fatores preditivos de sucesso ou falha na intubação, considerando tempo de visualização, clareza da imagem e montagem do dispositivo.

Uma meta-análise será conduzida com o software Review Manager (RevMan) 5.4 (The Cochrane Collaboration, 2020), comparando os achados deste estudo com pesquisas anteriores. Serão analisados tempos de visualização laríngea e intubação (COHEN T; NISHIOKA H, 2017; LAMBERT C; JOHN A, 2020; DE VILLIERS C et al., 2021). A abordagem de Variância Inversa, sob modelo de

Efeitos Aleatórios, utilizará a Diferença Média (MD) como medida de efeito, com intervalo de confiança (IC) de 95%.

A qualidade das evidências será avaliada pela abordagem GRADE (Guyatt et al., 2008), e o risco de viés em estudos não randomizados será analisado pela ferramenta ROBINS-I (Sterne et al., 2016). A presença de viés de publicação será investigada por *Funnel plots* e pelo teste de Egger.

Este protocolo foi registrado no PROSPERO (CRD42024XXXXXX, aguardando protocolo) para garantir transparência metodológica e sistematização dos resultados, seguindo o framework GRADE para reforçar a confiabilidade dos achados.

2.4 CRONOGRAMA

Tabela 4: Cronograma

	2022		**2023**		**2024**		**2025**	
Atividades/ semestre	**1º sem**	**2º sem**	**1º sem**	**2º sem**	**1º sem**	**2º sem**	**1º sem**	**2º sem**
Reunião da equipe de pesquisa, treinamento no uso do dispositivo e rastreamento dos profissionais envolvidos na validação. Revisão Sistemática (FASE II)	X	X	X		X	X		
Treinamento no uso do dispositivo e seleção dos profissionais envolvidos na validação. Revisão Sistemática (FASE II)	X	X	X	X	X	X		
Confecção dos dispositivos em PLA e carbono para as validações. Envio de carta-convite aos profissionais	X	X	X	X	X	X		
Confecção dos dispositivos em PLA e carbono para as validações.	X	X	X	X	X	X		
Contato com os profissionais participantes.	X	X	X	X	X	X		
Validação em manequins de simulação e preenchimento dos questionários		X	X	X	X	X		
Análise estatística dos dados		X	X			X	X	
Descrição dos Resultados			X		X	X	X	
Redação do artigo					X	X	X	

Envio para publicação							X	
Defesa da tese de doutorado							X	

2.5 ORÇAMENTO

Tabela 5: Orçamento do projeto

Item	**Qtd**	**Valor unitário (R$)**	**Valor final (R$)**
Filamentos PLA carbono (Slim3D) Kg	4Kg	R$100,00	R$400,00
Videolaringoscópio padrão ouro: (1) HYHJ – 1330	1	R$12.000,00	R$12.000,00
Impressora 3D para filamento	1	R$ 11.000,00	R$ 11.000,00
Recursos para transporte	3	R$ 200,00	R$ 600,00
Tablet Android	2	R$400,00	R$800,00
Microcâmera 7mm wifi	2	R$ 150,00	R$ 300,00
TOTAL			**R$25.100,00**

3. RELATÓRIO DO TRABALHO DE CAMPO (ENSAIO PRÉ-CLÍNICO)

3.1 INTRODUÇÃO

O presente relatório descreve o trabalho de campo realizado para avaliar a usabilidade de um videolaringoscópio impresso em 3D (PLA + Carbono) em comparação com um modelo comercial padrão. O estudo foi conduzido em ambientes clínicos simulados e reais, envolvendo profissionais da saúde de diferentes especialidades.

Este relatório apresenta a metodologia utilizada, os achados da pesquisa, os ajustes propostos e uma reflexão crítica sobre os desafios enfrentados durante a coleta de dados.

3.2 METODOLOGIA

3.2.1 Tempo do estudo

O estudo ocorreu entre março de 2022 e dezembro de 2024, no laboratório de simulação e no hospital universitário (UCPEL e UFPEL/EBSERH). O estudo contou com 3 fases: a primeira fase de avaliação de tarefas e heurísticas, a segunda fase de avaliação formativa, a terceira fase de avaliação pré-clínica (sumativa).

3.2.2 Coleta de Dados Demográficos

Os dados demográficos e a experiência com o uso de videolaringoscópios foram coletados para analisar possíveis correlações entre as características dos participantes e o uso do dispositivo. Um protocolo para técnicas de acesso às vias aéreas foi utilizado para identificar as tarefas associadas ao uso do dispositivo, bem como as tarefas críticas para a operação do videolaringoscópio. As tarefas críticas foram inicialmente determinadas por meio de uma revisão sistemática da literatura e consulta a especialistas em um laboratório de simulação médica. As avaliações iniciais de usabilidade incluíram análise

heurística e avaliação de tarefas, seguidas por estudos estruturados de usabilidade para refinamento do desempenho.

3.2.3 Seleção Amostral

Baseada em Regulamentação para Testes de Usabilidade. O processo de seleção amostral seguiu diretrizes regulatórias nacionais e internacionais para testes de usabilidade de dispositivos médicos. A análise formativa incluiu 11 médicos, alinhando-se às recomendações da ANVISA, FDA e ISO 62366-2, que exigem um mínimo de 10 usuários para avaliações formativas. Para a análise sumativa, a FDA recomendou um mínimo de 15 participantes por grupo ou pelo menos 25 usuários para detectar 90%–97% dos problemas de usabilidade. Seguindo essas diretrizes e revisões anteriores, a análise sumativa incluiu 60 participantes, distribuídos igualmente entre os centros que participam da pesquisa. Os participantes foram pré-selecionados a partir de listas do corpo clínico dos hospitais, e todas as sessões de teste de usabilidade foram agendadas previamente. O cálculo do tamanho amostral garantiu uma probabilidade de 99% de detectar erros de usabilidade ocorrendo a uma taxa de 3%, proporcionando robustez estatística.

3.2. 4 Abordagem Metodológica para Testes de Usabilidade (Fase 2 e 3)

Um estudo experimental qualitativo-quantitativo foi conduzido para avaliar a percepção do usuário e a usabilidade do Videolaringoscópio impresso em filamento 3D (PLA+ Carbono) em comparação com um dispositivo comercial padrão-ouro. Os materiais de estudo foram fornecidos pelo projeto a cada unidade de estudo. Uma análise formativa foi realizada envolvendo 11 (FDA/ANVISA) médicos das especialidades de anestesia e intensivismo. A análise sumativa ocorreu posteriormente e contou com 60 médicos de diferentes especialidades, que trabalhavam no ambiente intra-hospitalar.

3.2.5 Locais de realização

Os testes de usabilidade foram realizados em ambientes clínicos controlados (laboratório de simulação) e em cenários de unidade de terapia intensiva (UTI) para obter uma avaliação abrangente e realística. Os participantes foram médicos com no mínimo dois anos de experiência no manejo de vias aéreas (para médicos). Os critérios de exclusão utilizados consideraram médicos com menos de dois anos de experiência em intubação orotraqueal.

3.2.6 Cegamento

O estudo é cego-simples, não envolvendo os usuários. Os dispositivos foram identificados como VLP-1(COMERCIAL) e VLP-2 (3D), e os questionários por códigos numéricos. O avaliador/pesquisador recebeu envelopes lacrados contendo os questionários que seriam preenchidos, internamente numerados como 1 ou 2, para determinar qual dispositivo o participante utilizaria primeiro. Cada questionário possuiu um número de série único correspondente ao nome do participante. O cegamento não foi implementado aos participantes. Os participantes utilizaram primeiro o Videolaringoscópio que estivesse registrado no envelope e, posteriormente, o do segundo envelope, executando as mesmas tarefas críticas em cenários simulados, porém sabendo que um deles era o dispositivo estudado.

3.2.7 Treinamento

O avaliador/pesquisador de tarefas foi treinado pela equipe principal da pesquisa (UFPEL) para demonstração de uso do dispositivo, com a técnica específica de laringoscopia e intubação orotraqueal, conforme as diretrizes. Posteriormente e quando iniciado o estudo de campo, cada participante teve 20 minutos de treinamento, não sendo disponibilizado o manual do usuário, por encontrar-se em desenvolvimento. O treinamento ocorreu no mesmo turno da realização dos testes, individualmente, com intervalo de 20 minutos a hora entre o treinamento e o início da usabilidade.

3.2.8 Avaliação Heurística de Usabilidade (Fase 1)

Uma análise heurística foi conduzida por especialistas em usabilidade do laboratório de usabilidade (UCPEL), seguindo os 14 critérios heurísticos de Zhang, para identificar tarefas críticas durante o desenvolvimento do dispositivo. Essa análise auxiliou na detecção de falhas de uso (incapacidade de concluir a tarefa) e desvios de uso (conclusão da tarefa com dificuldade).

3.2.9 Avaliação de tarefas (Fase 1)

Posteriormente, quatro pesquisadores médicos participaram de um ambiente clínico simulado ao lado de um técnico de usabilidade/pesquisador. Os especialistas montaram e desmontaram o dispositivo, bem como realizaram o procedimento de intubação orotraqueal até alcançar a visualização laríngea bem-sucedida. O técnico de usabilidade/pesquisador observou a execução das tarefas e documentou as informações detalhadamente, seguindo um Check list padrão do projeto. A avaliação considerou a complexidade da tarefa, taxas de erro e riscos potenciais de segurança, fornecendo informações essenciais para o planejamento dos estudos de usabilidade.

3.2.10 Tempo de Realização das tarefas

Os participantes tiveram até três tentativas para intubação. Consideramos um tempo limite inicial de 10 segundos por tentativa como adequado, conforme a literatura. Porém, estabelecemos um limite máximo de 60 segundos para cada tentativa, utilizando um celular calibrado durante a avaliação. Se o participante não conseguiu em 60 segundos na primeira tentativa, poderia reiniciar o procedimento, com nova cronometragem e assim até a terceira tentativa. O tempo necessário para a passagem do tubo foi registrado como tarefa crítica. Após a terceira tentativa foi considerado como falha de uso e não realização da tarefa.

3.11 Material

Um kit contendo o material para a realização dos testes foi disponibilizado. O kit continha: 01 Manequim de treinamento para manejo de vias aéreas da marca

Laerdal ou Sdorf (Airway Management Trainer, Laerdal, Noruega ou SDORF) para replicar condições reais. A lâmina utilizada nos dispositivos foi do tamanho 4-5. O equipamento de intubação incluiu tubos endotraqueais (tamanhos 6.5, 7.0 e 7.5), com Bougie ou fio-guia, caso fosse necessária à sua utilização.

3.12 Configuração dos testes

Os participantes realizaram a montagem, configuração e intubação traqueal com o dispositivo, e as suas interações foram registradas para análise de usabilidade. Após o término de uso de cada dispositivo, cada participante foi conduzido para um ambiente reservado. Neste momento, iniciou-se o Debriefing (feedback semiestruturado sobre a sua experiência) para autoavaliação da sua experiência, que ocorreu com o técnico/pesquisador em simulação. Ao término do Debriefing, o participante preencheu os questionários contendo perguntas de tarefas críticas e do System Usability Scale (SUS). Um técnico de usabilidade documentou os erros, dificuldades e desempenho das tarefas, realizando entrevistas pós-tarefa para avaliar a percepção do usuário, desafios de usabilidade e áreas de melhoria no design. Todos os registros foram realizados em documentos de Check list elaborados pelos pesquisadores principais do projeto.

3.13 Documentação

A coleta de dados ocorreu por meio de formulários do Google Forms, questionários impressos e gravações de vídeo, permitindo a identificação de problemas de usabilidade e refinamentos potenciais no design. A avaliação seguiu as diretrizes da ABNT NBR IEC 62366-1, ABNT NBR IEC 62366-2, FDA e ISO para engenharia de fatores humanos.

3.3 OBSERVAÇÕES E ACHADOS PRELIMINARES

3.3.1 Fase Formativa – Primeiras Impressões e Sugestões

Os participantes relataram as seguintes dificuldades e sugestões de melhorias:

Design e ergonomia: O triângulo no cabo dificultava a empunhadura.
Montagem demorada: O dispositivo exigia conexão a um tablet ou celular, limitando seu uso em emergências.
Lâmina muito longa e espessa: Alguns médicos relataram dificuldade na inserção devido ao tamanho excessivo.
Dificuldade na visualização da via aérea: O posicionamento da câmera exigia ajustes manuais frequentes.

Com base nessas observações, o dispositivo foi modificado para a fase seguinte.

3.3.2 Fase Sumativa – Avaliação com 60 Médicos

Na fase sumativa, 60 médicos testaram a versão aprimorada do videolaringoscópio nos dois hospitais participantes.

Os participantes relataram melhoria na empunhadura e na qualidade da visualização. No entanto, algumas dificuldades persistiram:

Parte da lâmina muito larga, dificultando a passagem entre os dentes do paciente.
Rigidez do dispositivo, tornando a introdução mais difícil.
Preferência individual variada: enquanto alguns médicos preferiram uma lâmina mais longa, outros consideraram excessivamente extensa.

3.4 COMITÊ DE ÉTICA

A terceira fase do projeto foi submetida à avaliação do Comitê de Ética em Pesquisa da Universidade Católica de Pelotas (UCPEL)**,** sob o CAAE 59663522.7.0000.5339, com data de submissão em 08/06/2022**.**

Para garantir a ética e a transparência na condução da pesquisa, todos os profissionais participantes receberam o Termo de Consentimento Livre e Esclarecido (TCLE)**,** documento que detalha os objetivos do estudo, potenciais benefícios e possíveis riscos envolvidos. A assinatura do TCLE foi um requisito indispensável para a participação no estudo, assegurando que todos os

envolvidos compreendessem integralmente os termos e consentissem voluntariamente com sua participação. Esse procedimento está em conformidade com as diretrizes éticas e regulatórias vigentes para pesquisas científicas envolvendo seres humanos**,** garantindo a proteção dos participantes e a integridade do estudo.

3.5 PUBLICAÇÕES CIENTÍFICAS

A partir deste trabalho, foram redigidos três artigos científicos, direcionados a periódicos de alto impacto na área de usabilidade, ergonomia e revisão sistemática:

O primeiro artigo foi apresentado e redigido de acordo com os critérios estabelecidos pela revista Systematic Reviews, disponível em: Systematic Reviews – Submission Guidelines.

O segundo artigo foi submetido à revista Applied Ergonomics e encontra-se atualmente em avaliação pelo editor. Link: Applied Ergonomics – ScienceDirect.

O terceiro artigo submetido, após apreciação da banca examinadora, para o periódico Journal of Medical Systems (Reference: Submission ID 338d88ba-e98a-4cfa-bc0f-9252cc021b59). O repositório de dados (Datset) e as referências podem ser acessadas pelo link: Kraemer Moraes, Ana Cristina; Lund, Rafael; Scherer, Caroline; Corrêa e Silva, Milena; da Costa, Daniela; de Souza, Everton; Nascimento, Chiara (2025), “Clinical Ergonomic Evaluation of 3D-Printed vs. Commercial Video Laryngoscopes for Teaching and Practice”, Mendeley Data, V1, doi: 10.17632/dg9873krw6.1

Essas publicações reforçam a disseminação científica do estudo e ampliam seu impacto na comunidade acadêmica e profissional.

3.6 RELATÓRIO TÉCNICO E MANUAL DO USUÁRIO

Embora a elaboração de um relatório técnico e de um manual do usuário não estivesse prevista entre os objetivos iniciais desta pesquisa, esses documentos foram desenvolvidos em um único relatório após a validação do

produto, com o intuito de consolidar suas especificações técnicas e orientar seu uso prático.

A construção desses materiais complementares foi motivada pela necessidade de garantir a replicabilidade e a operacionalização adequada do produto em contextos reais de aplicação. O documento foi incluído como apêndice desta tese, visando ampliar sua utilidade prática e facilitar a adoção por usuários técnicos e operacionais. (Apêndice D)

4. ARTIGO 1

Publicado no periódico *Systematic Reviews*, disponível em: https://link.springer.com/article/10.1186/s13643-023-02406-y.

ADVANCEMENTS IN ADDITIVE MANUFACTURING FOR VIDEO LARYNGOSCOPES: A COMPREHENSIVE SCOPING AND TECHNOLOGICAL REVIEW

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ABSTRACT

The global healthcare crisis with the COVID-19 pandemic has placed a significant overwhelming demand for intubation procedures and the need for reliable and accessible video laryngoscopes. The purpose of this scoping and technological review is to provide a comprehensive overview of the current state of the art), covering the period from 2007 to 2022, pertaining to the manufacturing process, characteristics, and validation of video laryngoscopes produced using additive manufacturing techniques. Following the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR), an exhaustive search was conducted across nine prominent databases (PubMed, Web of Science, Scopus, Cochrane, Prospero, Scielo, Embase, Lilacs, Virtual Health Libraries-VHL) and four patent databases (EPO/ESPACENET, WIPO/PATENTSCOPE, National Institute of Industrial Property (INPI), Google Patents). The main materials utilized for impression, as well as the physical characteristics of the device are introduced first. Crucial aspects to facilitate proper visualization of the anatomical structures during endotracheal intubation as the optimal angulation of the blade, the mechanical resistance of the device, traction force on the jaw, intubation time, and the experimental methods employed to validate its performance were reviewed in terms of their recent advances.

Keywords*: Intubation equipment, Video laryngoscopes, Additive manufacturing, Fused deposition modeling, Technological aspects*

1 Introduction

The global healthcare crisis with the COVID-19 pandemic evidenced the overwhelming demand for intubation procedures and the need for a video laryngoscope has become more pronounced. Additive manufacturing has

emerged as a promising solution, enabling the rapid production and prototyping of video laryngoscopes[1,2].

Fused deposition modeling (FDM) has been widely employed since 2013[3,4] and polymers and filament have been explored to introduce the manufactured video laryngoscopes. Acrylonitrile butadiene styrene (ABS) and polylactic acid (PLA) are the predominant polymers materials utilized for prototyping, and their use is indicated in airway access training or for the projection of a new device[5,6,7]. When the demand calls for a more resistant material, exceeding 400 intubations, the primary choice is polycarbonate, utilizing electronic injection, as opposed to PLA, with an average number of 100 intubations[8].

The video laryngoscope blade is an essential part of the device. With a continuous curve in its design, initially described by Robert Macintosh in 1943[9,10], it can influence the performance and success of intubation[11]. Studies have shown that hyper-angulated blades perform better. Some studies indicate that blades with an angle of 70 degrees allowed 100% success in orotracheal intubation, compared to 89% success with 90-degree blades[7,11]. The blade angulation is also related to the traction force used for jaw opening and the laryngeal visualization time, providing ergonomic characteristics and resistance to equipment use[7]. The study of forces exerted on the handle and blade is essential to assess the lifespan of these blades and to evaluate the rate of complications with patients.

The identified traction forces vary among the different devices, primarily depending on the design and type of material used in the construction of the equipment. However, these data are scarce, as authors do not always prioritize this type of assessment in their studies, which are mostly clinical studies, often neglecting the detailed analysis of the device's design and mechanics[28][12]. Thus, a compilation of this data can assist in optimizing future devices.

Regarding the validation process of manufactured devices, a series of experiments and tests are conducted to assess their performance and functionality. This includes the analysis of factors such as ease of use, maneuverability, intubation success rate, time required for intubation, and potential complications during the procedure[7,9]. Additionally, validation studies may involve comparisons between video laryngoscopes and other existing

devices or techniques, simulated intubations on mannequins or cadavers, and evaluation of their efficacy in clinical settings with real patients. Although the use of mannequins for validation is not considered ideal, it is important because it allows for the assessment of the device in a standardized difficult airway scenario and its functionality before being validated in patients[10].

Considering these factors, we provide a comprehensive overview of the characteristics and protocol validation of the 3D-printed equipment.

The manuscript begins with a detailed account of the search strategies, descriptors used, databases employed, and eligibility criteria. Next, a flowchart illustrates the methods of study identification, screening, and inclusion. The results section provides an overview of the historical context and major trends in additive manufacturing for video laryngoscopes (VLPs). Additionally, aspects related to filament selection, forces applied for oral cavity opening, and equipment strength are discussed in this section. Furthermore, the literature's suggested angulation values, equipment validation mechanisms, and industrial applicability are addressed. Finally, the discussion and conclusion sections offer our perspectives on future research directions. Authors are encouraged to follow this structure to effectively present their findings and insights.

Table 1 Description of randomized clinical trials that compared 3D printing prototypes with commercial equipment in mannequins.

Author/Year	N	Comarck-Lehane Identification	Laryngeal visualization time	Intubation time	Intubation success rate	Intervention/ Control
Cohen T; Nishioka H./2017	64 (anesthesiologists)	VLB:100% MAC: 21% (p=0.000)	VLB:16.6seg MAC:39.1seg (p=0.001)	VLB:55.4seg MAC:91.8seg (p=0.042)	VLB:94.1% MAC:60% (p=0.003)	VBL (3D) MAC blade (commercial)
Lambert C; John S; John A./2020	43 (professionals)	Pentax vs TVL vs Macintosh (p<0.001)	No	TVL 17.5seg Pentax15.5seg Macintosh 27seg (p<0.0001)	TVL 88% Pentax 97.7% Macintosh 67.4%	TVL (Tanser)(3D) Pentax AWS(3D) Macintosh (commercial)
De Villiers C ; Alphonsus C ; Eave D ; et al 2021	100 (experienced anesthesiologists and consultants)	No	No	VLP(3D):13.3s MAC:18.2seg	No	VLP(3D) CMAC (commercial)
Ataman A; Altina E 2021	23 (emergency physicians and clinicians >2 years of experience)	No	AirAngel 13.6seg Glidescope 8.1seg	AirAngel 27.7seg Glidescope 20.1 seg	AirAngel 56% Gladescope 87%	AirAngel (3D) Glidescope (commercial)
Fonternel T; Rooyen H; Joubert G; Turton E.	36 anesthetics	C-MAC 80.6% class 1 Novel Device 50% (p=0.0045)	C-MAC 5seg Novel Device 9.4seg (p<0.001) (CI=6.2-1.0)	C-MAC 13.8seg Novel Device 19seg (p=0.001)	100%	C-MAC^{R} VL with D-blade

2 Methods

2.1 Search Strategy

This scoping review adhered to the recommendations and checklist derived from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR)[13,14]. The study search and selection process started in December 2021 and concluded in July 2022. A comprehensive search was conducted across various electronic databases, including PubMed, Web of Science, Scopus, Cochrane, Prospero, Scielo, Embase, Lilacs, and Virtual Health Libraries (VHL), without any filters or restrictions applied to the studies. Furthermore, technological documents were sourced from EPO/ESPACENET, WIPO/PATENTSCOPE, and the National Institute of Industrial Property (INPI). Gray literature from Google Scholar and Google Patents was also consulted.

2.2 Descriptors and Databases

The survey in databases employed Boolean operators “OR” and “AND” to identified relevant descriptors from MeSH, Emtree terms, and DeCS. The search terms included (Laryngoscopies) OR (Laryngoscope) OR (Laryngoscopy) OR (Laryngoscopic Surgical Procedures) OR (Intratracheal Intubation) OR (Endotracheal Intubation) OR (Intubation) OR (Laringoscopio) OR (Laringoscopia) OR **(**Intubação) OR (Intubação Endotraqueal) OR (Intubação intratraqueal) AND (Manufacturing Factory) OR (Manufacturing Industries) (Three-Dimensional Printings) OR (3-Dimensional Printing) OR (3-Dimensional Printings) OR (3 D Printing).

Additionally, a patent search was conducted using the International Patent Classification (IPC) approach with the following codes: A61 (medical or veterinary science), A61B (diagnosis, surgery, identification), and the groups and subgroups A61B1/267 (laryngoscopes) and A61B1/05 (camera in the distal end portion). A combined approach was utilized, employing IPC with the terms Laryngoscope AND Video.

2.3 Eligibility Criteria

The eligibility criteria or inclusion in this review encompassed the manufacturing process of video laryngoscope equipment or its components using additive manufacturing techniques, either with or without the integration of micro-cameras or a borescope.

Additionally, descriptive and comparative studies examining the differences between commercially available video laryngoscopes and those produced through additive manufacturing were included, along with clinical trials utilizing mannequins for comparison and usability assessments.

Articles solely focusing on the additive manufacturing of accessories, such as the blade, system function for commercial video laryngoscopes, traditional commercial laryngoscopes, or those intended for animal use, were excluded from consideration. No restrictions were imposed on publication dates or languages, and relevant articles and technological documents considered were translated into Portuguese for analysis.

2.4 Extraction Strategy

A two-stage screening process was implemented to assess the relevance of studies identified in the search, involving three reviewers at different stages. The sequence for identifying and selecting documents was as follows:

a. Identification of scientific studies, conference proceedings, and existing theses.
b. Initial title-based selection, discarding those lacking keywords.
c. Review of abstracts to identify the subject and its relevance to the research, excluding irrelevant ones.
d. Full article review.
e. Selection of relevant articles for the study.

In the initial stage, title alone was considered as a search criterion by two reviewers, and the Mendeley Reference Manager was employed to add selected articles based on the identification of eligibility criteria and the removal of duplicates. In the second stage, abstracts were reviewed, by the same two reviewers, and studies that did not meet the eligibility criteria were excluded.

The assessment of patents involved an evaluation of their titles, abstracts, claims, and drawings. A third reviewer examined the patent publications in the patent database. Furthermore, additional criteria, including the International Patent Classification (IPC) code, publication date, international registration (PCT), participation of international entities with technological significance, and commercial potential, were considered to determine their relevance. The sequence for identifying and selecting documents proceeded as follows:

a. Title selection.
b. Review of patent abstracts and IPC classification.
c. Review of the invention description.
d. Review of claims and verification of drawings.
e. Industrial applicability for those with WIPO (PCT) patents.

3 Results

3.1 Study Selection

An electronic search was conducted in December 2021 and July 2022 resulting in an initial retrieval of 1178 publications. After removing duplicate entries and screening for relevance based on the title, 1123 publications were excluded as they did not meet the eligibility criteria~~,~~ ~~–~~leaving 55 studies for abstract evaluation. Further evaluation of the full text led to the exclusion of 36 studies, resulting in 19 studies met the inclusion criteria. In the patent database, the search retrieved 2656 patents. After reviewing the titles, abstracts, and drawings, 2638 were excluded. Among the remaining 18 patents, 8 were excluded based on the exclusion criteria, leaving 10 patent documents for analysis. Overall, 29 documents, including both studies and patents, were considered relevant to the search. Figure 1 presents a PRISMA flowchart that provides a visual summary of the articles, from the initial identification stage to the final inclusion stage.

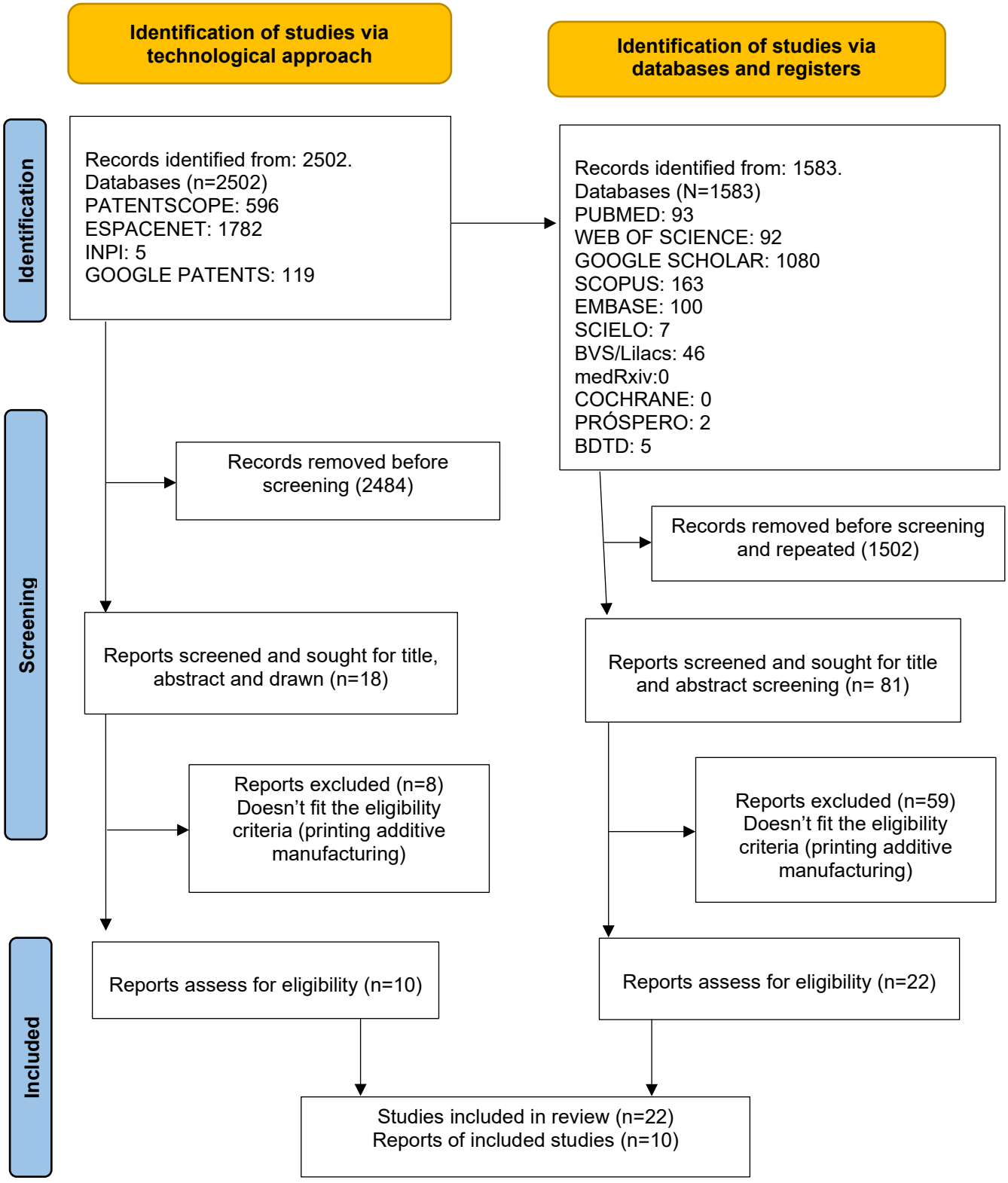

Figura 1 - PRISMA flowchart of the included studies and technological approach. PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

3.2 Study Characteristics

The search encompassed articles published between 2016 and 2022. A technological approach identified a total of 19 publications, five originating from the United States and the remaining publications from emerging countries, including: Brazil (2), Argentina (1), Equator (1), México (1), South Africa (2), and Turkey (1). Among the identified publications, the majority consisted of scientific articles (six in total), followed by four clinical randomized studies and one systematic review. The demographic data of the included articles can be found in Supplemental Table 1. Regarding patents, a selection process yielded a total of 10 relevant publications. The patent applications originated from various countries, including Brazil (4), Chile (2), Greece (1), Spain (1), China (1), and the United Kingdom (1) (Table 1).

Table 1. Studies encountered according to the type of publication/study, authorship, title, journal/institution, country of study, and year of publication

Publication/Study	Author	Title	Journal	Country	Year
Descriptive Study	Paydafar J; Wu X; Halter R.	MRI- and CT-Compatible Polymer Laryngoscope	Otolaryngology-Head and Neck Surgery	USA	2016
Descriptive Study	Christiansen J; Swanks S; Hsiung R.	3D printing the affordable video laryngoscope	Anesthesia & Analgesia	USA	2017
Controlled Randomized Clinical Trial	Cohen T; Nishioka H.	Comparison of a low-cost 3D printed video laryngo-borescope blade versus direct laryngoscope for simulated endotracheal intubations	Anesthesia & Analgesia	USA	2017
Cross-sectional Study	Cabrera D; Massano G; Fernández S; et al.	Low-cost laryngoscope video developed using 3D printing technology	Revista Chilena de Anestesiología/ Chilean Society of Anesthesiology	Argentina	2018
Descriptive Study	Dinsmore M; Sin V; Matava C.	3D Printed Thermal Laryngoscope	Journal of Medical Systems	Canada	2019
Cross-sectional Study	Cardoso G.C; et al.	Use of 3D-printed video laryngoscope in IOT teaching during the 2019/2020 pandemic	40th Scientific Week of the Clinical Hospital of Porto Alegre	Brazil	2020

Table 1. Studies encountered according to the type of publication/study, authorship, title, journal/institution, country of study, and year of publication (cont.).

Publication/Study	Author	Title	Journal	Country	Year
Descriptive Study	Habib M; Sims R; Inziello	Design and Optimization of Patient - Specific Pediatric Laryngoscopes	Proceedings of the 2020 Design of Medical Devices Conference (DMD2020)	USA	2020
Descriptive Study	Huysamen H ; Kinnear W ; Fonternel T et al.	3D Printed Laryngoscope for Endotracheal Intubation	South African Journal of Industrial Engineering	South Africa	2020
Cross-sectional Study and Randomized Clinical Trial	Lambert C; John S; John A.	The 'Tansen videolaryngoscope': a low-cost device for resource-limited settings, combining a smartphone-compatible endoscope and three-dimensional printed blade.	Eur J Anesthesiolo	UK	2020
Letter to the editor	Almeida V; Almeida V; Campos G.	Challenges of prototyping, developing, and using video laryngoscopes produced by inhouse manufacturing on 3D printers	Brazilian Journal of Anesthesiology (English Edition)	Brazil	2021
Descriptive Article	Quiroga J; Flor O; Solórzano S; et al.	Design of a Videolaryngoscope with sensor and pressure alert	Revista Athenea en Ciencias de la Ingeniería	Ecuador	2021
Case Report Study	Maya Marcílio C; Meléndez Ordoñez J; Montes Ríos A	Hybrid laryngoscope: A reasonable option cost for approaching the airway difficulty. A case report	Revista Chilena de Anestesología Chilean Society of Anesthesiology	Mexico	2021

Table 1. Studies encountered according to the type of publication/study, authorship, title, journal/institution, country of study, and year of publication (cont.).

Publication/Study	Author	Title	Journal	Country	Year
Descriptive Study	García R.M.C	Low-cost video laryngoscopy with 3D printing technology. A concept proof	Anesthesia and Analgesia	Spain	2021
Descriptive Study	Hughey et al, 2021	3D-printed laryngoscope for military austere environments	BMJ Military Health	USA	2021
Randomized Clinical Trial, controlled	De Villiers C ; Alphonsus C ; Eave D ; et al.	Innovation in low-cost video-laryngoscopy: Incubator V1-Indirect compared with Storz C-MAC in a simulated difficult airway	Trends in Anesthesia and Critical Care	South Africa	2021
Descriptive Study	Triantopoulos A; Triantopoulos O; Kostopoulos V; et al.	Presenting an innovative 3D-printed video laryngoscope	Trends in Anesthesia and Critical Care	Greece	2021
Randomized Clinical Trial	Ataman A; Altina E.	Comparison of a commercial 3D fabricated laryngoscope (Airangel ® with a widely used video laryngoscope (Glidescope ®): Randomized controlled cross-over study	Trends in Anesthesia and Critical Care	Turkey	2021
Systematic Review	Hamal PK, Yadav RK, Malla P	Performance of custom made videolaryngoscope for endotracheal intubation: A systematic review.	PLoS One	Nepal	2022

Table 1. Studies encountered according to the type of publication/study, authorship, title, journal/institution, country of study, and year of publication (cont.).

Publication/Study	Author	Title	Journal	Country	Year
Descriptive Study	Londoño MJ, Arango, JF, Izasa JF	Design and Development of a low-cost pediatric videolaryngoscope	Proceedings of the International Conference on Engineering Design (ICED23)	Bordeaux, France	2023
Descriptive Study	Kienle LL, Schild LR, Bohm F, Grasslin R, Greve J, Hoffmann TK, Schuler PJ	A novel 3D-printed laryngoscope with integrated working channels for laryngeal surgery	Frontiers in Surgery	Germany	2023
Randomized Cross-over Study	Fonternel T, Rooyen H, Joubert G, Turton E	Evaluating the usability of a 3D-printed Video Laryngoscope for tracheal Intubation of a Manikin	Medical Devices: Evidence and Research	South Africa	2023

3.3 Trends in VLP in Additive Manufacturing

The trends in Video Laryngoscope (VLP) development through additive manufacturing have emerged relatively recently. Early publications primarily focused on the initial stages of producing laryngoscope prototypes for otolaryngology, utilizing processes like light-curing technology[15]. Notably, patents spanning from 2007 to 2021 have extensively employed ABS photopolymerization and fused deposition techniques for VLP fabrication. Fused Deposition Modeling (FDM) has emerged as a prominent choice for rapid prototyping of laryngoscopes, reflecting a prevailing trend in the field [2,16]. This evolution in additive manufacturing techniques has ushered in new pathways for enhancing VLP design and manufacturing methods, aligning with the evolving needs of the medical field and advancing the potential for improved patient care.

3.3.1 Filaments of Choice

The utilization of fused deposition modeling (FDM) for impressions, particularly with the thermoplastic polymer ABS, has been highlighted as the favored approach for rapid prototyping. However, it is essential to note that ABS equipment should be confined to training exercises using simulators due to its carcinogenic properties and lack of compatibility with *in vivo* tissue[2,16,17]. Since the advent of the COVID-19 pandemic in 2020, there has been a heightened emphasis on adopting environmentally friendly thermoplastic polymers. Polylactic acid (PLA) has emerged as a biocompatible, biodegradable thermoplastic polyester sourced from renewable materials that poses no harm to human health[6,18]. Furthermore, augmenting PLA with materials like carbon or onyx has exhibited enhanced physical attributes,

filament robustness, and product longevity[19,20]. While the incorporation of PLA with other filaments enhances polymer properties, it may also escalate the cost of prototypes, which are still in the exploratory study phase[2,16,20]. Recent explorations have delved into novel combinations of thermoplastic polymers, including polyethylene terephthalate glycol (PETG)[20], CCTREE polypropylene[8], and Nylon[8]. Technological resources have also noted alternative materials such as quartz, silica, sustainable vegetable plastic, ASA, Tristan, and Nylon, all of which bestow durability to the device. This evolving landscape of thermoplastic material investigations provides a foundation for enhancing the development of Video Laryngoscopes (VLP) through additive manufacturing, aligning with the ongoing progression of medical requirements and elevating the potential for advancing patient care.

3.3.2 Related Forces

Although sparsely discussed, several considerations regarding the resistance and force exerted on a Videolaryngoscope can be inferred from the literature references. Generally, two types of forces are assessed in studies: the force required to open the oral cavity and the equipment's resistance force, associated with a minimum usage force. This latter force is relevant due to the potential for deformities and fractures in the device.

References [12] and [20] report force values capable of inducing deformity alterations in the device. In both studies, device resistance was linked to the filament material employed in Videolaryngoscope fabrication. Specifically, in [20], the material polyethylene terephthalate glycol-modified (PETG), renowned for its robustness and ease of printing, was chosen. Finite element analysis (FEA) was employed to assess stress distribution. Results revealed that the ideal blade

resistance was achieved at a force of 100N, characterized by a mass of 102 g, Von Mises stress of 29.0 MPa, and volume of 79 cm^3, suggesting the viability of using PETG filament for the Videolaryngoscope blade. Other researchers, as in [12], studied ABS and identified a minimum force of 84N as the required resistance for safe blade usage.

Regarding the maximum force necessary for opening the oral cavity, a technical document [21] compared, through experimental trials on mannequins, an ABS-manufactured device with a metal-blade Macintosh laryngoscope. The authors obtained an average force of 18.18 N for the ABS VLP, compared to 22.87 N for the metal device. Although the devices had different masses, the authors attributed the results mainly to the optimized angulation of the ABS VLP relative to the metal one, rather than the devices' masses themselves, which they claimed minimally influence the direction of applied jaw-opening traction force. These findings align with the study by [11], which asserts that a commercial Glade scope Videolaryngoscope equipped with a Macintosh blade requires a minimum force of 25 N for adequate laryngeal visualization.

3.3.3 Blade Angle and Higienization

The Macintosh blade design is the most prevalent among the examined studies, primarily due to its capacity to ameliorate minor intubation difficulties and optimize neck mobility angle. Beyond these factors, further advantages have been underscored with the utilization of this blade, including ease of attachment, illumination, field of view, clinical applicability, applied force, and intubation duration, all of which were significantly influenced by the blade type[12]. Regarding blade angles, some authors emphasize that hyper angulated blades offer the capability to

achieve a comprehensive view of the glottis, even in the presence of a large tongue and restricted neck mobility, with a majority of participants able to attain a complete glottis view using video-assisted devices[7,17]. Ideal blade angulations vary, ranging between 70° and 90° according to Moraes et al. [21], and 45° and 90° for Cohen et al[22]. Angulations between 0° and 15° are considered challenging for usage, while those between 45° and 60° have been described to facilitate cervical hyper angulation for improved visualization[12,17,22].

Regarding the cleansing of metal blades, it was demonstrated that standardized disinfection techniques did not effectively neutralize proteinaceous materials present in secretions such as blood, which come into contact with the blade and handle. In a study evaluating the disinfection process of 100 conventional laryngoscopes, a notable 38% contamination rate of the handle was observed, with the presence of Streptococcus viridians in the culture, thereby questioning the efficacy of the process and suggesting the use of disposable blades[29]. The recommended hygiene procedure involves initiating the process at a temperature below 35°C using an ultrasonic device, capable of removing proteins and preventing coagulation. This is followed by rinsing with warm detergent to ensure proper removal, ultimately culminating in thermal disinfection for reusable blades[12,30].

For devices manufactured through additive manufacturing, no specific sterilization and cleansing protocol has been indicated. Instead, standardized hospital protocols for reusable devices and ethylene oxide disinfection are suggested [20]. As of now, there are no studies addressing microbial contamination or validation of hygiene and disinfection processes for these additive manufacturing devices.

3.3.4 Equipment Validation

In our study, comparative data were obtained using metal laryngoscopes, video laryngoscopes with Macintosh blades, and 3D-printed video laryngoscopes on simulation mannequins with experienced physicians using the devices. Team training, resistance tests, and comparisons with commercial video laryngoscopes were conducted using SimMan3G simulation mannequins with a difficult airway, involving a fully inflated tongue and stiff neck, to assess the efficacy of the 3D-printed video laryngoscope. A total of 231 professionals experienced in intubation procedures participated in the studies [1,7,8,20,22].

Five experimental studies examined the performance of the 3D-printed video laryngoscope on mannequins[1,7,8,20,22]. Intubation success rates and intubation times were among the key parameters analyzed in these studies.

The intubation time was significantly shorter when using the 3D-printed video laryngoscope developed by De Villiers et al.[8] (average time: 13.3 s, minimum time: 5.1 s), compared to the devices developed by Ataman et al.[1] and Lambert et al.[7] (27.7 s and 17.5 s, respectively). Additionally, Ataman´s and Cohen´s[22] models, which were developed based on the Air angel and Macintosh models, exhibited comparable and shorter laryngeal visualization times (13.6 s and 16.6 s, respectively) when compared to commercial Glide scope and Mac group/Mac cable equipment (8.1 s and 39.1 s) [3,14,20,26].

Furthermore, the intubation success rate was higher for the Cohen model (94.1%) when compared to other 3D-printed prototypes and commercial devices [7,9,10].

However, a systematic review of five randomized studies conducted on actual patients concluded that there is limited evidence supporting the use of 3D-

printed Videolaryngoscope in clinical practice. This limited evidence is attributed to the absence of standardized protocols and highlights the consideration of potential risks, such as injuries, as factors that underscore the safety of device use in real patients[23].

In the same study, it was identified that the highest rates of intubation success and intubation times, along with the lowest rates of complications, were achieved when inexperienced physicians utilized the Glade scope brand's Macintosh-bladed Videolaryngoscope. On the other hand, no significant differences were observed between devices when used by experienced anesthesiologists [7,9,10].

3.3.5 Industrial Applicability

Two documents, PCT WO2019075588A1[23] and PCT WO2020003192A1[25], offer valuable insights into the potential and industrial applicability of video laryngoscopes. These documents suggest the fabrication of devices using durable materials such as metal, polycarbonate, and polymers. Moreover, the publication WO2015104444A1[26], accompanied by an international preliminary report on patentability, recommends a hyper angulation of the blade within the range of 30 to 60 degrees, exhibiting characteristics akin to well-established video laryngoscope models like the PENTAX AWS, AIRTRAQ, AMBU KING VISION, MCGRATH GLIDESCOPE, C-MAC, and VIVIC-TRAC. This patent introduces promising features and functionalities comparable to those found in industry-standard equipment (Table 2).

Table 2. Description of technological documents

Publication/Year	Country	Title	Inventor	Claimed
ES2524654A1·2014-12-10 PCT/ES2015/070013 WO2015104444A1	Spain	Video-laryngoscope blade with connection to smartphones (Machine-translation by Google Translate, not legally binding)	CARNER BONET BERNART	Characterized Video-laryngoscope blade with connection to smartphones by comprising anatomical blade; a tunnel-guide of semirigid plastic, suitable for the passage of a boogie, which tunnel-guide runs along the underside of the blade. Comprising a chamber and a lighting element type LED; said system image capture being connected to wires inside the blade and connecting to a smartphone.
WO2019075588A1·2019-04-25 PCT/CL2018/050100 (Industrial applicability in few claims)	Chile	Medical device for endotracheal intubation of humans and production method thereof	JUDITH BORDONES CARTAGENA	Characterized because it comprises a handle, a folding shovel, a video image system, and a washing system that pass through the folding blade and a channel in the left side to slide an endotracheal tube. Where said parts are manufactured in a resistant material such as a metal of surgical use and / or a polymer for medical use and / or a composite material for medical use that resists compression and / or a combination among themselves.
CL2017002471U1·2018-02-02	Chile	Clinical teaching video laryngoscope with a plastic structure of biodegradable plant origin, developed with 3D technology, which allows the coupling of a camera to visualize anatomical structures in human beings for the realization of endotracheal intubation.	MAX RODRIGO CORVALAN ASTUDILLO	The device its body manufactured in a single structure allows to make it portable. No more claims are described in patent.

Table 2. Description of technological documents (cont.).

Publication/Year	Country	Title	Inventor	Claimed
GB2575110A WO2020003192A1· 2020-01-02 PCT IB2019/055449 (Industrial applicability in all claims)	United Kingdom	WIRELESS LARYNGOSCOPE	EAVE DYLAN; DE VILLIERS CHRISTIAAN TERTIUS; DE VILLIERS JACQUES ALBERT.	Characterized by the single part is made from injection-molded plastics. Wherein the insertion member is angled or curved from the first axis to the second axis through a total angle of between 100 and 135 degrees. Has uneven sides fouled, to thereby dissuade a user from cleaning the laryngoscope for reuse. A flat surface extending along a plane that is angled between 30 and 60 degrees from the first axis.
CN110724310A·2020-01-24	China	Degradable material for anesthetic laryngoscopes, and preparation method thereof	WANG QIUPING	A degradable material for anesthesia laryngoscope, characterized in that it is made of raw materials of vinyl-modified polylactic acid, glucopyranoside, vinyl, PGA fiber, itaconic acid, hydroxyapatite, and glycan.

Table 2. Description of technological documents (cont.).

Publication/Year	Country	Title	Inventor	Claimed
BR 20 2019 014222 2 U2	Brazil	CONFIGURATION APPLIED IN LARYNGOBOROSCOPE OR VIDEO LARYNGOSCOPE 3D FOR SMARTPHONES.	IVAN DIAS FERNANDES PEREIRA / THIAGO MATTIA	Characterized by a blade in 3D impression using POLICARBONATO, ASA, ABS, PETG, TRYTAN, NYLON); A blade with insertion of the camera (borescope with connexon USB, 7mm and 6 LEDs)
GR20180100390A·2020-04-15	Greece	VIDEO LARYNGOSCOPE FOR INTUBATION	TRIANTOPOULOS ORESTIS-KONSTANTINOS ALEXIOU; PAPANAOUM MAGDALINI EVANGELOU; KOSTOPOULOS VASILEIOS EVANGELOU; TRIANTOPOULOSALEXIOS GEORGIOU	Characterized by the fact that the tracheal tube has a slope of 6.82 and 3.73 with respect to the axis. Adapted to the anatomical features of the operator and made of polymeric material with 3D printing technology and with 3 different front configurations.
BR 102020026194 0 21/12/2020	Brazil	ANATOMIC VIDEOLARINGOSCOPE	ANA CRISTINA BEITIA KRAEMER MORAES / CHIARA DAS DORES DO NASCIMENTO / EVERTON GRANEMANN SOUZA	Characterized by two parts connected and take an internal channel with a micro camera into the blade, and symmetrical half and external channel to the passage of aspiration. The angle is specific to guarantee the safe in the access of the airway

4 Discussion

The objective of conducting this scoping and technological review is to present a holistic exploration of contemporary advancements. Encompassing the timeframe from 2007 to 2022, this review delves into the manufacturing processes, attributes, and validation protocols of video laryngoscopes crafted through additive manufacturing methods.

In the realm of additive manufacturing, the availability of materials accessible for widespread use in 3D printers has led to notable choices such as ABS and PLA filaments. These materials have found applications in prototyping, validation, and airway access training on mannequins[16,17]. Nevertheless, limitations are associated with the use of ABS, primarily due to its carcinogenic characteristics and endocrine effects. On the other hand, PLA, while more prone to deformity over time, can exhibit layer delamination and bacterial accumulation upon repeated use, owing to its porous nature. Given the prevalence of 3D printing in medical devices, alternative materials have gained attention, characterized by enhanced mechanical and thermal resilience, as well as compatibility with ethylene oxide sterilization. Prominent among these materials are PETG, PLA combinations infused with elements like carbon, silica, and onyx, along with PC-ISO (polycarbonate)[20]. However, the paramount consideration resides in the identification of filaments deemed safe for human contact, adhering to the regulations set forth by North American health agencies, exemplified by Rokit's plastics and Skinflex[17].

Regarding the feasibility of employing certain materials in the design of a video laryngoscope, tests evaluating force to appraise material strength and force required for laryngeal visualization have been expounded upon[27]. In ABS devices, greater resistance to force-induced motions was noted[21]. Studies involving

combinations of thermoplastic polymers, like polyethylene terephthalate glycol (PETG), exhibited differing resultant forces[20], emphasizing the necessity of comprehensive measurement during device assessment.

Regarding the force magnitudes, experimental investigations involving 24 patients and commercial devices unveiled notable findings. The application of force at the lingual base was studied using both a comparative Macintosh laryngoscope and a commercial Glide scope VLP. Data acquired through sensors, encompassing metrics such as peak, average, and impulse forces, revealed a substantial reduction exceeding 50% in the peak force (25N) when utilizing the Glide scope Videolaryngoscope, as compared to the average force of 41N exerted with the Macintosh laryngoscope metal during laryngoscopy[28].

In a comparative manner, the study conducted by Rassam in 2005[12] entailed the integration of vertical force measurements through employment of a mass balance (Mettler PM16, Mettler Instruments, High Wycombe, UK) and horizontal force measurements via a force transducer (AFG 500 N, Mecmesin Ltd, Horsham, UK). The amalgamation of these distinct forces culminated in a resultant force, whereby the pinnacle force denoted the utmost value during laryngoscopy. A comprehensive examination spanning over a thousand cases demonstrated a closely aligned peak force exhibited by the Macintosh laryngoscope metal (84N)[12], resembling the force output of PETG (100N)[20]. Conversely, a scrutiny of 1009 mannequin laryngoscopies revealed a peak force (vertical-to-horizontal force ratio) oscillating between 32 and 39 N upon deployment of both metal and plastic Macintosh blades. The duration of intubation averaged 5.1 seconds and was discernibly influenced by blade dimensions and angulation, rather than the

experience of the anesthetist1[2]. It is noteworthy that these values substantially deviated from those of the ABS prototype (18.8N) [21,27].

Comparative evaluation of 20 different disposable and non-disposable blade materials, excluding polymer filament material, indicated that laryngoscopy duration exhibited a direct correlation with increased force. Consequently, lighter devices facilitate visualization and reduce intubation time. Moreover, the utilization of polycarbonate blades could be repeated for up to 100 intubations without damage or fracture—a figure analogous to predictions for polymer filament blades[8,12].

With regard to blade angulation, the video laryngoscope models produced demonstrated a faithful replication of the conventional Macintosh laryngoscope model, specifically utilizing the number 3 blade pattern that attaches to the handle. The interrelation between the blade's angulation and its attachment to the handle emerged as a pivotal factor in diminishing the risk of equipment fracture and enhancing oral cavity accessibility. These enhancements were particularly pronounced in the context of the Macintosh model, where blade angulation was meticulously optimized to ensure optimal laryngeal visualization[7,8]. Certain studies have underscored the significance of this attribute in enhancing laryngeal visualization, albeit without explicitly delineating an ideal blade angulation. These studies assert that angles ranging from 45° to 60° facilitate superior visualization without necessitating cervical hyperextension, with a preference for hyper-angled blades.

In contrast, an investigation comparing Glide scope blades with varying angulations in 162 patients indicated that a 70° angle yielded reduced intubation time and higher success rates, rendering it more preferable than the 90° angle[1,22]. These ranges of angulations recur in technological documents[21,25].

Several device attributes contribute to ease of use and glottic visualization. An optimal distance of 5.5 cm from the blade's tip was identified as ideal for micro camera positioning, enabling effective laryngeal visualization[18]. The incorporation of the handle in 3D-printed models enhances the video laryngoscope's ergonomic profile, consequently facilitating smoother intubation[2]. Notably, investigations involving commercial devices revealed that micro camera illumination diminishes over repeated use and subsequent sterilization cycles. Despite variations in luminosity, these alterations did not significantly impair visualization[12]. Conversely, the absence of a smartphone support mechanism for displaying micro camera images was identified as a hindrance to effective visualization. The detachment of images due to their presentation on a separate device extended laryngeal visualization time and the duration required for successful intubation[1,16,17].

The validation of the video laryngoscope prototype encompassed assessments conducted on simulation mannequins and experienced professionals, underscoring the preliminary testing phase of the equipment. The utilization of mannequins was recommended to ascertain the basic functionality of the device. However, the new blades must undergo patient-based testing before reaching the consumer market. Comparative tests with conventional equipment, such as metal and plastic blades, are imperative to identify the optimal performance of the device[12,31].

During simulations involving mannequins, a standardized scale consistently informed the studies. Key evaluation parameters encompassed intubation time, laryngeal visualization time, and intubation success rates within the context of 3D-printed models. Primary parameters, particularly intubation time and success rate, were deemed essential for evaluation. Intubation failure was defined as instances

requiring 120 seconds or more for intubation within a maximum of 3 attempts[32]. Intubation time was measured from the device's oral cavity entry to the insertion of the Oro-tracheal tube through the vocal fold. The utilization of the 3D-printed VLP yielded shorter intubation times, with a minimum of 5.1 seconds and an average of 13.3 seconds[8]. This minimum time aligns with the shortest duration recorded in conventional studies, at 5 seconds, involving diverse Macintosh blades in both metal and plastic[12]. The highest intubation success rate achieved was 94.1%[22].

5 Limitations and Risk of Bias

In this study, limitations may be present in the selection phase and complete reading of the articles, leading to selection bias. In addition, comparisons are limited owing to the heterogeneity between studies.

6 Conclusions

The paramount feature of the Videolaryngoscope is its hyper-angled blade, ideally positioned within the range of 70° to 90°[1,8]. The jaw traction force required for this type of blade should approximate 25N, while the minimum force capable of inducing deformation should fall between 84N and 100N. Validation tests performed on simulation mannequins enable the assessment of prototypes and emphasize primary evaluation parameters, namely intubation time and success rate. These parameters are influenced by the degree of blade angulation. Nonetheless, patient tests must precede product availability in the market, as they facilitate the validation of other parameters not encountered in simulation mannequins.

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Supplementary Information

The online version contains supplementary material available at
Additional file 1: Table S1. Studies encountered according to the type of publication/study, authorship, title, journal/institution, country of study, and year of publication. 13643_2023_2406_MOESM1_ESM.docx (28.6KB, docx)
Additional file 2: Table S2. Description of technological documents. 13643_2023_2406_MOESM2_ESM.docx (16.7KB, docx).

Declarations

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this study.

Funding

The authors thank the financial support from the innovation program Catalisa-ICT register # ICT/22:29083269, SEBRAE, FUNDEP-MG and the Brazilian National Council for Scientific and Technological Development (CNPq). Scientific and Technological Development (CNPq) register #DT-1D Productivity Scholarship in Technological Development: 306225/2021-2.

Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have influenced the work reported in this study.

Availability of Data and Material

The data that directly supports the study results are in Mendeley Reference Manager (https://www.mendeley.com/reference-manager/library/all-references),

and technological database (https://worldwide.espacenet.com/) (https://patentscope.wipo.int/search/pt/advancedSearch.jsf) (https://busca.inpi.gov.br/pePI/jsp/patentes/PatenteSearchAvancado.jsp).

Authors' Contributions

ACBKM designed project administration, conceptualization, methodology, data curation, software, writing – original draft, preparation, writing – review and editing, funding acquisition, and investigation. validation. CDN designed project administration, supervision, writing—original draft, preparation. EGS designed supervision, writing—original draft, preparation. RGL, EP, and NLV designed project administration, validation, writing—original draft, preparation, writing—review and editing, submission, and funding acquisition. All authors read and approved of the final manuscript.

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5. ARTIGO 2

Submetido ao periódico Applied Ergonomics e encontra-se atualmente em revisão pelo editor desde o dia 19 de fevereiro. Link: Applied Ergonomics – Science Direct.

SYSTEMATIC REVIEW OF USABILITY EVALUATIONS IN MEDICAL DEVICES: METHODOLOGICAL CHOICES, HEURISTIC APPLICATION, AND CONFOUNDING FACTORS

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ABSTRACT

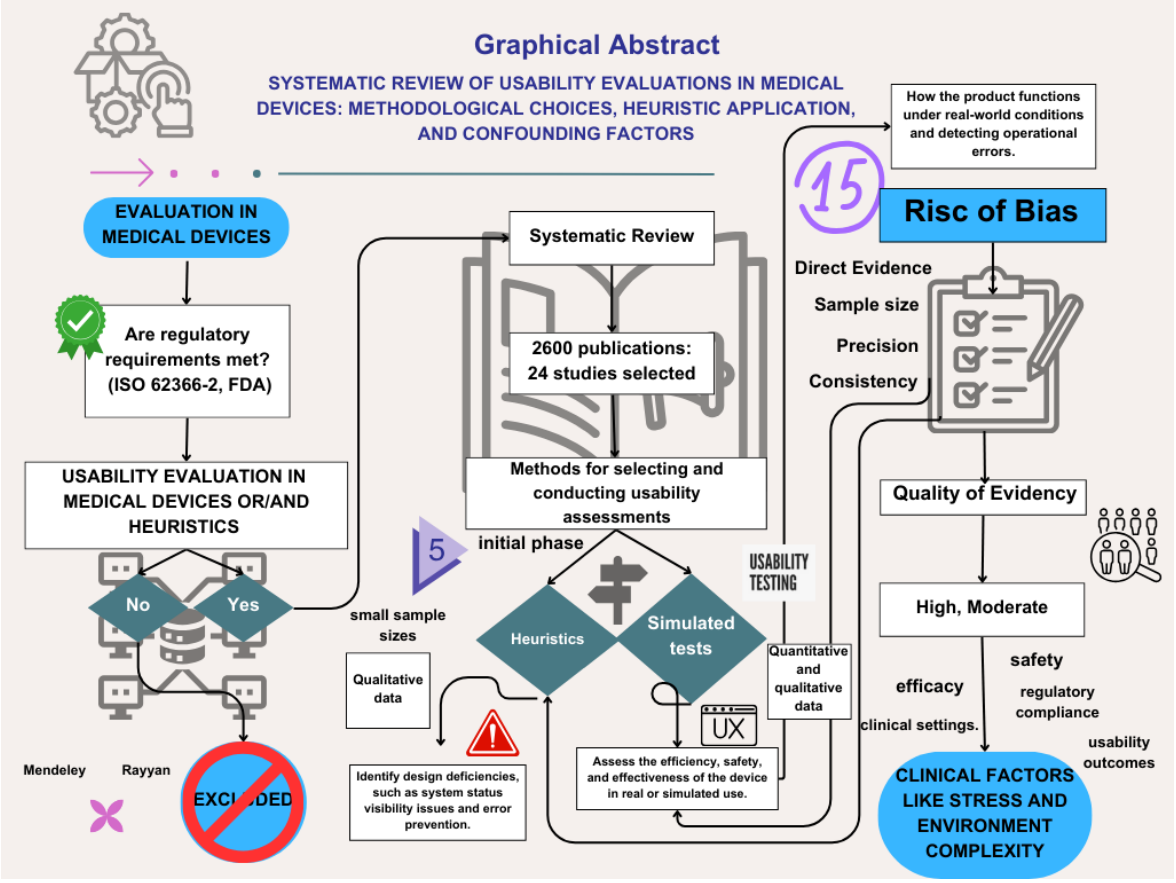
Usability evaluations play a crucial role in the development of medical devices, as required by ISO 62366-2 and FDA regulations, which mandate rigorous testing to ensure user safety. This study aims to systematically review how usability assessments are selected and conducted during product development, identifying confounding factors that may compromise replicability. It also explores how these practices help ensure devices meet regulatory safety criteria. A comprehensive search was conducted in databases including PubMed, Scopus, Web of Science, Lilacs, and Google Scholar, covering the period from April 2024 to January 2025. The search yielded 2,598 publications, with 921 studies deemed eligible after removing duplicates and conducting initial screening. Applying strict inclusion criteria, 24 studies were selected for usability analysis. Qualitative data were categorized using BARDIN's methodology, while the GRADE approach assessed evidence quality. Most studies showed a moderate risk of bias, though the quality of evidence regarding device safety and efficacy ranged from moderate to high. Simulated tests proved effective for evaluating critical tasks and mitigating unpredictable variables. However, limitations exist in generalizing results to real clinical settings, as simulations fail to fully capture factors like user stress and the complexity of hospital environments. These factors can affect the replicability and reliability of usability results. Thus, complementing simulated evaluations with tests

in actual clinical environments is essential to confirm device applicability and ensure safe, effective use. This dual approach strengthens the validity of usability assessments and enhances patient safety in real-world scenarios.

Keywords: Human-Centered Design; Usability Evaluation; Summative Evaluation.

GRAPHICAL ABSTRACT

Usability evaluations are essential for medical device development, as mandated by ISO 62366-2 and FDA regulations. This systematic review analyzed 24 studies from 2,600 publications, highlighting methods for selecting and conducting usability assessments. Simulated tests effectively evaluated critical tasks but showed limitations in replicability due to unaccounted clinical factors like stress and environment complexity. Complementing simulations with real-world testing enhances device safety, efficacy, and regulatory compliance, ensuring more reliable and applicable usability outcomes in clinical settings.



1 Introduction

Usability evaluation is a critical step in the development of medical devices, as it ensures that users can operate equipment safely and effectively. Organizations such as the FDA and ISO 62366-2 regulate these tests, requiring manufacturers to conduct rigorous assessments throughout the development process, particularly for high-risk Class III and IV devices[1,2]. With the increasing complexity of electromedical devices, evaluation methodologies have been employed to detect potential usability issues at various stages of product validation.

Factors such as the development phase, task identification, evaluation timing, and the involvement of the intended user are decisive in selecting the appropriate method, as they can lead to increased time and costs in product validation[3]. Some studies have shown that usability problems can initially be identified through heuristic analysis, which allows for the detection of a significant number of usability errors, following human factors engineering criteria[3,7]. Heuristic evaluations should be conducted by a team of experts, with the primary advantage being reduced evaluation time and costs [3]. However, usability methods mandated by regulatory bodies involve the participation of probable users in formative and summative evaluations, typically conducted through simulation[3,5,8-16].

In the evaluation of critical tasks, simulated tests help eliminate unpredictable variables; however, there are limitations in generalizing these results to real clinical settings[9,17]. Factors such as stress and the complexity of hospital environments are not fully captured in controlled simulations, which may impact the replicability of the results[4,5,9]. In usability assessments, information regarding usage errors and task identification is gathered through focus groups, interviews, and questionnaires, necessitating the involvement of specific users, which in turn requires more time and resources[3,8,9,10,11].

The aim of this study is to identify how usability evaluations are selected and conducted during product development, how heuristic methods are applied, and to detect potential confounding factors that could compromise the replicability of these

evaluations, given that usability aims to ensure devices meet established safety and efficacy criteria[3,4,8,9,12,13].

2 Methods

2.1 Search strategy

This scoping review was conducted in accordance with the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Systematic Reviews (PRISMA-2020)[18]. The identification and selection of relevant studies were independently performed by two researchers utilizing the Mendeley Reference Manager and the Rayyan Systematic Review tool to ensure methodological rigor and minimize selection bias. The literature search commenced in May 2024 and concluded in January 2025.

A comprehensive electronic search was carried out across five major databases: PubMed, Web of Science, Scopus, Lilacs, and Google Scholar. The search strategy did not impose restrictions on publication year or language, thereby maximizing the inclusion of relevant studies across diverse contexts and geographical regions.

This review was guided by the following research questions: What usability evaluation methods are currently employed for medical devices? Should these methods effectively diagnose errors in medical devices? How has the quality of evidence in usability studies evolved over time? The target population included healthcare professionals, with or without patient involvement, while the intervention focused on usability assessment methodologies. Clinical trials were the primary study design of interest. In addition to database searches, supplementary data were obtained from the official websites of international regulatory bodies overseeing medical device standards and guidelines.

2.2 Descriptors and databases

Keyword identification was performed using the DeCS/MeSH databases. Boolean operators "OR" and "AND" were applied to refine and optimize search

results, ensuring the retrieval of studies aligned with the review's objectives. The search strategy incorporated controlled vocabulary and free-text terms from MeSH, Emtree, and DeCS. The following search terms were employed: *(UX AND method) OR (Usability AND testing) AND (Medical AND equipment) OR (Medical AND device); (“usability testing”) AND ("medical devices").*

2.3 Eligibility criteria

Studies were deemed eligible if they investigated devices, equipment, or implants classified as medical devices by international regulatory standards[19], specifically for use in hospital or healthcare service environments. The review considered a broad spectrum of usability evaluation methods, including human factors analysis, heuristic evaluations, formative and summative assessments, and simulation-based validation protocols. Studies involving healthcare professionals, with or without patient interaction, were included.

Exclusion criteria encompassed studies focusing on surgical techniques, in vitro diagnostic tools, non-medical equipment, telemedicine, remote or at-home validation procedures. Additionally, studies unrelated to healthcare contexts or employing design methodologies not aligned with usability evaluation were excluded. Descriptive and comparative studies examining methodological variations in usability validation, as well as studies employing specific questionnaires for user experience evaluation, were included.

2.4 Data extraction strategy

A rigorous three-phase screening process was implemented to ensure the relevance and quality of the studies included in this review. Three independent reviewers participated in the selection process at different stages to enhance reliability and reduce potential biases. The selection process consisted of the following steps:

a. Identification of relevant scientific articles, conference papers, and theses.
b. Preliminary screening based on titles, with exclusion of studies lacking pertinent keywords.

c. Abstract screening to assess study relevance in alignment with the research objectives.
d. Full-text review to evaluate methodological robustness and relevance.
e. Final selection of studies meeting all eligibility criteria for inclusion in the analysis.
f. A senior reviewer conducted a final assessment to ensure consistency and resolve any discrepancies in the selection process.

In the initial phase, two reviewers independently screened the titles, and eligible studies were managed using Mendeley Reference Manager. Duplicate records were systematically removed using the Rayyan Systematic Review tool. In the second phase, the same reviewers critically assessed the abstracts, excluding studies that did not meet the inclusion criteria. The final phase consisted of a comprehensive full-text review to confirm the studies' eligibility for inclusion in the final analysis.

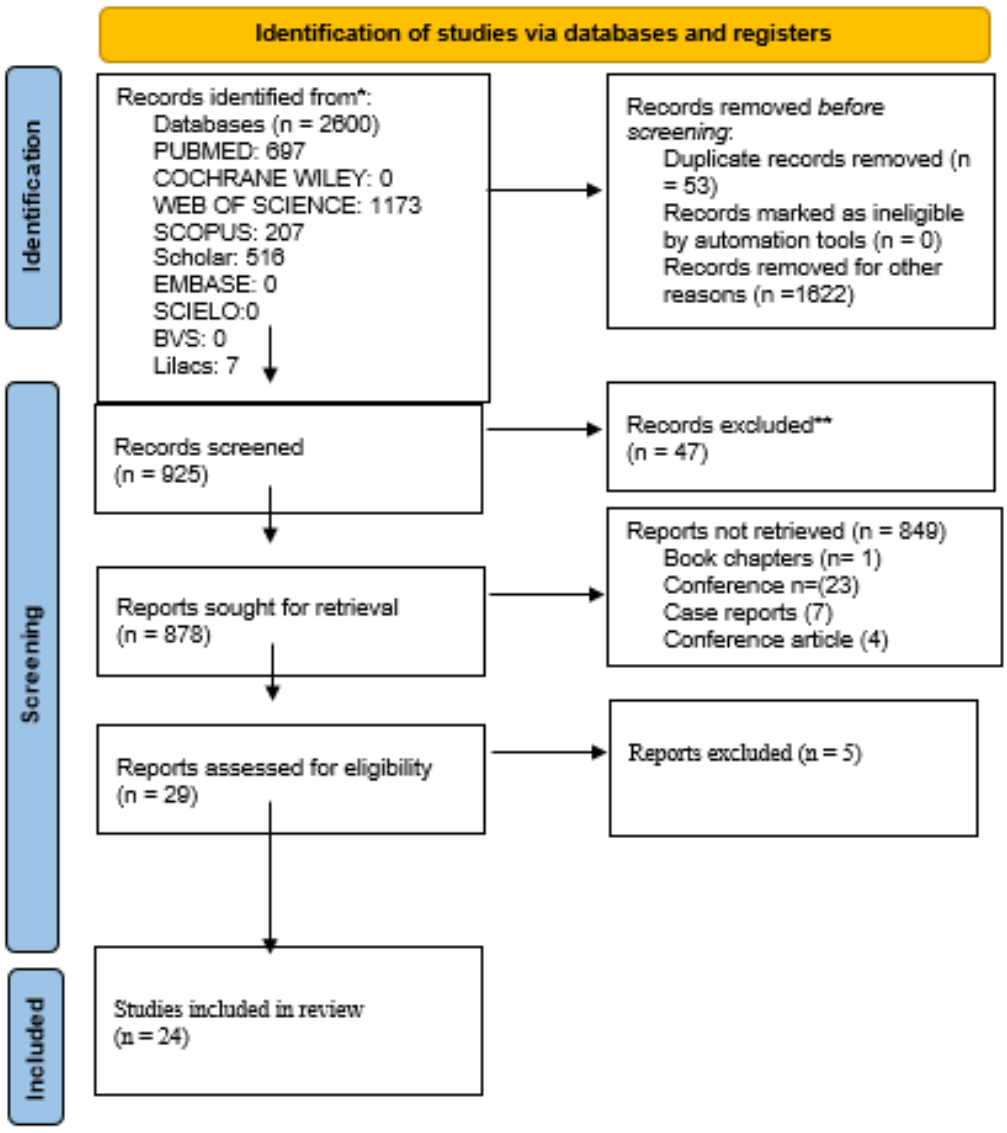
3 Results

3.1 Study selection

An exhaustive electronic search was conducted between May 2024 and January 2025, yielding an initial total of 2,598 publications. No restrictions were applied regarding publication year and language. Following the removal of duplicate records and an initial title-based relevance screening, 1,677 publications were excluded for failing to meet the predefined eligibility criteria. This process resulted in 921 studies advancing to the abstract screening phase.

Subsequent abstract evaluations led to the exclusion of an additional 845 studies due to misalignment with the inclusion parameters. A comprehensive full-text review was then performed on the remaining studies, resulting in the exclusion of 5 further articles that did not meet methodological or thematic criteria. Ultimately, 24 studies fulfilled all inclusion criteria and were incorporated into the final analysis. The study selection process is illustrated in Figure 1, following the PRISMA 2020 flow diagram for systematic reviews.

Figure 1. PRISMA 2020 flow diagram for new systematic reviews including searches of databases and registers only.



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3.2 Bardin content analysis

A systematic content analysis following Bardin's methodology was employed, encompassing pre-analysis, material exploration, and result treatment, followed by inference and interpretation. This approach aims to address the research questions and categorize key parameters guiding usability evaluations. The process adhered

to the principle of exhaustiveness, ensuring a comprehensive review of all selected articles, and the principle of representativeness, by analyzing the entirety of articles retrieved from representative databases. Subsequently, the corpus was subjected to deeper analysis to establish criteria and categories based on the extracted data[20].

Each article was examined in detail to identify recurring patterns and themes, resulting in the emergence of seven categories: Validation Method Employed; Number of Participants; Population Evaluated; Evaluation Criteria (Metrics); Context of Use (Scenarios); Confounding Factors; Statistical Analysis.

3.2.1 Validation method employed:

The studies classified usability tests into formative/qualitative and summative/quantitative categories. Additionally, several studies emphasized heuristic evaluation, which employs predefined criteria and principles to assess system or equipment interaction, particularly in defining tasks for usability assessments[8]. The differences between Heuristic Evaluation and Usability Testing are summarized in Table 1.

Table 1.: Differences between Heuristic Evaluation and Usability Testing according to the study

Criterium	Heuristic Evaluation	Usability Testing
Definition	Evaluation based on guidelines (heuristics) conducted by experts.	Practical tests where real users perform specific tasks to identify usability issues.
Participants	Usability or human factors experts.	End-users' representative of the target audience, such as healthcare professionals and patients.
Objective	Identify design deficiencies, such as system status visibility issues and error prevention.	Assess the efficiency, safety, and effectiveness of the device in real or simulated use.
Types of Data	Qualitative data based on design criteria and expert observations.	Quantitative and qualitative data, including task completion times, errors, and user feedback.
Cost	Generally, it is cheaper and faster.	It can be more expensive due to the need to recruit participants.
Time Required	Fast, it can be completed in a few hours or days.	More time-consuming, requiring planning, execution, and analysis.
Type of Feedback	Technical, based on best design practices.	Practical, based on user experience and behavior.
Examples of Heuristics	System status visibility, consistency, error prevention.	Not applicable, as it focuses on the user experience.
Applicability	Useful for identifying general design and usability issues before user testing.	Essential for understanding how the product functions under real-world conditions and detecting operational errors.
Advantages	Quick, cost-effective, and efficient in identifying common issues.	Identifies real-world problems that affect users. Provides detailed insights into actual use, revealing issues that experts might overlook.
Limitations	May not detect specific issues that arise in real-world use.	Requires more time, resources, and logistical planning; results may be influenced by user behavior.
Complementarity	Identifies deficiencies that can be further tested in practical environments.	Issues identified during use can be explained by design deficiencies detected in heuristic evaluation.

Simulated tests adhered to FDA and ISO 62366 recommendations for evaluating the safety of medical devices[17]. The design of clinical studies assessing usability followed methodological frameworks to clinical trials[21]. Data collection included quantitative measures such as the number of errors or usage failures, task completion times, and statistical analysis of errors, as well as qualitative insights on user experience[6, 17, 22].

3.2.2 Number of participants:

The articles discussed the required number of participants for summative or pre-clinical validation to ensure statistical validity and robustness in usability testing, typically exceeding the sample sizes used in formative analysis[9]. Most studies followed FDA guidelines, recommending a minimum of 15 participants per group or at least 25 intended users to identify 90–97% of usability issues[17]. However, studies such as Parreira P. et al. (2020) adhered to ISO 62366-2 regulations, suggesting a minimum sample of 8–10 intended users to detect 95% of usability problems[17].

Sample size calculations were based on a cumulative probability formula[23]: R=1−(1−p) nR = 1 - (1 - p)^ nR=1−(1−p)n. Where R represents cumulative probability, p is the probability of a single test detecting a usability problem (typically set at 0.31), and n is the number of participants. A sample size of n=8 was deemed adequate to achieve a 95% detection rate. For formative analysis, a minimum of five participants was considered sufficient, while summative analysis required at least 15 participants, following statistical guidelines outlined in AAMI/ANSI-HE75:2009[23].

Clinical trials conducted by Mohamed Elfadil O. and Lamaj G.[12, 22] employed samples of 60 participants, distributed across five groups with an average of 12 participants per group. Lamaj study[22] included a sample of 154 patients, achieving a 99% probability of detecting usage errors with a 3% occurrence rate.

3.2.3 Evaluated population

In most studies, the target population comprised healthcare professionals; however, some studies included mixed populations with patients participating in

usability tests. Eligibility criteria were applied to select users and recruitment sites. Variability was observed among professionals regarding their experience with the equipment and familiarity with the technology[8], as well as among inexperienced participants. Participants underwent usage training prior to testing to facilitate interaction with the equipment, enhance familiarity, and improve comprehension.

Evaluators employed user manuals, instructional videos, and presentations related to product use[10,12-15,24]. In certain cases, only the user manual was provided in formal training[25]. Lageat[13] conducted successive usability validations, demonstrating that increased reliance on the user manual during training significantly reduced the percentage of usage errors, regardless of participant experience. This finding supports previous research emphasizing the necessity of training prior to usability evaluations.

Coldewey et al. [25] identified prior experience with similar equipment and previous training as exclusion criteria, as these factors could influence test outcomes. The same study highlighted limitations related to the participants' high educational levels and the narrow age range (26–35 years), which may not accurately represent the broader population intended to use the equipment[26].

3.2.4 Evaluation criteria (metrics)

The metrics used in the studies were classified into primary and secondary categories[26,27], focusing on critical tasks evaluated in summative usability tests. Primary metrics were more specific and included factors such as the initial user-equipment interaction context, the number of tasks proposed and goals achieved, procedure completion time, and the type and frequency of errors. Secondly, metrics encompassed aspects of user interaction and satisfaction with the equipment, addressing more complex issues such as documentation of usage errors, operational difficulties, near-miss incidents, and successful task completions.

Usage errors were defined as actions or omissions leading to unintended or unexpected outcomes by the user [5, 25, 28]. Demographic data collection questionnaires were administered immediately after the evaluations to minimize bias[22]. The evaluated metrics enabled comprehensive result analysis and were

collected through specific usability testing questionnaires. Among these, the System Usability Scale (SUS) stood out as a quantitative method widely used to evaluate various technologies and successfully applied in the medical field for assessing home medical devices. SUS analysis involved calculating mean scores, standard deviations, and 95% confidence intervals[29]. The questionnaire typically consisted of 10 to 14 items, scored using a five-point Likert scale. A favorable usability score was defined as any score exceeding 80.8[22].

The quantitative questionnaire was complemented by a post-test qualitative questionnaire featuring open-ended questions about the user experience, with responses categorized for subsequent analysis[22]. Studies also considered participant feedback as a critical component of the evaluation process[14].

3.2.5 Context of use (scenarios)

Usability tests were conducted in simulated environments, including controlled laboratory settings and hospital scenarios. Simulation-based testing is recommended by both the FDA and IEC 62366 standards as a safe and effective method for evaluating new medical devices[17]. Usability evaluation in these contexts ensures that prototypes meet requirements for efficacy, efficiency, safety, and user satisfaction, while minimizing usage errors. These tests are critical for gathering feedback to inform design improvements and to identify user-equipment interaction challenges[10, 11, 15, 16, 25].

The simulated environments were designed to closely mirror real-world scenarios in which tasks would be performed authentically[9, 17]. Tasks were structured into scenarios that could be completed in any sequence[12], with selections based on instruction manuals and formative evaluations. Critical tasks were identified according to FDA guidelines, focusing on those that could lead to serious harm if performed incorrectly[13, 28]. Upon scenario completion, debriefing sessions were conducted to identify the root causes of errors made during tests[13].

Lageat et al.[13] highlighted that simulated studies do not fully replicate real-world conditions and may influence user feedback and performance. Beltzer et al.[26] and Pager et al.[10] observed that experienced participants often expressed neutral

or negative sentiments regarding their confidence in device usage and understanding of the instructions for use (IFU). Conversely, inexperienced participants provided more varied responses, frequently including positive observations. Nevertheless, both studies emphasized that usability testing in simulated environments is crucial in the development of medical devices, as it helps to identify and correct issues that might otherwise go unnoticed[10, 28].

3.2.6 Confounding factors

Several confounding factors were identified that may have influenced the outcomes of the usability tests. Small sample sizes, although compliant with existing regulations and guidelines, may limit the generalizability of the findings[4]. Variability in the participants' prior training and technical skills could have impacted test results[8]. A positive correlation was observed between the clarity of user instructions and the perceived quality of the product, highlighting the importance of well-designed instructional materials[30].

Methodological precision was also a concern, as factors such as the timing of simulation initiation (immediate vs. delayed start) can introduce variability in the results[8, 12]. The exclusive reliance on simulated, non-clinical studies without evaluating the impact on clinical outcomes may limit the applicability of the findings to real-world settings[12]. Furthermore, the absence of control or comparator groups in most studies reduces the robustness of the conclusions drawn[13].

The presence of evaluators during testing scenarios may have influenced participant behavior, potentially introducing performance bias[30, 10]. Initiating usability assessments immediately after training may not accurately reflect real-world usage conditions, where delays between training and application are common[6]. The use of different validation questionnaires, other than the standardized System Usability Scale (SUS), with proprietary Likert-scale items, may have introduced inconsistencies in data interpretation[10, 14]. Lastly, repetitive task performance during testing may not mirror actual daily use, affecting the ecological validity of the results[19, 23].

3.2.7 Statistical analysis

Data was systematically organized and analyzed using appropriate statistical methods based on intra-study comparisons. Su et al.[14] conducted a comparative analysis of results obtained from various evaluation questionnaires. The System Usability Scale (SUS) was employed to measure user perception, while the NASA-TLX was used to assess mental, physical, and temporal workload. The Technology Acceptance Model (TAM) evaluated perceived usefulness and ease of use. Internal consistency was assessed using Cronbach's alpha, and correlations between SUS scores and factors such as user satisfaction, task assistance, comparison metrics, and perceived utility were analyzed using Spearman's correlation coefficient[14].

Liu et al.[5] and Candidori et al.[15] performed comparative task analyses across different equipment types. The Friedman test was applied for non-parametric comparisons of task performance. For comparative analyses of task completion times, ANOVA was utilized. Additionally, post hoc analyses were conducted using the Wilcoxon test with Bonferroni correction to adjust for multiple comparisons, thereby ensuring the robustness of the statistical findings[5,15].

3.3 Analysis of evidence quality and risk of bias (GRADE-ROBINS-I)

The risk of bias analysis was conducted using the GRADE framework, with the study registered on the GRADEpro platform via Cochrane (GRADEpro GDT: Guideline Development Tool [Software], McMaster University and Evidence Prime, 2024)[30]. Each article was independently assessed based on the PICO research question framework. The characteristics of the studies included in the systematic review are detailed in Table 2 . Subsequently, a combined analysis of the selected articles was performed, focusing on 11 key elements for outcome evaluation: Study Design, Population, Intervention, Comparator, Outcome, Sample Size, Risk of Bias, Consistency, Direct Evidence, Precision**,** and Quality of Evidence**.** The assessment of evidence quality and bias risk is detailed in Table 3.

Table 2. Characteristics of studies included in the systematic review, categorized by study design, population, intervention, comparator, and outcomes.

Study	Study Design	Population (P)	Intervention (I)	Comparator (C)	Outcome (O)
Haig et al., 2020	Observational study, simulated usability assessment	Surgical teams experienced in laparoscopic surgery	Use of the Versius robotic system in critical and non-critical tasks	Not applicable (validation study without control group)	Safety and efficacy in using the system in a simulated environment
Aune et al., 2023	Observational study validated in three iterative phases, including technical development, clinical studies, and usability testing	Healthy term newborns aged 1 to 15 days, weighing 2500 g to 4500 g	Smartphone-based system to assess bilirubin levels	Total Serum Bilirubin (TSB) and Transcutaneous Bilirubin (TcB)	Correlation between bilirubin levels estimated by the system and TSB and TcB values
Black et al., 2023	Observational study using heuristic evaluation	Usability experts	Evaluation of 5 pulse oximeter models using 15 usability heuristics	No direct comparator: different devices were assessed	Identification of usability issues and severity
Parreira et al., 2020	Observational study (qualitative and quantitative)	Nurses from public and private hospitals with experience in intravenous administration	Use of a double-chamber syringe for intravenous administration	Traditional syringes	Effectiveness, efficiency, and user satisfaction
Elfadil et al., 2022	Observational study, simulated use	Patients and healthcare professionals using enteral feeding systems	Use of a portable enteral feeding system to enhance patient mobility	Traditional feeding methods (gravity/infusion pumps)	Success rate in simulated use and mobility evaluation
Clebone et al., 2019	Observational study, usability approach	Anesthesiologists from 9 institutions	Development and testing of Pedi Crisis 2.0 mobile app	No comparator	Time to locate critical information and usability evaluation
Lageat et al., 2021	Iterative human factors study with formative tests and final validation study	Patients' caregivers and healthcare professionals, individuals with dexterity limitations	Use of a disposable push-on-skin autoinjector for subcutaneous injections	Conventional autoinjector devices and manual injectors	Success rate in critical tasks and user satisfaction
Rätz et al., 2024	Observational study with a mixed-methods approach (qualitative and quantitative), using an unsupervised simulated scenario	Healthy participants, including physiotherapists with varying levels of experience	Use of a portable rehabilitation device combining active grasp movements and passive pronosupination	Conventional robotic rehabilitation devices that do not offer sensory feedback	Usability assessment, haptic feedback, and perceived safety during use
Lamaj et al., 2022	Multicenter observational study with a mixed-methods approach, including usability tests, qualitative questionnaires, and SUS scale	Cancer patients undergoing chemotherapy and healthy volunteers	Use of the PointCheck device for severe neutropenia screening without the need for blood sampling	Traditional neutropenia monitoring methods based on blood samples	User-perceived usability, ease of use, and confidence in the device

Table 2. Characteristics of studies included in the systematic review, categorized by study design, population, intervention, comparator, and outcomes (cont.).

Study	Study Design	Population (P)	Intervention (I)	Comparator (C)	Outcome (O)
Reitz et al., 2021	Observational study with mixed methods (qualitative and quantitative), using simulation and standardized questionnaires	Lay users and healthcare professionals (HCPs), with no prior experience with APD	Use of two APD cycler models: sleep safe harmony (Fresenius Medical Care) and Home Choice Pro (Baxter International)	No direct comparator; focus on evaluating different APD cycler models	Usability, perceived workload, execution time, and rate of operational difficulties
Santos-Costa et al., 2022	Observational study with mixed methods (qualitative and quantitative), using simulation and standardized questionnaires	Nurses involved in peripheral intravenous catheterization (PIVC) procedures	Development and usability assessment of an innovative Peripheral Intravenous Catheterization Pack (PIVC-P), tested in a simulated clinical setting	Traditional materials and methods used for PIVC procedures	Primary outcomes: (i) Number of tasks and goals achieved, (ii) Procedure execution time, (iii) Type and frequency of errors. Secondary outcomes: (i) Intention to use, (ii) Satisfaction with usability.
Oliveira et al., 2021	Cross-sectional, quantitative, exploratory descriptive study, with task in a controlled environment	Nursing professionals from two pediatric ICUs (42 with BI-1 and 30 with BI-2)	Use of two volumetric infusion pump models (BI-1 and BI-2) to infuse solutions in a set volume and time	No external comparator; focus on comparison between the two infusion pump models (BI-1 and BI-	Success rate in task execution and compliance with the operation checklist
Coldewey et al., 2023	Randomized controlled study in a simulated resuscitation scenario with two comparative groups	laypersons without prior experience in medical emergencies or AED devices	Use of two AED models: Trainer 3 (Philips Medical Systems) and LIFEPAK CR-T (Medtronic Physio-Control)	No external comparator; focus on comparing two different AED models	Time to deliver the first shock (Time to Shock, TTS) and occurrence of usage errors during the simulation
Lageat et al., 2021	Iterative study with three formative studies and one validation study, including simulated tests with moderators and qualitative questionnaires	patients, caregivers, and healthcare professionals, with or without experience with autoinjectors	Use of BD Intevia™ 1 mL push-on-skin autoinjector for subcutaneous administration, with varying levels of training and access to instructions for use (IFU)	No direct comparator; focus on evaluating the autoinjector prototype and the effectiveness of instructions and training	Success rate in performing critical tasks, error rates, and subjective evaluation of user experience
Chaniaud et al., 2020	Observational study with a mixed-method approach (quantitative and qualitative), including practical tests and questionnaires	University students (average age: 20.72 years) with varying levels of prior health knowledge	Use of two medical devices (iHealth BP7 and iHealth PO3) for collecting physiological data in a simulated context	No external comparator; focus on evaluating devices relative to users' prior knowledge	Effectiveness (handling errors), efficiency (execution time), and satisfaction (SUS score)
Petracca et al., 2021	Observational study with mixed methods (qualitative and quantitative), using exploratory and confirmatory focus groups	Patients with hemophilia A, caregivers, patient association representatives, and hematologists	Use of a mobile app (ePRO) developed for collecting patient-reported outcomes in hemophilia A	No direct comparator; focus on validating and refining the app based on user feedback	Usability evaluation (MAUQ scale), user satisfaction, and data collection effectiveness

Table 2. Characteristics of studies included in the systematic review, categorized by study design, population, intervention, comparator, and outcomes (cont.).

Study	Study Design	Population (P)	Intervention (I)	Comparator (C)	Outcome (O)
Poncette et al., 2022	Observational study with mixed methods (qualitative and quantitative), using simulation tests and 'think-aloud' protocols	Anesthesiologists, ICU nurses, and respiratory therapists	Use of the Vital Sync 2.4 system with pulse oximetry and capnography sensors, enabling real-time remote monitoring via tablets	No external comparator: evaluation based on comparison between two interface design versions (A and B)	Efficiency (deviation from normative path), effectiveness (task completion rate), and perceived usability (SUS score)
Beltzer et al, 2024	Observational study with mixed-method approach, including practical tasks and post-session interviews.	Experienced with CGM and inexperienced	Use of the Fiber Sense CGM system for continuous glucose monitoring in a simulated environment	No direct comparator; focus on prototype evaluation without prior training	Success rate in executing critical tasks and System Usability Scale (SUS) score
Pager et al., 2020	Multicenter observational study with a mixed-method approach, including formative and human factors validation studies	Patients with chronic diseases, patients with motor limitations, and healthcare professionals	Use of a 2.25 mL prefilled glass syringe with an 8 mm ultra-thin wall needle for subcutaneous administration of viscous solutions	2.25 mL prefilled glass syringe with a 12.7 mm special thin wall needle	Success rate in complete dose delivery, ease of use, and participant preference
Liu et al., 2019	Observational study with mixed approach: heuristic evaluation and simulated use testing	Nurses from five clinical units across three public hospitals, stratified by clinical experience (≤8 years and >8 years)	Evaluation and comparison of four infusion pump models, two traditional and two smart pumps with drug libraries	No direct comparator, only comparison among different infusion pump models	Performance in critical task execution, error frequency, and usability perception
Jiang et al., 2020	Prospective observational usability study, evaluating task performance, workload, and user experience	Respiratory therapists with experience in ventilator maintenance	Usability evaluation of the maintenance interface of three ventilators (Evita 4, Servo I, and Boaray	Comparison of the three ventilators to identify usability differences	Task completion time, error rate, physiological workload (eye fixation duration), perceived workload (NASA-TLX), and user experience
Deshpande et al., 2024	Observational study with mixed approach: heuristic evaluation by specialists and usability testing with patients	post-surgical adult patients without opioid use disorder and specialists (physician, surgeon, educator)	Use of the "Opiate Program for You" (OPY) app to guide patients on opioid administration, discontinuation, and disposal post-surgery	No direct comparator; focus on identifying usability issues of the OPY app	Perceived usability, ease of use, interface clarity, and educational content effectiveness

Table 2. Characteristics of studies included in the systematic review, categorized by study design, population, intervention, comparator, and outcomes (cont.).

Study	Study Design	Population (P)	Intervention (I)	Comparator (C)	Outcome (O)
Su et al., 2023	Pilot observational study with a mixed-method approach (qualitative and quantitative), including functionality testing and perception questionnaire	respiratory therapists experienced in postural drainage and percussion techniques (PD+P).	Use of the **COAD-MoAcCare system** to remotely guide and monitor PD+P during home pulmonary rehabilitation.	Conventional telemonitoring methods (video calls and phone calls).	Usability, perceived workload, and accuracy in PD+P execution.
Candidori et al., 2024	Observational study with mixed approach (quantitative and qualitative), using emergency simulation and statistical analysis	Two groups (60): 17 doctors (gynecologists and obstetricians) and 45 non-doctors (students and professors)	Use of the BAMBI device for uterine tamponade, with different training methods for non-medical participants	Traditional CBT device (Condom Balloon Tamponade) used by doctors as a comparison solution	Procedure success rate, tamponade efficacy, and execution time

Notes:

1. All studies followed observational designs with usability assessments, qualitative, or mixed methods.
2. Some studies lacked direct comparators and instead focused on validating new devices.
3. Primary outcomes were mainly usability, safety, efficiency, and satisfaction.
4. Simulated environments were commonly used for usability validation.

Table 3. Assessment of Evidence Quality and Bias Risk in Usability Studies.

Study	Sample Size	Risk of Bias	Consistency	Direct Evidence	Precision	Quality of Evidence
Haig et al., 2020	68 surgeons	Low, no critical task failures observed	Consistent: 98% of tasks successfully completed	Direct evidence: study conducted in a realistic simulated environment	High precision, with few errors identified	High, with recommendations for future pre-clinical testing
Aune et al., 2023	16 healthcare professionals, 201 newborns	Moderate, mitigated through iterative processes and clinical validations	High consistency across different phases	Direct evidence based on clinical studies conducted in hospitals	High, with significant correlation (r=0.85) for TSB[a]	High, with CE[b] approval as a medical device
Black et al., 2023	2 usability experts	Moderate; bias controlled through evaluator training and result validation	High, with consistent identification of usability issues across similar devices	Direct evidence from evaluations conducted in simulated environments with real devices	Good, with systematic data collection and detailed problem analysis	High, with practical application suggested for future evaluations and training
Parreira et al., 2020	68 nurses	Moderate; controlled through iterative methodology and validation with end-users	High; consistent results across study phases despite reported difficulties in using the functional prototype	Direct evidence obtained from simulated tests conducted by nurses with varying levels of experience	High; quantitative and qualitative data converge on a positive usability assessment of the device	High, with potential design adjustments before clinical implementation
Mohamed Elfadil et al., 2022	68 (healthcare professionals, patients, and caregivers)	Moderate; controlled through iterative methodology and validation with end-users	High; consistent results across study phases despite reported difficulties in using the functional prototype	Direct evidence obtained from simulated tests conducted by nurses with varying levels of experience	High; quantitative and qualitative data converge on a positive usability assessment of the device	High, with potential design adjustments before clinical implementation

Table 3. Assessment of Evidence Quality and Bias Risk in Usability Studies (cont.).

Study	Sample Size	Risk of Bias	Consistency	Direct Evidence	Precision	Quality of Evidence
Lageat et al., 2021	86 (healthcare professionals, caregivers, and patients)	Low, reduced through training and improvements in design and instructions	High; progressive reduction of usage errors over successive testing cycles	Direct evidence based on realistic simulations with actual devices in multiple contexts	High, with strong correlation between design improvements and error minimization	High, recommended for clinical implementation due to successful testing outcomes
Rätz et al., 2024	13 (patients and physiotherapists)	Low, controlled through simulated environments and clear instructions	High, consistent results with evaluations of similar devices	Direct evidence from laboratory experiments in realistic scenarios	High; short setup times and overall positive device acceptance	High, with potential for clinical application in home and group rehabilitation
Lamaj et al., 2022	154 patients	Moderate, controlled through multi-environment testing and inclusion of diverse user profiles	High, consistent results across participants with varying levels of experience and age	Direct evidence from controlled environment simulations and multicenter studies	High, with an average SUS[3] score of 86.1, indicating excellent usability	High, with potential for home application to improve neutropenia monitoring
Beltzer et al., 2024	30 patients	Moderate, bias mitigated through iterative analysis and detailed feedback collection	High, consistent results across two user groups despite differences in experience	Direct evidence from realistic simulations in controlled environments	SUS[3] scores: 47 (Group 1) and 52 (Group 2), below the acceptance threshold of ≥68	High, with recommendations for design and instructional improvements
Su et al., 2023	11 patients and 1 respiratory therapist	Moderate, mitigated through systematic evaluation and expert validation	High, with consistent results across different participants and usability evaluations	Direct evidence from realistic simulations in a controlled home environment	High, with SUS[3] score of 74.1 and 97.5% accuracy in PD+P[4] execution	High, with potential for clinical application after improvements and future studies

Table 3. Assessment of Evidence Quality and Bias Risk in Usability Studies (cont.).

Study	Sample Size	Risk of Bias	Consistency	Direct Evidence	Precision	Quality of Evidence
Pager et al., 2020	104 (healthcare professionals, caregivers, and patients)	Low, controlled through iterative methodology and realistic simulations	High, consistent results across different user groups and contexts	Direct evidence from multicenter simulated studies using real devices	High, with significantly higher success rates for the 8 mm syringe (63%) compared to the 12.7 mm syringe (42%)	High, with recommendations for clinical implementation and design improvements
Coldewey et al., 2023	28 physicians	Moderate, mitigated through randomization and controlled simulation environment	High, with consistent results across both study groups, confirming significant differences between devices	Direct evidence obtained through realistic resuscitation scenario simulations	Good, with a significant difference in median shock delivery time: AED[5]1 = 61 s, AED[5] = 93.5 s ($p < 0.05$)	High, with recommendations for device design improvements and the development of better interface practices
Liu et al., 2019	16 nurses	Moderate, mitigated through prior familiarization with devices and detailed error analysis	High, consistent results across different participants and validation of heuristic findings	Direct evidence from realistic simulated tests and detailed heuristic evaluation	Good, with execution times and error rates varying across models, highlighting key differences	High, with clear recommendations for clinical device selection decisions
Deshpande et al., 2024	5 patients	Moderate, mitigated through iterative design based on collected feedback	High, with consistent results between heuristic tests and patient usability evaluations	Direct evidence obtained through interactive prototype simulations and qualitative interviews	High, with high ease-of-use scores (SEQ[6] ranging from 6.4 to 6.7 on a 7-point scale)	High, with clear recommendations for improving the app's design and functionality in future versions

Table 3. Assessment of Evidence Quality and Bias Risk in Usability Studies (cont.).

Study	Sample Size	Risk of Bias	Consistency	Direct Evidence	Precision	Quality of Evidence
Candidori et al., 2024	62 (healthcare professionals, instructors, and students)	Low, mitigated through controlled simulation and iterative evaluation methodology	High, with consistent results across different groups and training modes	Direct evidence obtained through realistic simulations in laboratory and hospital environments	High, with the BAMBI device showing faster setup times and higher success rates compared to CBT[7]	High, with recommendations for design improvements and large-scale training
Reitz et al., 2021	13 (physiotherapists and patients)	Moderate, mitigated through standardized training, but influenced by variations in participants' clinical experience.	High, but with variations in task execution times between different peritoneal dialysis cycler models	Based on laboratory simulations, without clinical validation, but with realistic scenarios for user-device interaction evaluation.	SUS[3] score of 87.5 for one model and 77.5–55 for the other, suggesting significant usability differences between devices.	High, but recommendations include clinical evaluation before full adoption.
Santos-Costa et al., 2022	13 nurses	Moderate, mitigated through a simulated environment and structured checklist, but bias may stem from nurses' prior familiarity with similar materials.	High, as nurses' performance was consistent across different evaluation aspects (time, errors, satisfaction).	Based on structured practical tests, evaluating nurses' technical performance, simulating specific clinical procedures.	High and homogeneous SUS[3] scores, with less variability among participants.	High, with greater immediate applicability in hospital settings, as it simulates a common nursing procedure.
Oliveira et al., 2021	72 nursing technicians and nurses	Moderate, risk mitigated through controlled environment and prior participant training	High, consistent results between the two participant groups and pump models	Direct evidence obtained through realistic simulations conducted in controlled environments	Good, with an average task completion rate of 91.7%, and greater efficiency observed in BI-1[8]	High, with recommendations for pump design improvements and continuous training

Table 3. Assessment of Evidence Quality and Bias Risk in Usability Studies (cont.).

Study	Sample Size	Risk of Bias	Consistency	Direct Evidence	Precision	Quality of Evidence
Chaniaud et al., 2020	137 patients (blood pressure monitor test) and 147 (oximeter test)	Moderate, controlled through homogeneous participant selection and simulated environment	High, consistency observed across different levels of user knowledge and device usability	Direct evidence obtained in controlled laboratory settings with standardized usability measures	Good, significant correlation between prior knowledge and error reduction (r=-0.191 for monitor, r=-0.263 for oximeter)	High, with practical recommendations for designers and health educators
Petracca et al., 2021	22 healthcare professionals and patients	Moderate, mitigated through continuous design iterations and inclusion of relevant stakeholders	High, with consistent results across different prototype refinement phases	Direct evidence obtained through realistic simulations and iterative app validation	High, MAUQ[9] score increased from 5.32 to 6.20 between two test rounds	High, with recommendations for continued longitudinal evaluation during the POWER study
Poncette et al., 2022	10 physicians	Moderate; risk mitigated through iterative approach and continuous design improvements based on user feedback	High; significant improvements in efficacy and efficiency of the revised design (B) compared to the original (A)	Direct evidence obtained through realistic simulations in hospital settings with actual devices	High; significant increase in SUS[3] score from 68.5 (design A) to 89 (design B), p=0.003	High, supporting clinical implementation and continuous improvement of monitoring system interfaces
Jiang et al., 2020	16 respiratory therapists	Moderate; small sample size may reduce representativeness	Moderate; heterogeneous participant experience may affect reproducibility	Low to Moderate; use of both objective and subjective measures, but may not cover all practical challenges	Moderate; robust statistical testing, but variability in participant experience may affect results	Moderate; good methodology, but limited general applicability due to the restricted number of ventilators tested
Clebone et al., 2019	46 anesthesiologists	Low; diverse sample reducing bias	High; testing in multiple scenarios with iterative feedback	High; simulated testing with anesthesia professionals	High; excellent System Usability Scale scores	High; strong methodological foundation, replicable for other medical applications

Notes:

[1] TSB (Total Serum Bilirubin) / TcB (Transcutaneous Bilirubin): Bilirubin measurement methods used for neonatal jaundice assessment.
[2] CE Approval: Medical device approved under European Union regulations for clinical use.
[3] SUS (System Usability Scale): Standardized usability questionnaire; ≥68 indicates good usability.
[4] PD+P (Postural Drainage and Percussion): Therapy used for pulmonary clearance.
[5] AED (Automated External Defibrillator): Evaluated in simulated emergency scenarios.

The GRADE analysis facilitated a comprehensive evaluation of usability studies, addressing critical aspects that directly influence the reliability and applicability of results in practical settings. The majority of articles exhibited a moderate risk of bias, with the exception of some randomized clinical trials, which demonstrated lower risk levels. In specific cases, comparisons were made with other evaluation methods, such as user interviews, rapid prototyping, and the application of specialized standards.

The analysis revealed that precision and evidence quality ranged from moderate to high, with only a few instances of low-quality evidence, particularly when assessing parameters like safety, ease of use**,** and efficacy. For example, the initial quality of evidence in studies utilizing heuristic methods was generally moderate when compared to studies incorporating direct user feedback, which often achieved very high evidence quality.

Nevertheless, the studies employed robust and controlled methodologies, including repeated tests, standardized measurements, and rigorous statistical analyses. Variations in results due to differences in sample characteristics did not compromise the overall validity of the studies, as samples were selected based on FDA and ISO 62366-2 regulatory guidelines.

The application of these principles enhances confidence in the efficacy and safety of electromedical devices, providing precise reflections of real-world performance. This, in turn, improves decision-making processes and strengthens confidence in recommendations regarding technology adoption.

Discussion

The validation processes highlighted the consistent application of human factors engineering principles as methodological references. The rigor with which these methodologies were implemented ensured the reliability and robustness of the results. However, applicability may be compromised due to confounding factors (Section 3.2.6). Variations among studies were primarily attributed to differences in equipment characteristics, sample sizes, development stages, and testing protocols. Most studies

were preclinical usability assessments[17], indicating that the majority of products were still in the prototype validation phase.

Evidence quality was rated as moderate, constrained by indirect evidence and imprecision from prototype testing in simulations. This underscores the need for real-world studies with finalized devices to confirm efficacy. Heuristic analysis by human factors experts detects ~60–70% of usability issues[8], with three to five evaluators optimizing error detection, while a single evaluator identifies ~35% of critical issues [8,31].

In the final stages of development, user testing is key to summative validation, allowing users to operate equipment in predefined simulations without instructor assistance during pre-clinical trials[28]. Formative (developmental) and summative (final) validations complement each other at different lifecycle stages. Lageat et al.[13] used summative evaluation with real users, while Pager et al.[10] applied formative testing with prototypes. Task criticality was crucial in assessing error severity, especially in summative evaluations[8].

Sample size determination in these studies adhered to guidelines established by the FDA and ISO 62366, ensuring that the number of participants reflected the intended user population for usability testing. A key consideration in sample selection was the categorization of participants, with FDA recommendations emphasizing the need for a sample that is representative of the target user group. Studies with small samples (n=5) identified 55–85% of usability issues[23]. A systematic review[31] refined these estimates, indicating that n=15 detected 90–97%, n=20 identified 95–98.4%, and n=50 achieved nearly 98–100%, though full accuracy remained challenging.

Variations in sample sizes contributed to differences in the complexity and fidelity of errors identified. Studies employing larger samples demonstrated greater variability in findings, attributing these differences to methodologies outlined in specific research[23,31,32].

The need for larger sample sizes is particularly evident in summative usability tests, where the final prototype is evaluated in a controlled environment prior to clinical use. Both ISO 62366 and the FDA recommend sample sizes of at least 15 to 20

intended users for summative testing. These recommendations consider the device's risk classification, testing protocols, and risk evaluation criteria. However, the sample size may vary depending on the interaction with the equipment, the task complexity, or the diversity of user categories (e.g., general users, healthcare professionals, or specific environments).

To minimize validation bias, formative test participants should not join summative tests. The recommended formative sample size is typically n=5 [10,12,13,15,33]. Santos-Costa et al. [27] used 5 participants for formative and 13 for summative testing, aligning with prototype evaluations. Oliveira et al. [16] employed 72 participants for summative testing (42 for Model 1, 30 for Model 2), highlighting the need for greater robustness in preclinical simulations to ensure device safety and efficacy.

According to Sauro and Lewis[32], determining the appropriate sample size for summative studies should begin by clearly identifying the measurement objective. The greater the desired measurement precision, the higher the associated costs. Consequently, sample size estimation aims to optimize resource allocation, avoiding the recruitment of more participants than necessary[20].

However, when the sample size is fewer than thirty participants, the statistical power of the tests may be compromised. Similarly, overestimating the sample size can lead to unnecessary resource expenditure. Therefore, each study must carefully determine and calculate the optimal sample size for scientific validation, considering factors such as a ±5% margin of error, a 95% confidence level, and a 0.5% standard deviation[34].

Validation conducted in simulated environments has proven to be an essential tool for testing and evaluating the usability of medical devices. By eliminating unpredictable variables in controlled settings, this approach ensures consistent results focused on the execution of critical tasks, free from the interference of external factors. However, this method presents limitations due to its restricted generalizability to real clinical scenarios, which may involve additional complexities and stressors not replicated in simulations, ultimately affecting usability outcomes.

Human and clinical interactions may be underrepresented, particularly in studies with patients or complex devices. Simulations often overlook user familiarity with technology, hospital complexities, and illness-related psychological and physiological effects. Additionally, many studies lack appropriate comparators [10,12,13,15,21,22,25].

Petracca et al. [7] highlighted the impact of prior skills on remote monitoring use, while Pager et al. [10] emphasized the need for training in pre-filled syringe efficiency. Result replicability varies with device complexity and healthcare team training. Real patient interactions and unpredictable factors were not fully assessed, and sample sizes were often unrepresentative across clinical settings [21].

Including laypersons without formal training enhances validity for similar populations, though replicability varies with training levels [24,26]. To improve control in summative studies, Sauro and Lewis [32] suggest: ensuring task comprehension, providing unbiased full-scenario execution, preferring less experienced participants, assessing significance and variance, using homogeneous groups for statistical power, and allowing individuals to perform multiple critical tasks to enhance precision [11].

Conclusion

Usability evaluations for medical devices, guided by ISO 62366-2 and FDA regulations, are fundamental to ensuring safety and effectiveness. While heuristic evaluations are valuable in early development, they may overlook real-world clinical complexities, underscoring the need for validation in practical healthcare settings.

Although controlled simulations reduce variability, their generalizability remains limited due to human factors and confounding variables (e.g., user training disparities, absence of direct comparators, and deviations from clinical workflows).

Future studies should prioritize large-scale, real-world evaluations with diverse healthcare professionals and patient populations to enhance the clinical applicability of usability findings. Strengthening the integration of usability science into regulatory frameworks will be critical to optimizing medical device performance and patient safety.

Acknowledgments

We would like to express our sincere gratitude to researcher Juan Mora Delgado for generously sharing the AI tool he developed, which significantly contributed to the evaluation of confounding factors in this study.

We also extend our appreciation to the Brazilian National Research Council (CNPq) for supporting this systematic review and for providing financial assistance through the research grant (406417/2024-5) and the author's research fellowship (306225/2021-2).

Author's contributions

Ana Cristina Beitia Kraemer Moraes: Conceptualization, Methodology, Writing – Original Draft.

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All authors have read and approved the final manuscript.

Availability of data and materials

The data that directly support the findings of this study are available in Mendeley Reference Manager at https://www.mendeley.com/reference-manager/library/usability-references and in Rayyan reviews at https://new.rayyan.ai/reviews/1304107/screening.

Conflict of interest

The authors declare no conflict of interest.

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6. ARTIGO 3

Submetido após apreciação da banca examinadora para o periódico Journal of Medical Systems (Reference: Submission ID 338d88ba-e98a-4cfa-bc0f-9252cc021b59).

O repositório de dados (Datset) e as referências podem ser acessadas pelo link: Kraemer Moraes, Ana Cristina; Lund, Rafael; Scherer, Caroline; Corrêa e Silva, Milena; da Costa, Daniela; de Souza, Everton; Nascimento, Chiara (2025), “Clinical Ergonomic Evaluation of 3D-Printed vs. Commercial Video Laryngoscopes for Teaching and Practice”, Mendeley Data, V1, doi: 10.17632/dg9873krw6.1

Design, Usability Evaluation, and Educational Deployment of a 3D-Printed Video Laryngoscope for Airway Management Training: A Mixed-Methods Study

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ABSTRACT

Introduction:

The development of a 3D-printed video laryngoscope (VLP-3D) offers a low-cost, accessible alternative to commercial models, with potential for training and clinical use. This study evaluates its usability, safety, and feasibility in accordance with international regulatory standards.

Methods:

A mixed-method study was conducted with 60 physicians. Usability assessments included heuristic analysis (Zhang's principles), structured testing in simulated and clinical environments, and the System Usability Scale (SUS), subdivided into perceived usability and learnability. Objective metrics included intubation time, success rate, and laryngeal visualization time. Statistical analyses comprised Kruskal–Wallis, Pearson correlation, logistic regression, Wilcoxon tests, and meta-analysis (RevMan 5.4). Risk of bias was evaluated using ROBINS-I and GRADE.

Results:

VLP-3D and VLP-C achieved high usability scores (87.01 vs. 85.09; Grade A) with no significant differences in performance ($p > 0.05$). Perceived usability and learnability were equivalent (M = 3.25 and 2.56), with a weak but significant correlation in the VLP-3D group ($r = 0.241$; $p = 0.046$). Logistic regression showed low predictive power (Nagelkerke $R^2 = 0.14$) due to class imbalance. Meta-analysis confirmed procedural equivalence with existing literature.

Conclusion:

VLP-3D demonstrated comparable usability and efficiency to the commercial device, supporting its application in training and potential clinical use. The study also proposes a structured, reproducible framework for medical device usability evaluation.

Keywords: Airway management. Human factors. System Usability Scale. 3D-printed medical devices. Usability evaluation. Videolaryngoscope.

1 Introduction

The evaluation, validation, and clinical assessment of medical devices present significant challenges for the healthcare industry, especially for companies engaged in Research and Development (R&D). Regulatory compliance with institutions such as the Brazilian Health Regulatory Agency (ANVISA)[1,2], the U.S. Food and Drug Administration (FDA)[3], the European Medicines Agency (EMA), and the International Organization for Standardization (ISO)[4] is essential for product certification and market approval. Adherence to these standards ensures user safety, reduces operational errors, and improves the reliability and clinical effectiveness of health technologies[4]. Furthermore, integrating human factors and user-centered design is essential to ensure that devices align with the cognitive and ergonomic needs of their users[5].

The fabrication of video laryngoscopes (VLPs) through additive manufacturing (3D printing) emerged as a novel solution during the COVID-19 pandemic. It offers significant advantages in cost reduction, manufacturing scalability, and accessibility, particularly in resource-limited settings. Beyond its clinical utility, the 3D-printed video laryngoscope serves as a powerful tool for training and simulation in airway management[6]. Video laryngoscopes have become the gold standard for complex intubations due to their ability to offer indirect glottic visualization, improving outcomes in anesthetic and emergency procedures[7–10].

This study introduces the VLP-3D, a patented, low-cost, anatomical, and ergonomic 3D-printed video laryngoscope, developed using Design Thinking principles[11-14]**.** The development process began with user needs assessment, followed by usability interaction analysis, problem definition, prototyping, and iterative validation [5-6,9,10,14]. The prototype was modeled in Fusion 360 (Autodesk, USA) and fabricated using PLA Carbon, PETG, and antiviral PLA filaments[13]. A Huawei–Xiaomi micro-camera (7–8 mm) was integrated into the structure, enabling real-time image transmission to mobile devices. The blade and handle were ergonomically structured to optimize tongue displacement and glottic visualization, and a swallowtail joint mechanism ensured stability and controlled detachment [8,12].

Usability assessment is vital in the context of airway devices, where design errors can have life-threatening consequences [14,15]. This study applies validated protocols and international usability standards, including ABNT NBR IEC 60601-1:2010**,** ABNT NBR IEC 62366-1 and 62366-2**,** FDA³, and ISO 62366[1-4]**,** to compare the VLP-3D with a conventional commercial model (VLP-C). The evaluation combines heuristic analysis, structured usability testing, and subjective feedback instruments [5,16-18] such as the System Usability Scale (SUS)[18]**,** adapted for the Portuguese-speaking population[18,19,20].

One methodological innovation in this study is the separate assessment of perceived usability (operational ease) and perceived learnability (cognitive effort to learn), which adds analytical depth to user experience evaluation[21]. Additionally, a binary logistic regression model was applied to explore factors influencing intubation success, and a meta-analysis was conducted to position the results within existing literature[22].

The findings seek to verify whether 3D-printed medical devices can be valid, cost-effective alternatives to commercial devices, especially in educational and training contexts where simulation fidelity is essential[6,9-11,22]. The VLP-3D shows potential for promoting airway management skills among students and professionals, contributing to preparedness in emergency scenarios [23-27].

Moreover, this study proposes a structured and reproducible methodological framework for usability studies involving medical devices, bridging technical validation with educational applications[28-34]. By combining regulatory alignment**,** formative and summative testing**,** and statistical robustness, this research contributes both to airway management innovation and to the broader methodological development of usability science in medical ergonomics[35-39]**.**

2 Methodology

2.1 Demographic Data Collection and Heuristic Usability Assessment

Demographic information and previous experience with video laryngoscopes were collected to assess potential associations with device performance. A procedural protocol for airway access techniques[40] was used to define operational tasks and

identify critical functions of the videolaryngoscope, based on a systematic literature review and expert consultation within a medical simulation environment[22].

A heuristic[5] usability assessment was conducted following Zhang's 14 usability principles, performed by four human factors specialists[33-35,37-39]. This process aims to identify use errors (failure to complete a task) and use difficulties (task completion with effort). These insights informed the identification of critical tasks and supported the development of the usability study protocol[18,34-39].

Subsequently, four medical professionals and one usability technician conducted simulated task analyses involving repeated assembly and use of the device until successful laryngeal visualization and endotracheal intubation were achieved. The technician documented usability issues, including errors, hesitations, and inefficiencies, with special attention to task complexity and potential patient safety implications[34-36].

2.2 Methodological Approach for Usability Testing

This was a qualitative–quantitative experimental study comparing the usability of a 3D-printed video laryngoscope (VLP-3D) to a commercial model (VLP-C). The study followed international usability standards for medical devices[15-18].

Formative[40-43] evaluation was conducted from November 2022 to February 2023 at HUSFP Hospital, involving 11 physicians (intensivists and anesthesiologists). Summative evaluation took place between March and October 2024 at two institutions: HUSFP/UCPEL Hospital and EBSERH/UFPEL Hospital, with 60 physicians from different specialties.

Participants were selected based on a minimum of two years' clinical experience in orotracheal intubation. Those with less experience were excluded. Each participant received 20 minutes of standardized training, including device assembly/disassembly, videolaryngoscopy technique, and mannequin-based practice[9,22-25].

A single-blind procedure was implemented: the researcher collecting outcome data was unaware of the device used. Device identification was anonymized using internal

coding (VLP-1 or VLP-2), and data collection instruments were labeled with serial numbers only.

Each participant performed intubation[28] using both devices, starting with the commercial device (VLP-C) followed by the VLP-3D. Time to glottic visualization and endotracheal tube insertion were recorded, along with success/failure outcomes[9,22-25]. Participants then completed the System Usability Scale (SUS)[19-21] questionnaire and a semi-structured feedback form[34-38].

Task execution occurred in simulated environments (Laerdal Airway Management Trainer) and clinical settings (ICUs and operating rooms)[9,22-25]. Devices used size 4 blades, and participants could use guidewires if needed. A usability technician documented performance and conducted post-task interviews [1,2,34,35].

2.3 Regulatory-Based Sample Selection for Usability Testing

Sample size followed FDA[3], ISO 62366[4], and AAMI/ANSI HE753 guidelines for usability studies[33-35,44]. The involved 11 users, meeting the minimum of 10 recommended for identifying 80–90% of usability problems. The included 60 users—30 per hospital site—ensuring robust statistical power (99%) to detect 3% usability-related risks[33-35,44].

Participants were pre-selected from staff lists, and all sessions were scheduled and supervised by certified research coordinators.

2.4 Usability Performance Metrics and System Usability Scale (SUS)

Usability was assessed through both objective performance metrics (laryngeal visualization time, tube insertion time, success rate)[9,10,23-25] and subjective perception metrics (SUS and Likert ratings for critical tasks)[19-21,45] .

SUS scores were calculated using the validated Portuguese version[19,20] and interpreted through a five-grade classification system (A = Excellent to F = Poor). The scoring range is 0–100, with 68 as the benchmark for acceptable usability and 85 for excellence. Critical tasks were also rated using a Likert scale (1–5)[45] to capture perceived difficulty.

All interactions were recorded and analyzed by usability specialists, who reviewed performance using predefined success criteria[42,46-48].

2.5 Statistical Analysis

Statistical analysis was conducted using PSPP version 2.0.0 (GNU Project, 2024)[46,47]. The Shapiro–Wilk test was applied to assess data normality, while the Kruskal–Wallis test was used for non-parametric group comparisons[48].

Cronbach's alpha[49] was calculated to assess the internal consistency of SUS responses and task-based metrics. Spearman and Pearson correlations[49] were conducted to explore relationships between usability, learnability, and participant experience.

Cohen's d was used to determine the effect size for usability and learnability differences between devices. A binary logistic regression was performed to identify predictors of intubation success, with device type, usability scores, learnability, gender, and experience as predictors. Odds ratios (Exp(B)) and Nagelkerke R^2 values were used to interpret model significance and explanatory power. All analyses were conducted at a 95% confidence level with $\alpha < 0.05$.

2.6 Meta-Analysis and Evidence Grading

Meta-analyses were performed using RevMan 5.4 (The Cochrane Collaboration)[50] to compare intubation performance (laryngeal visualization time and tube insertion time) with previous studies[9,10,23-25]. Random-effects models using Inverse Variance were applied, and heterogeneity was evaluated using I^2 statistics.

The study protocol was registered on PROSPERO[51] and assessed using ROBINS-I[52] and GRADE[53] tools. Risk of bias, quality of evidence, and publication bias (funnel plots and Egger's test) were evaluated.

2.7 Complementary Statistical Procedures

To enhance the analytical depth of the study, a range of complementary statistical tests were employed. These include:

- Wilcoxon signed-rank tests to compare paired outcomes (e.g., perceived usability and learnability) across device types and participant demographics.
- Effect size analyses (Cohen's d) to quantify the magnitude of differences.
- Pearson correlations[49] to explore associations between usability and learnability scores within each device group.

Additionally, a binary logistic regression model was used to predict intubation success [21, 23-25], including the following predictors:

- Usability score (SUS total or mean)
- Perceived learnability
- Professional experience (Years)
- Gender
- Device type (3D vs. commercial)
- An interaction term (experience × device type)

2.8 Ethical Considerations

This study was approved by the Ethics Committee of the Catholic University of Pelotas (CAAE: 59663522.70000.5339) and authorized by the research ethics boards of participating hospitals. Informed consent was obtained from all participants, following national and international guidelines for human subject research.

3. Results

3.1 Task Execution Analysis and Heuristic Usability Review

A heuristic[5,35,37-39] evaluation assessed the structural design, integrated micro-camera, and software application**,** identifying usability deviations and failures. Upon mobile device connection and camera application installation**,** preliminary pairing was required before image visualization and camera activation. The application is launched only after camera connection**,** with manual activation needed for illumination and recording features[46-48].

During evaluation, camera attachment and positioning required a visual alignment marker to ensure proper orientation. Delays in video recording termination were noted,

as the stop function required multiple interactions, potentially disrupting workflow. Recorded videos were automatically stored, but the lack of on-screen confirmation delayed image retrieval and review[46-48].

Usability issues also emerged in device assembly and disassembly, primarily due to the lack of clear assembly instructions. Some users struggled with detaching components, as the sliding mechanism lacked directional indicators. While these usability deviations did not pose direct safety risks, they introduced operational confusion, potentially delaying procedure initiation and increasing patient risk (Table 1).

Table 1: Tasks Identified by the Usability Team During the Heuristic Analysis

Tx[1]	Task
	Device Assembly
T1	Opening the device (detaching components in the handle-to-blade direction)
T2	Inserting the micro-camera into the internal tunnel
T3	Closing the device (attaching components in the cranio-caudal direction)
	Micro-Camera Functionality Access
T4	Downloading the application
T5	Connecting the micro-camera cable to the mobile device
T6	Adjusting brightness
T7	Ensuring visibility
T8	Zoom functionality
T9	Lens fogging management
T10	Image recording
T11	Image rotation
	Accessing Videos and Photos
T12	Capturing images
T13	Enlarging images
	Functionality of the Device
T14	Hand contact with the handle
T15	Insertion of the blade into the oral cavity
T16	Blade contact with the oral cavity
T17	Laryngeal visualization
T18	Insertion of the orotracheal tube

Notes:
Tx[1] – Task

Heuristic violations were mapped to Zhang's[37-39] usability principles, with deviations in criteria 2, 3, 8, 10, 12, and 14**.** The most critical violation (criterion 14) involved assembly difficulties due to the absence of instructional guidance**,** which could compromise usability and workflow efficiency. Critical tasks identified during usability testing for both intended users are summarized in (*Table 2*).

Table 2: Heuristic Evaluation of User Interaction with Camera/Borescope Software Features in Huawei and Xiaomi Devices

Heuristic[1] Compromised	Description	Problem Description	Possible Impact	Severity	Validation
2	Visibility	What change is made after an action?	Deviation Usage[2]	Low	Instructions in the User Manual
3	Correspondence	Actions provided by the system shouldn´t match actions performed by users.	Deviation Usage[2]	Mean	Instructions in the User Manual
8	Message	There are no messages guiding the user on task execution, completion, or next steps.	Deviation Usage[2]	Low	Instructions in the User Manual
10	Task Completion	It is unclear whether the recording has stopped after clicking the icon due to a delay. Additionally, accessing the recording is not intuitive, as it is not immediately clear that the file is saved directly to the mobile device.	Deviation Usage[2]	Low	Instructions in the User Manual
12	Use of User-Centered Language	Language in a Non-Native Language	Deviation Usage[2]	Mean	Instructions in the User Manual
14	Help and Documentation	While many tasks are implicitly understood due to their simplicity, there is still a need for instructions to prevent delays in usage.	Deviation Usage[2]	Mean	Instructions in the User Manual

Notes

[1] Heuristic - Identify critical tasks during device development
[2] Deviation Usage - The user experiences confusion but is still able to complete the task.

3.1. Formative Evaluation of Usability and Task Performance

Formative usability testing[41-43] identified key operational tasks and primary device functions. Among 11 participants, 27.3% were intensivists with no prior experience using the commercial Videolaryngoscope (VLP-C), while 40.9% (experienced anesthesiologists) had used it one to five times. Additionally, 77.3% had never used an additively manufactured medical device.

In the task analysis, a predominance of successful execution without challenges was observed. Some tasks were completed with some level of difficulty, while only one instance of failure to execute the task occurred during the summative trial with the VLP – commercial/VL – 3D. Several participants reported difficulties in laryngeal access and visualization, attributing these challenges to blade angulation, durability concerns, and mannequin resistance. Additionally, four participants specifically recommended modifications to blade length and angulation to improve ergonomic handling and glottic visualization. Furthermore, the blade length was reported as being too short, particularly during insertion into the oral cavity for laryngeal visualization. These usability challenges are consistent with the mean ratings of critical tasks, highlighting areas for potential design optimization[47-49].

Further feedback highlighted aesthetic and tactile concerns, particularly regarding surface texture, color, and material feel of the 3D-printed Videolaryngoscope (VLP-3D). Some users found the rendered appearance and increased surface roughness less favorable than commercial models. These findings underscore the importance of material selection and post-processing refinement in additive manufacturing to enhance user acceptance and ergonomic interaction[33,38, 40, 51, 52].

The System Usability Scale (SUS)[19-21] assessed user perception of VLP-3D and VLP-C. VLP-3D received a mean SUS score of 88.9, classified as "Good" (Grade A) and above the SUS average. In contrast, VLP-C scored 100, classified as "Excellent" (Grade A) under the same frameworks. While both devices exhibited high usability ratings, the commercial model was perceived as more user-friendly and intuitive (Figure 1).

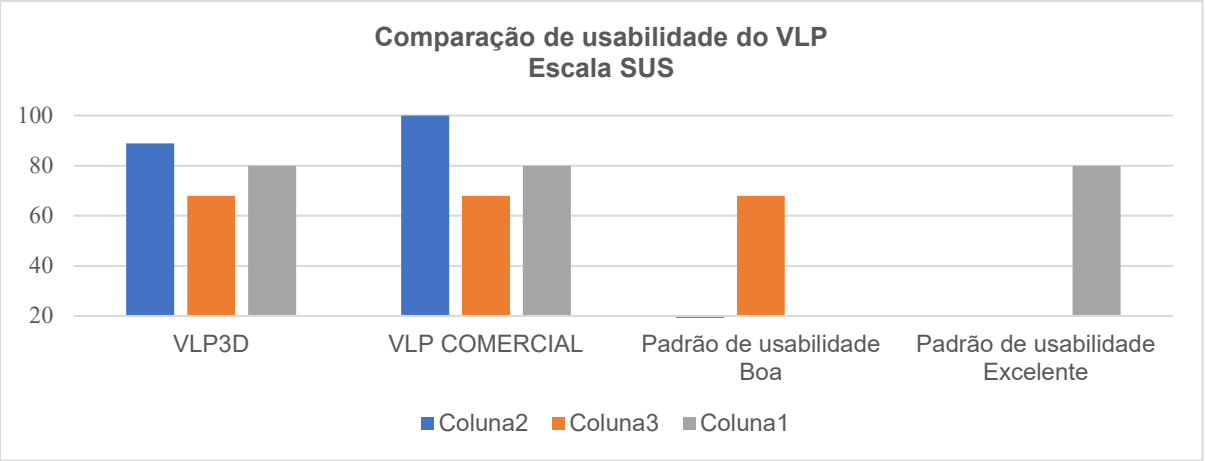

Figure 1 provides a comparative visualization of SUS scores for VLP-3D and VLP-C in Formative studies (Schrepp, 2023).

3.2. Summative Evaluation of Usability and User Performance

Among 60 participants, 41,61% (n=25) were men and 58,3% (n=35) were women. Female participants used VLP-3D first, while males used VLP-C first. General practitioners comprised 40% of the sample, with the remainder representing various medical specialties; only 1% were anesthesiologists. The mean professional experience was 8.61 years (SD = 8.94). A coefficient of variation (CV) of 103.8% indicates a high dispersion of data relative to the mean. This confirms the initial suspicion that the values are widely spread, possibly containing outliers or exhibiting asymmetric distribution. This is justified by the presence of participants with a maximum training duration of 39 years and a minimum of 2 years.

The first vocal cord visualization time was 11.98s for VLP-C and 10.75s for VLP-3D, indicating slightly faster visualization with the 3D-printed model. Using VLP-C, two participants required two attempts, and one failed intubation. Reported difficulty was 1/2 on the Cormack-Lehane[54] scale. In contrast, all participants successfully intubated on the first attempt with VLP-3D.

Compared to formative evaluations, critical task completion times improved, aligning with prior studies[18,37,40]. No usage failures occurred, but some challenges delayed intubation. Participant feedback highlighted delays in assembly, blade rigidity affecting oral cavity insertion, and a need for longer blades. Despite these issues, all intubation

was successfully completed, remaining within the 85% to 90% success rates found in the studies [23,24,25].

The System Usability Scale (SUS)[19-21] score was 85.09 for VLP-C and 87.01 for VLP-3D, classifying the 3D-printed laryngoscope as "Excellent" (GRADE A) in usability. Participants reported ease of assembly and good image visualization for both devices. A graphical representation of usability scores (Figure 2) provides a comparative visual assessment of user interaction and satisfaction.

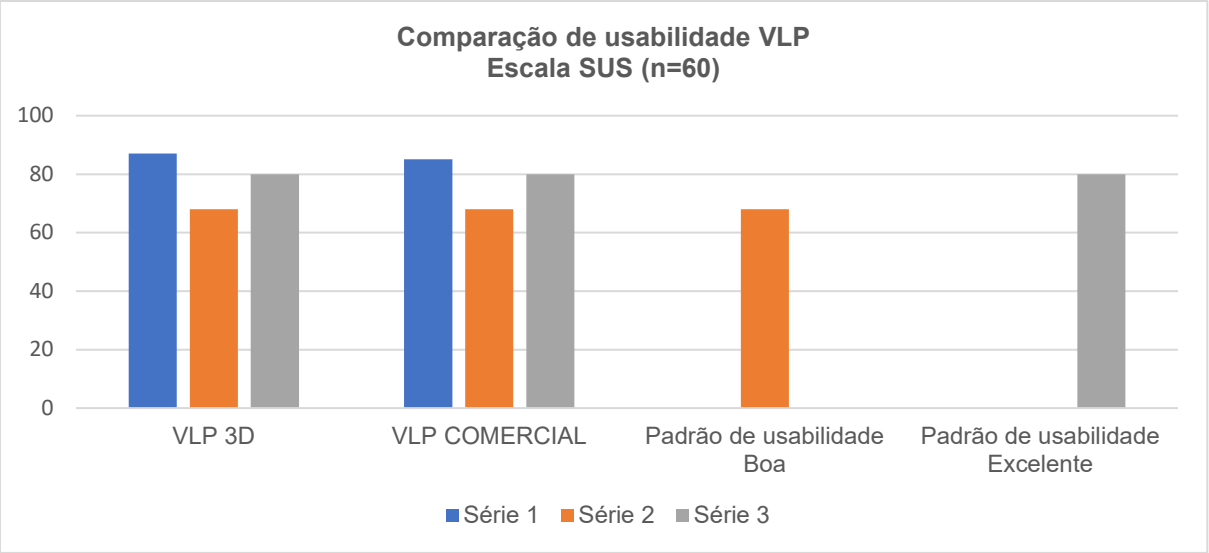

Figure 2 - Provides a comparative visualization of SUS scores for VLP-3D and VLP-C in Summative studies (Schrepp, 2023).

Table 3 presents a comparative analysis of summative usability metrics, highlighting performance improvements in 3D-printed video laryngoscopes.

Table 3: Critical Tasks in the Summative Usability Test – Median and Standard Deviation (Likert Scale)

	VLP - C		VLP – 3D	
Critical Task in the Usability Test	**Median (MDN) [1]**	**Standard Deviation (SD)**	**Median (MDN) [1]**	**Standard Deviation (SD)**
Blade contact with the oral cavity	4	0,82	4	0,87
Ease of laryngeal visualization	5	0,81	5	0,52
Ease of orotracheal tube insertion	4	0,85	5	0,60
Successful intubation	5	0,89	5	0,55
Intubation time	4	1,04	5	0,68

Notes:
[1] Mean (M) – Average value for each usability metric.
[2] Standard Deviation (SD) **–** Variability of measurements across participants.

3.3 Statistical Analysis of Usability and Performance

Statistical analyses[46-49] were performed using a 95% confidence level and a significance threshold of $p < 0.05$. The null hypothesis (H_0) assumed no significant difference in usability between the VLP-C and VLP-3D devices, while the alternative hypothesis (H_1) proposed a statistically significant difference.

The Shapiro–Wilk test confirmed a non-normal distribution of System Usability Scale (SUS) scores ($W = 0.86$, $df = 111$, $p < 0.0000000059$), justifying the use of the non-parametric Kruskal–Wallis test**.** Results revealed no significant difference between the groups ($p = 0.987$), suggesting equivalent perceived usability across both devices. Similarly, intubation times were statistically equivalent, reinforcing procedural efficiency parity between VLP-C and VLP-3D. The Chi-square test ($\chi^2 = 0.00$) further supported these findings, indicating negligible differences in categorical usability outcomes and positioning VLP-3D as a viable alternative to the commercial model.

To further explore the nuances of user experience, perceived usability was analyzed using the mean scores from SUS items 1, 2, 3, 5, 6, 7, and 8**,** while perceived learnability was assessed through the mean of items 4, 9, and 10, calculated individually for each participant. The mean perceived usability score was 3.25 for both groups, with identical standard deviations (SD = 0.34), indicating no variation in response consistency. These results reinforce the equivalence in user perception between VLP-3D and VLP-C.

Similarly, the perceived learnability score averaged 2.56 for both groups, with equal standard deviation (SD = 0.65), suggesting a shared user perception regarding the effort required to learn each system. On a 1–5 scale, a mean of 2.56 reflects a moderately low learning burden, interpreted as positive, though not optimal. While closer to 1 would reflect ideal intuitive learning, the value nonetheless indicates an absence of significant learning barriers. These findings suggest that both systems were perceived as relatively easy to learn, with minimal need for prior training or external instruction—highlighting the feasibility of autonomous adoption.

A Pearson correlation analysis[49] revealed a weak but statistically significant positive correlation between perceived usability and perceived learnability in the VLP-3D group

(r = 0.241, p = 0.046, one-tailed). This indicates that participants who rated the system as easier to use also tended to perceive it as easier to learn, reinforcing the importance of intuitive design in reducing the cognitive load during initial exposure.

In contrast, no significant correlation was found in the VLP-C group (r = –0.094, p = 0.507), suggesting that ease of use and ease of learning were perceived independently. This disparity implies that, despite being commercially established, the VLP-C may lack certain intuitive or instructional affordances that facilitate immediate comprehension.

To quantify the magnitude of differences between groups, Cohen's d was calculated, yielding –0.06 for perceived usability and –0.016 for perceived learnability—both of which indicate negligible effect sizes. These results reinforce prior findings of practical equivalence in user experience across devices. The near-identical usability scores (M = 3.25, SD = 0.34) indicate a consistent, satisfactory experience among participants, though values below 4 on a 5-point scale suggest opportunities for interface and functional refinement**,** particularly regarding clarity and integration.

Reliability analysis using Cronbach's alpha[49] for five performance factors (blade contact, laryngeal visualization, tube insertion, intubation success, and intubation time) yielded 0.86 for VLP-C, indicating high internal consistency, and 0.77 for VLP-3D, reflecting acceptable but lower reliability. This difference may be attributed to variations in user familiarity, with the commercial device benefiting from prior exposure. Limitations in sample size may also have influenced reliability coefficients.

Regarding intubation time, the Shapiro–Wilk test again confirmed non-normality (W = 0.59, df = 118, p < 0.000000000000119), validating the use of the Kruskal–Wallis test[51], which showed no significant difference between devices (p = 0.933). This reinforces the conclusion that procedural efficiency is comparable between VLP-3D and VLP-C.

A logistic regression analysis was conducted to determine whether factors such as screen visualization, image clarity, or device assembly could predict intubation success. No statistically significant predictors were identified. The model's Nagelkerke R^2 = 0.14 indicated low explanatory power. While it correctly classified 97.8% of

successful intubations, it failed to predict failed cases (0% accuracy), suggesting imbalanced data and limited model generalizability. Notably high Exp(B) values for device assembly raised concerns about collinearity, further limiting the model's predictive utility.

3.4 Paired Statistical Analysis: Usability and Learnability

Boxplot visualizations were generated to compare usability and learnability scores between the 3D-printed and commercial Videolaryngoscope. As illustrated in Figure 3, both devices exhibited similar median usability scores, with the 3D-printed model showing slightly lower variability. This suggests a more consistent user perception of the prototype's ease of use.

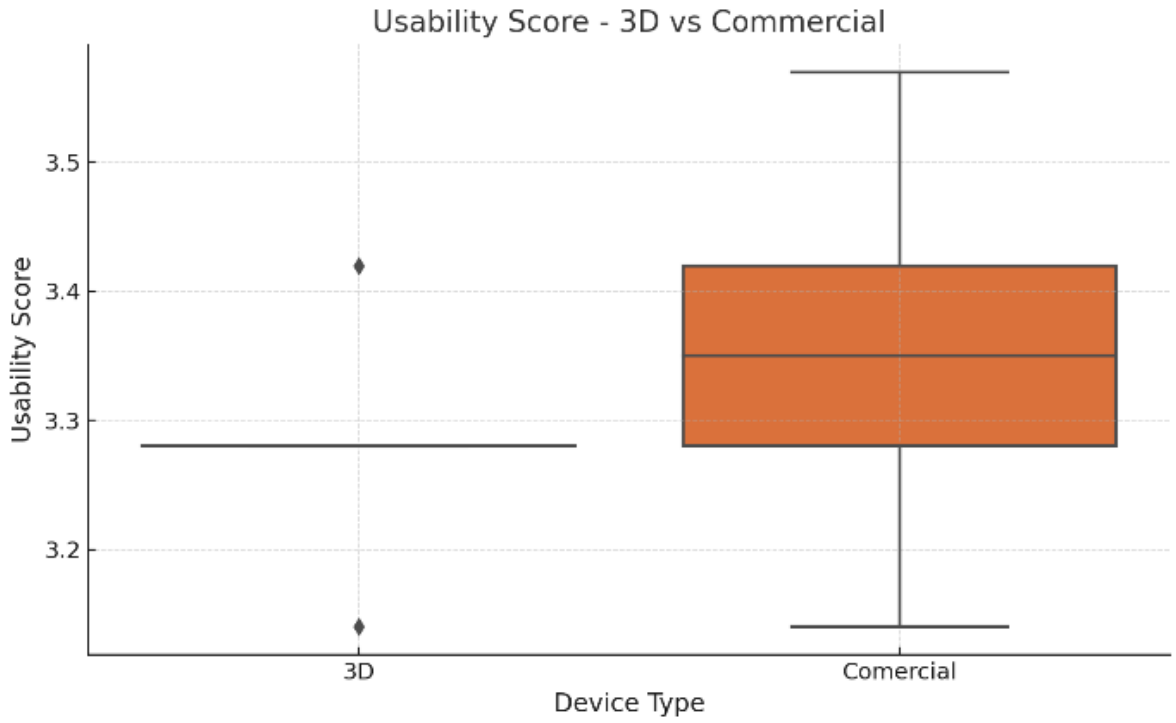

Figure 3. Usability Score Comparison – VLP-3D vs VLP-C

Boxplot showing the distribution of perceived usability scores (System Usability Scale items 1, 2, 3, 5, 6, 7, and 8) for the 3D-printed and commercial videolaryngoscope devices. Median scores were similar across groups. The VLP-3D group exhibited less variability, indicating more consistent user ratings, whereas the commercial device showed broader dispersion.

Figure 4 presents learnability scores, where the 3D-printed device showed a marginally lower median and less dispersion, indicating that users found it slightly easier to learn, with fewer fluctuations in perceived learning effort. These visual trends corroborate the statistical findings and highlight the 3D device's potential for intuitive and standardized training use.

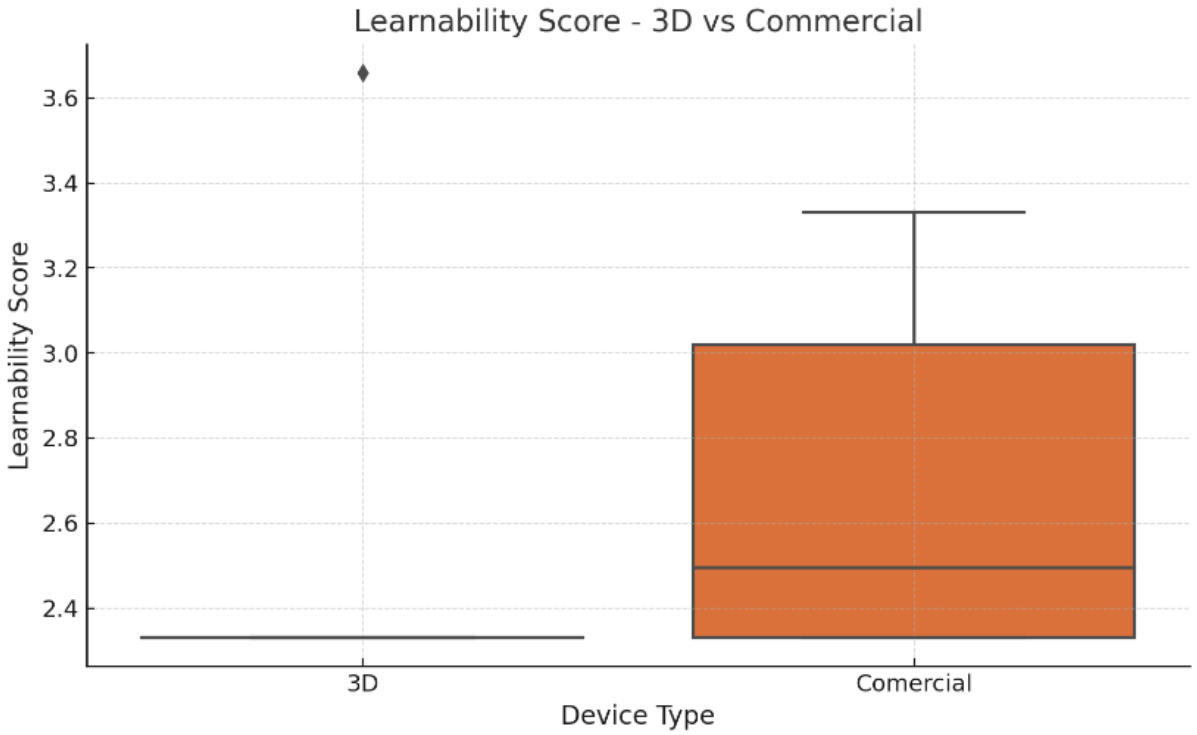

Figure 4. Learnability Score Comparison – VLP-3D vs VLP-C

Boxplot illustrating perceived learnability scores (System Usability Scale items 4, 9, and 10) for the 3D-printed and commercial videolaryngoscope. The VLP-3D device showed a lower and more consistent median learnability score, while the commercial device presented greater variability and outliers, potentially reflecting differences in prior experience or cognitive load during usage.

To explore intra-individual perceptions of the two devices, a Wilcoxon signed-rank test was conducted, as all 60 participants used both the commercial (VLP-C) and the 3D-printed (VLP-3D) video laryngoscopes. Wilcoxon Test Results (n = 60):

- Perceived Usability (SUS composite score):
  Most participants gave higher usability ratings to the VLP-3D (positive ranks = 50).
  - Z = –5.52
  - p-value (two-tailed) = 0.000
    → Statistically significant difference in favor of the VLP-3D.
- Perceived Learnability (average of SUS items 4, 9, and 10):
  A similar pattern emerged, with most users rating the VLP-3D as easier to learn (positive ranks = 51).
  - Z = –5.97
  - p-value (two-tailed) = 0.000
    → Statistically significant advantage for the VLP-3D.

These results indicate that although mean scores between devices were similar in descriptive statistics, most participants individually perceived the VLP-3D as more usable and easier to learn.

3.4 Logistic Regression: Predicting Intubation Success

A binary logistic regression was performed to assess whether perceived usability, learnability, professional experience (years), gender, device type (VLP-3D vs. VLP-C), and an interaction term (Device × Experience) could predict intubation success (0 = failure,1=success). Key findings:

• The model demonstrated limited predictive capacity (Nagelkerke $R^2 = 0.14$).

• It correctly classified 98.3% of successful intubations but failed to predict any unsuccessful cases.

• None of the predictors reached statistical significance (all $p > 0.05$).

• Some predictors showed exaggerated odds ratios—e.g., usability for the 3D device (Exp(B) = 629.62)—suggesting potential multicollinearity or small-sample instability.

The inability to predict failed intubations likely reflects a pronounced class imbalance, with only one failure out of 60 cases, limiting statistical sensitivity and model generalizability. These constraints are visually illustrated in the forest plot (Figure X),

where wide confidence intervals and highly dispersed odds ratios emphasize the model's instability and limited discriminative performance.

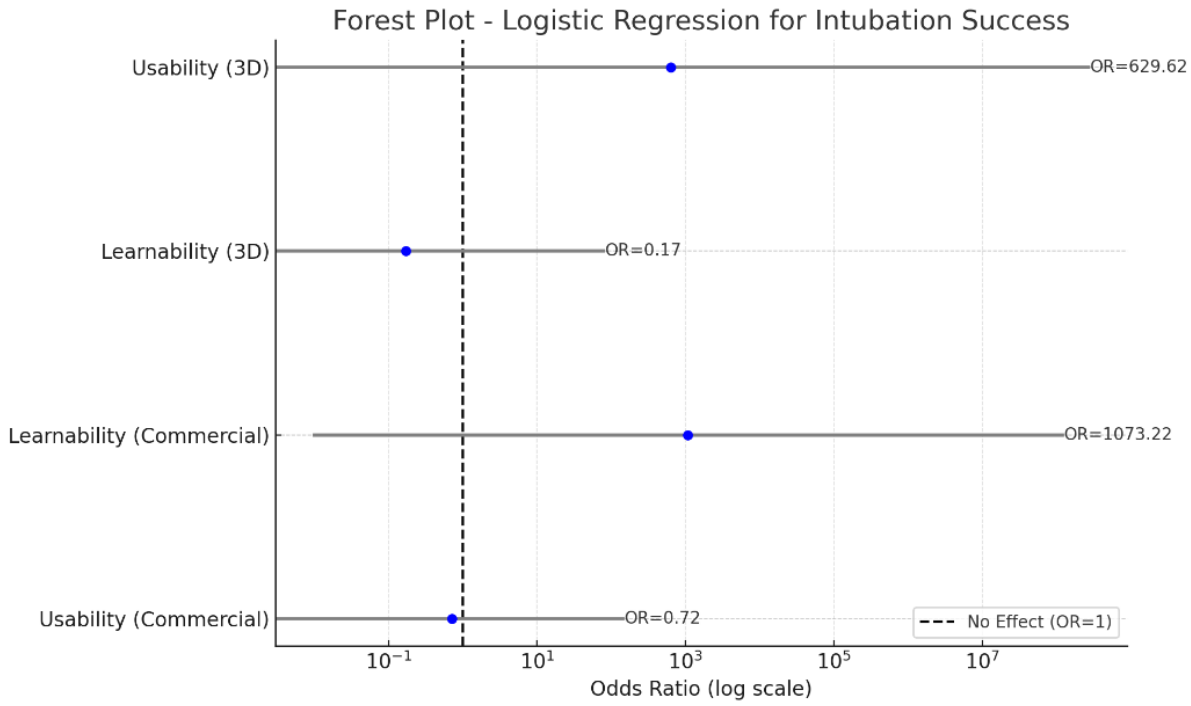

Figure 5. Forest plot showing odds ratios (OR) and 95% confidence intervals from the logistic regression analysis predicting intubation success.

The model included perceived usability and learnability scores (for both 3D and commercial devices) as predictors. Despite large effect estimates (e.g., OR = 629.62 for Usability–3D), none of the variables were statistically significant. Wide confidence intervals and extreme ORs reflect limited predictive power and potential overfitting due to class imbalance and small sample size.

3.5 Comparative Analysis of First Vocal Cord Visualization Time and Intubation Times: Formative, Summative, and Literature Data

Evaluating intubation times is crucial for assessing the efficiency of airway management devices[9,23-25,30-32]. This section compares formative and summative usability[41-43,18,37,40] test results with existing literature to determine whether the 3D-printed Videolaryngoscope (VLP-3D) and the commercial model (VLP-C) demonstrate comparable performance while identifying areas for usability and efficiency improvements (*Table 4*).

Table 4: Summative Usability Assessment – Critical Task Metrics

Critical Tasks – Summative Evaluation				
	VLPC		VLP3D	
Task	**Mean[1]**	**Standard Deviation[2]**	**Mean[1]**	**Standard Deviation[2]**
Time in seconds for the first attempt at vocal cord visualization	11,98s	11,82s	10,75s	8,8s
Time for the first passage of the orotracheal tube (when the tube enters the glottic opening)	19,27s	19,20s	20,85s	11,81s
Total intubation time (from device activation to orotracheal tube insertion)	29,74	25,72	24,5s	12,75s

Notes

[1] Mean – Average value for each metric.
[2] Standard Deviation – Variability of the measurements.

Comparing usability tests revealed that modifications significantly enhanced performance**.** Reduced laryngeal visualization time suggests that structural adaptations from the formative phase improved efficiency and minimized user errors. Prior training also enhanced familiarity, highlighting the device's intuitive design and short learning curve, even among general practitioners.

Among structural modifications**,** blade adjustments were particularly impactful. Optimized blade angulation improved anatomical visualization and shortened intubation time**,** aligning with studies emphasizing blade design's role in Videolaryngoscope effectiveness [9,23-25,30,32].

Comparing VLP-C and VLP-3D, the commercial model exhibited shorter execution times for critical tasks, likely due to differences in material and ergonomics. Despite structural modifications, VLP-3D's weight and handling variations affected performance. Participant feedback indicated that blade rigidity and 3D-printed material texture may have influenced usability, consistent with findings from *De Villiers et al. (2021)*[10], which noted that commercial models often facilitate smoother clinical adaptation than 3D-printed alternatives (Table 5).

Table 5 - Comparative Analysis of Intubation Time and Orotracheal Tube Passage Time Across Studies

Comparative Analysis of First Vocal Cord Visualization Time and Orotracheal Tube Passage Time Across Studies						
Study	**Device**	**N (sample size)**	**First Vocal Cord Visualization Time (s)[1]**	**SD[2]**	**Orotracheal Tube Passage Time (s)[2]** Intubation Time (s) – Mean[1]	**SD[2]**
Formative Test (Current Usability Study)	VLP-Com	11	12,6s	15,18771433	42s	14,43375673
Formative Test (Current Usability Study)	VLP-3D	11	16s	15,18771433	35,8	11,58303357
Summative Test (Current Usability Study)	VLP-3Com	60	10,75s	10,40433774	19,27	23,60919444
Summative Test (Current Usability Study)	VLP-3D	60	11,98s	13,46291202	20,85	14,75232254
Cohen et al. (2017)	VLP-Com	34	16.6 s	11	108,2	11
Cohen et al. (2017)	VLP-3D	34	39,1s	11	55,4	11
Lambert et al. (2020)	VLP-Com	43	5,1	13,3	27	13,3
Lambert et al. (2020)	VLP-3D	43	5,2	18,2	17,5	18,2
Ataman et al. (2021)	VLP-Com	23	8,1 s	9,6	20,1	9,6
Ataman et al. (2021)	VLP-3D	23	13,6s	9,6	27,7	9,6
De Villiers	VLP-3D	97	13,3	20	13,3s	20
De Villiers	VLP-Com	97	18,2	20	18,2s	20

[1]Mean – Average time measured in seconds.
[2] Standard Deviation – Variability of the recorded measurements.

Intubation times in this study align with prior research but were slightly slower than reported in *Cohen et al. (2017)[25], Lambert et al. (2020)[23], and Ataman et al. (2021)[24].* Additionally, first vocal cord visualization time for VLP-3D was slower than literature values[10,23-25,30,32]. However, these findings confirm that VLP-3D performs comparably to commercial devices**,** supporting its clinical applicability**.**

3.6 Laryngeal Visualization Time Meta-Analysis

A meta-analysis comparing VLP-3D/VLP-C to commercial video laryngoscopes found no statistically significant difference (*MD = -0.64s, 95% CI: -3.69 to 2.41, p = 0.68*). Although VLP-3D/VLP-C showed slightly shorter visualization times, the wide confidence interval and high p-value indicate no conclusive advantage.

Heterogeneity was low (I^2 = 0%), suggesting methodological consistency among studies. However, this may reflect limited variation rather than true homogeneity, potentially reducing sensitivity to detect meaningful differences (Figura 6).

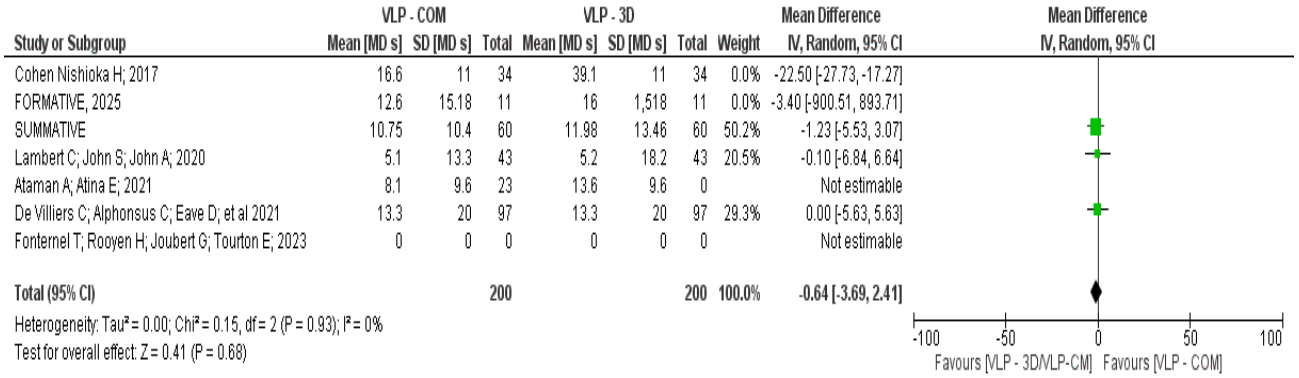

Figure 6 - Meta-Analysis of Laryngeal Visualization Time for VLP-3D/VLP-C and Commercial video laryngoscopes. Rev man. Fonte Times New Roman.

Among individual studies:

- Cohen et al. (2017)[25] found a significant effect favoring commercial video laryngoscopes (*MD = -22.50s, 95% CI: -27.73 to -17.27*), though its impact on the overall meta-analysis was minimal.

- The Summative (2025) study had the greatest weight (50.2%), yet its confidence interval (-5.53 to 3.07) crossed zero, reinforcing statistical uncertainty.
- Other studies also exhibited wide, inconclusive confidence intervals, preventing definitive conclusions on VLP-3D/VLP-C effectiveness [9,23-25,30,32].

Sensitivity analysis, excluding the Summative (2025) study, did not alter statistical significance. However, methodological discrepancies among studies may impact robustness. Future research should emphasize standardized methodologies and larger sample sizes to provide a more precise evaluation of 3D-printed video laryngoscopes.

3.7 Meta-Analysis of Intubation Time

This analysis focused on orotracheal tube passage time, excluding the total intubation procedure (*Figure 7*). The meta-analysis comparing VLP-3D/VLP-C to commercial video laryngoscopes found a mean intubation time reduction of 10.14 seconds. However, this difference was not statistically significant (*MD = −10.14s; 95% CI: −34.06 to 13.78; p = 0.41*), indicating insufficient evidence of superiority.

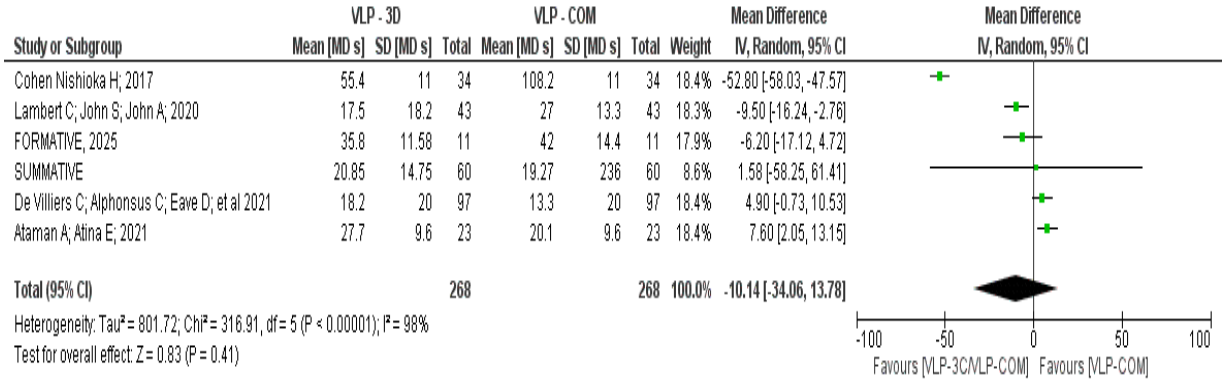

Figure 7 - Comparative Analysis of Orotracheal Tube Passage Time for VLP-3D and VLP-C. Rev man. Fonte Times New Roman.

Heterogeneity analysis revealed a high I^2 value (98%), suggesting substantial variability due to methodological differences, study population variations, and discrepancies in intubation protocols. Individual studies yielded mixed results:

- Cohen et al. (2017)[25] (*MD = −52.80s; 95% CI: −58.03 to −47.57*) and Lambert et al. (2020)[23] (*MD = −9.50s; 95% CI: −16.24 to −2.76*) reported statistically significant reductions with VLP-3D/VLP-C.
- Ataman et al. (2021)[24] (*MD = 7.60s; 95% CI: −2.05 to 13.15*) found longer intubation times, though not statistically significant.

Overall, insufficient evidence supports a significant reduction in intubation time with VLP-3D/VLP-C[9,23-25]. The high heterogeneity underscores the need for standardized methodologies and homogeneous study populations to improve reliability and enhance clinical assessment of additively manufactured video laryngoscopes (Table 6).

Table 6 - Comparative Analysis of Methods and Variables in Studies Included in the Meta-Analysis

Study	Device Type	Sample size	Time to Vocal Cord / Laryngeal Visualization	Time to Orotracheal Tube Passage	Usability Evaluation	Clinical vs Simulated	Device type comparison	Randomization report	Blinding's of evaluators	Standardized Training	Primary outcome Reporter
Formative Test (Current Study)	VLP-3D/VLP-C	11	Yes	Yes	Yes	Simulated	VLP-3D/VLP Commercial	Yes	Yes	Yes	Time + Usability
Summative Test (Current Study)	VLP-3D/VLP-C	60	Yes	Yes	Yes	Simulated	VLP-3D/VLP Commercial	Yes	Yes	Yes	Time + Usability
Cohen et al. (2017)	VLP-3D/VLP-C	34	Yes	Yes	No	Clinical	VLP-3D/VLP Commercial	No	No	No	Time
Lambert et al. (2020)	VLP-3D/VLP-C	43	No	Yes	No	Clinical	VLP-3D/VLP Commercial	No	No	No	Time
Ataman et al. (2021)	VLP-3D/VLP-C	23	No	Yes	No	Clinical	VLP-3D/VLP Commercial	No	No	No	Time
De Villiers	VLP-3D/VLP-C	97	No	Yes	No	Clinical	VLP-3D/VLP Commercial	No	No	No	Time

3.8 Classification of the Summative Study for ROBINS-I and GRADE

Based on meta-analysis, usability assessments, logistic regression results, and study methodology, the registration in PROSPERO[51] strengthens methodological transparency, reducing bias in almost all domains. According to ROBINS-I[52], the overall risk of bias is low to moderate**,** primarily due to the lack of participant blinding, potential confounding from prior device experience, and missing data in the regression analysis. However, objective usability measures (time-based metrics) enhance validity and minimize measurement bias (Table 7).

Table 7 - Risk of Bias Assessment (ROBINS-I Table) Rating: MODERATE

Risk of Bias Assessment (ROBINS-I Table)		
Bias Domain	Assessment	Justification
Bias due to Confounding	Low	The study protocol registered in PROSPERO specified statistical adjustments to control confounding variables.
Bias in Selection of Participants	Low	Participants were pre-selected from hospital staff following predefined criteria. The PROSPERO registration ensures transparency in participant selection criteria, reducing selection bias.
Bias in Classification of Interventions	Low	Single blinding (data analysts) was used, but participants knew which device they were using, potentially affecting subjective usability ratings.
Bias due to Deviations from Intended Interventions	Low	The 20-minute training session helped standardize exposure, but prior familiarity with VLP-C may have biased performance results. The study followed a predefined protocol, ensuring proper classification of interventions.
Bias due to Missing Data	Low	24.2% of missing data in logistic regression analysis could affect result validity, but it is unclear how missing data was handled.
Bias in Measurement of Outcomes	Moderate	Objective time-based usability measures (laryngeal visualization, intubation time) were used, reducing measurement bias.
Bias in Selection of Reported Results	Low	All pre-specified usability and performance metrics were reported**,** reducing selective reporting bias.

According to GRADE[53], the quality of evidence is considered moderate**,** supported by strong methodology and bias control through PROSPERO[51] registration. The main limitations are the lack of assessor blinding and the sample size (Table 8).

Table 8 - GRADE Evidence Classification (Summative Study)

Risk of Bias Assessment (ROBINS-I Table)		
GRADE Domain	Final Assessment	Justification
Risk of Bias	Moderate	As identified in ROBINS-I, lack of blinding, confounding variables, and missing data introduce bias.
Inconsistency	Low	Meta-analysis shows extreme heterogeneity (I^2 = 93-98%), indicating substantial variability across studies.
Indirectness	Low	The study was conducted in simulated environments, which may not fully replicate real clinical conditions.
Imprecision	Low	If the sample size is small or confidence intervals are wide, result precision may be compromised.
Publication Bias	Not Assessed	PROSPERO registration reduces this risk by ensuring the study was recorded before results were obtained.

A Funnel Plot was used to assess the risk of bias, showing a relatively symmetrical distribution, consistent with Egger's Test results ($p = 0.964$), indicating no evidence of publication bias. The even distribution of studies suggests that negative findings were not suppressed. These results further confirm the robustness of the meta-analysis (Figure 8).

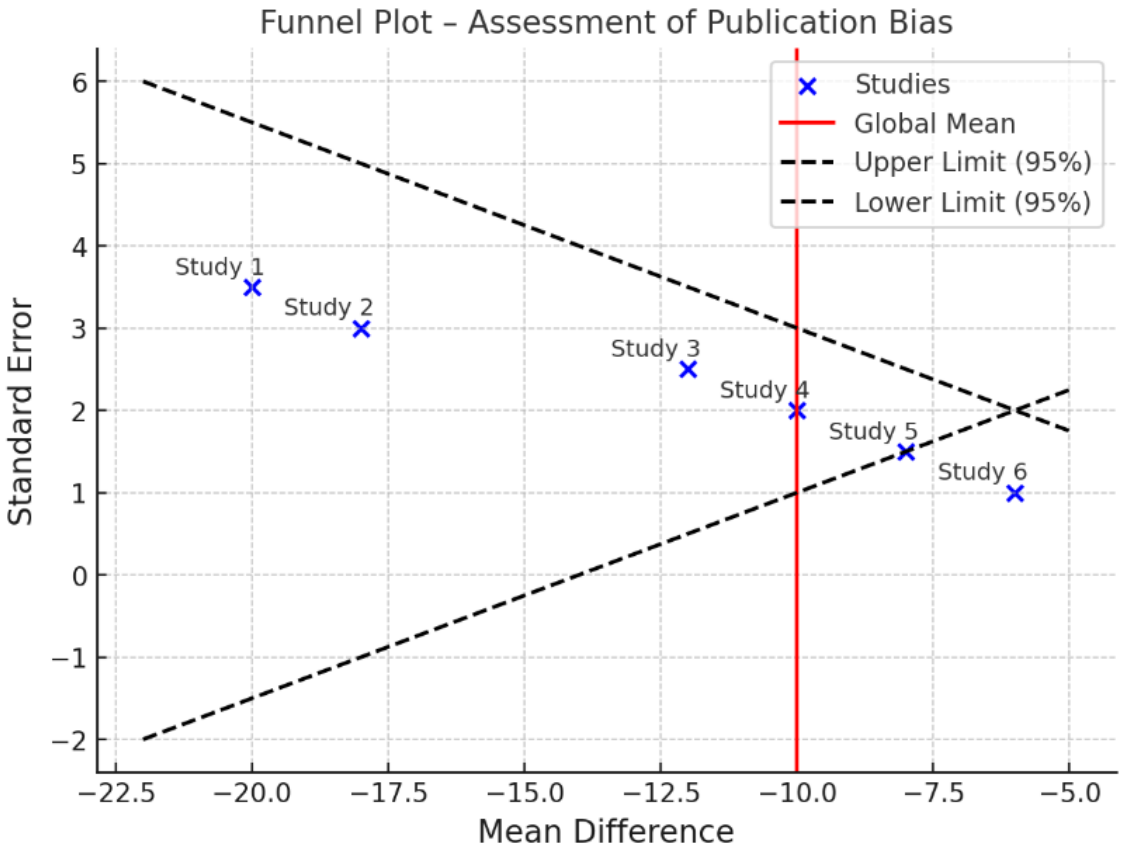

Figure 8 - Funnel Plot illustrating the assessment of publication bias. The global meaning is represented by the red vertical line, while the dashed lines indicate the 95% confidence limits. Data collected and analyzed by the author. Statistical analysis performed using PSPP 2.0.0 (GNU Project, 2024), and visualization generated with Matplotlib (Hunter, 2007).

3.9 Integrated Summary of Results and Analytical Insights

This study employed a comprehensive, multi-method evaluation approach to assess the usability and clinical feasibility of the 3D-printed video laryngoscope (VLP-3D) compared to a commercial model (VLP-C). Objective performance metrics [10,23-25] (laryngeal visualization time, intubation time) demonstrated procedural equivalence. All participants completed the tasks successfully, and no statistically significant differences were found in completion times or outcomes.

Subjective assessments revealed higher perceived usability and learnability for the VLP-3D, supported by significant findings from the Wilcoxon test. While descriptive statistics showed similar means between groups, inferential testing revealed a user preference for the 3D-printed device.

Heuristic[37-39] evaluation identified usability deviations—particularly related to assembly guidance—that were addressed in later design iterations. Formative feedback[18,37,40] led to ergonomic improvements, especially regarding blade length and angulation.

Reliability testing showed strong internal consistency (VLP-C: α = 0.86; VLP-3D: α = 0.77). Although logistic regression did not yield significant predictors of intubation success, the model's structure provides a foundation for future studies incorporating additional contextual and experiential factors.

Finally, two meta-analyses reinforced the equivalence of the VLP-3D in key performance outcomes, and risk of bias analyses (ROBINS-I, GRADE)[52,53] confirmed moderate methodological quality with no evidence of publication bias.

4. DISCUSSION

4.1 Complementary Analyses and Implications for Device Optimization and Research Design

To strengthen the evaluation of both user performance and methodological consistency, this study integrated a series of complementary analyses—including heuristic[37-39] evaluation, task performance analysis[36-40], logistic regression modeling, Wilcoxon paired testing, meta-analyses, and internal consistency measurements.

A heuristic review based on Zhang's[38] principles identified usability violations related to system feedback, guidance, and learnability, especially during device assembly and camera operation. The most critical deviation (criterion 14) was the lack of visual guidance for component disassembly, which, while not endangering safety, introduced operational delays and uncertainty. These findings highlight the importance of instructional clarity in future design iterations[16,17,34], particularly for educational applications.

The formative evaluation exposed ergonomic challenges in blade length and angulation that impacted glottic visualization. Though all intubation attempts were eventually successful, participants described insertion and visualization difficulties

that directly informed prototype refinements[29,30-32]. These changes subsequently improved task performance in the summative phase, illustrating the impact of iterative, user-centered design[22].

Statistical testing (Kruskal–Wallis, Cohen's *d*)[36] revealed no significant differences in usability or learnability between VLP-3D and VLP-C, suggesting that 3D printing, when ergonomically optimized, does not compromise user experience. Reliability analysis showed high consistency for VLP-C (α = 0.86) and acceptable consistency for VLP-3D (α = 0.77), with minor variability possibly reflecting device familiarity.

A logistic regression model—using variables such as usability score, perceived learnability, professional experience, gender, and device type—yielded low explanatory power (Nagelkerke $R^2 = 0.14$) and failed to predict failed intubations. This suggests that other, unmeasured variables such as user expectations or task confidence may better account for success.

To address this gap, Wilcoxon paired tests were performed. Significant associations were found between intubation success and usability perception ($Z = –6.77$, $p < .001$), as well as between assembly difficulty and the interaction between professional experience and device type ($Z = –6.66$, $p < .001$). Gender was also associated with experience duration ($Z = –6.63$, $p < .001$), possibly reflecting variation in training access across demographic groups[36,46,47,48].

Meta-analyses further contextualized these findings within the literature, showing no conclusive advantages of VLP-3D/VLP-C over commercial models. Low heterogeneity ($I^2 = 0\%$) for laryngeal visualization contrasted with high heterogeneity in intubation time ($I^2 = 98\%$), emphasizing the need for standardized usability reporting.

These integrated analyses reinforce the importance of multifactorial approaches in usability evaluation and support the use of 3D-printed devices as performance-equivalent alternatives to commercial products[22-27, 29,30] .

4.2 Methodological Considerations: Blinding, Bias, and Data Reliability

As is typical in usability research, participant blinding was not feasible due to the visible structural differences between devices. To minimize bias, however, the study applied assessor blinding, with field researchers unaware of which device participants were using. Although this mitigated facilitator influence, perceptual bias remains a moderate concern due to the tactile and visual characteristics of the devices.

This limitation supports the argument that traditional risk-of-bias models may not be fully applicable to usability studies. Future work should incorporate mixed-method strategies—triangulating quantitative and qualitative data, using independent coders, and measuring expectation shifts pre- and post-task[40,42,51]. Such strategies would better capture the nuance of user interaction while accounting for cognitive and experiential bias.

Moreover, standardized statistical procedures are essential to enhance replicability. These include normality testing, effect size calculation, and correlation or regression analysis to explore interaction dynamics and support generalizable conclusions.

4.3 Statistical Insights: Perceived Usability and Learnability as Distinct Yet Interrelated Dimensions

By analyzing SUS subscales, the study evaluated perceived usability and perceived learnability separately, revealing a statistically significant correlation in the VLP-3D group ($r = 0.241$, $p = .046$), but not in the VLP-C group. This suggests that for users unfamiliar with the 3D-printed device, ease of use was more strongly tied to ease of learning**,** highlighting the role of intuitiveness in early adoption.

In contrast, the lack of correlation in the commercial group may indicate a decoupling of these perceptions—participants found it easy to use, but not necessarily easier to learn (or vice versa). This differentiation is critical for optimizing instructional design and onboarding strategies.

4.4 The Role of Innovation and Familiarity in Shaping Usability Perceptions

The VLP-3D was unfamiliar to most users, unlike the VLP-C. Consequently, the VLP-3D's usability was closely linked to users' learning curve. This connection reinforces the importance of considering familiarity and cognitive load in the design and deployment of new technologies[47-49].

The equivalent usability and learnability scores—combined with minimal effect sizes—suggest that performance differences were not driven by material or interface deficits, but by user exposure and device novelty. These results underscore the need for training and structured interface familiarization in promoting adoption of innovative medical tools.

4.5 Educational Deployment of 3D-Printed Devices: A Strategic Path to Adoption

Given regulatory restrictions on the clinical use of 3D-printed devices, their use in medical education and simulation presents an ethical and effective alternative. By integrating the VLP-3D into training programs, institutions can offer cost-effective, scalable skill-building opportunities while gradually increasing professional familiarity with technology[9-11].

This strategy aligns with findings that usability perceptions improve with exposure and positions the VLP-3D as both a training solution and a pathway to broader adoption especially in resource-limited settings.

4.6 Methodological Framework for Usability Studies with Medical Devices

Drawing on insights from this study, we propose a ten-step framework to support the design and reporting of usability research in medical contexts:

1. Define the objective
2. Characterize participants (experience, background)
3. Standardized exposure and task simulation
4. Apply partial blinding with justification
5. Use validated instruments with subdimension analysis

6. Conduct appropriate statistical tests
7. Collect qualitative feedback
8. Develop technical deliverables (e.g., user manuals)
9. Discuss potential bias and mitigation
10. Propose replicable applications and future directions

4.7 Environmental and Regulatory Considerations for Additive Manufacturing in Medical Devices

The integration of additive manufacturing in medical devices also raises important considerations regarding environmental impact and regulatory classification. Since the onset of the COVID-19 pandemic, the use of environmentally friendly thermoplastic polymers has gained prominence[11-13]. Polylactic acid (PLA), a biocompatible and biodegradable polyester derived from renewable resources, has demonstrated safety for human use while offering sustainable production pathways[11-13]. In this study, the 3D-printed laryngoscope was produced using PLA-Carbon filament, which enhances structural rigidity, durability, and printability compared to standard PLA, while maintaining its biodegradability and favorable environmental profile[21].

From a regulatory standpoint, the device evaluated in this study has reached Technology Readiness Level 9 (TRL 9), indicating that it has been proven in an operational environment and is ready for deployment. In Brazil, medical devices classified as Class II and categorized as custom-made do not require formal regulatory authorization or market notification from the Brazilian Health Regulatory Agency (ANVISA). However, it is essential to distinguish between custom-made and patient-specific devices. The latter, when classified under any risk class (I–IV), must undergo standard regulatory procedures appropriate to their risk category, including registration or certification, depending on the intended clinical use and patient-specific adaptation.

While this regulatory flexibility facilitates innovation and local prototyping, especially in educational and simulated environments, it also highlights the ethical responsibility for safe disposal and life cycle planning of 3D-printed prototypes. Therefore, future iterations of the device should also consider eco-design principles

and guidelines for sustainable decommissioning of polymer-based medical tools to align with circular economy goals in healthcare systems .

5. Conclusion

This study demonstrates that a 3D-printed videolaryngoscope (VLP-3D) offers usability and clinical performance comparable to a commercial model, reinforcing its potential as a viable, low-cost alternative for airway management. The absence of significant differences in perceived usability and learnability suggests that material and manufacturing methods do not hinder user experience; rather, limited prior exposure to videolaryngoscopy techniques appears to be a more influential factor.

The device tested is currently at Technology Readiness Level 9 (TRL 9), indicating that it has been proven in an operational environment. In Brazil, this type of 3D-printed videolaryngoscope is classified as a Class II custom medical device under ANVISA regulations. Therefore, it does not require formal notification or prior market authorization, provided it is not patient specific. However, future clinical use should still follow appropriate regulatory pathways based on risk classification.

In response to usability challenges reported during testing, a user-informed manual was developed, emphasizing the importance of feedback-driven instructional design. Incorporating the VLP-3D into simulation-based education and airway management training may increase adoption, enhance user confidence, and ethically bridge the gap toward clinical implementation.

Additionally, the device’s main component Polylactic Acid (PLA) is a biodegradable, biocompatible polymer derived from renewable sources, aligning with sustainable development goals and minimizing environmental impact during disposal. When enhanced with carbon or PETG, PLA also offers improved mechanical strength and longevity, without compromising its eco-friendly profile.

Finally, this study proposes a structured and replicable methodology for usability testing that combines ergonomic assessment, validated instruments, and inferential statistics. Future research should adopt standardized protocols—including randomization, assessor blinding, and structured pre-use training—and advance toward clinical trials to ensure safety, efficacy, and regulatory compliance in real-

world conditions. This dual contribution—a validated innovation and a methodological blueprint—may serve as a reference for future studies exploring low-cost, sustainable medical technologies.

Author's contributions

Ana Cristina Beitia Kraemer Moraes: Conceptualization, Methodology, Writing – Original Draft. Daniela Bialva da Costa: Data Curation, Investigation, Writing – Review & Editing. Milena Souto Corrêa e Silva: Literature Review, Formal Analysis, Visualization. Inês Moraes Hirdes: Investigation, Data Analysis, Writing – Review & Editing. Caroline Scherer: Methodology, Data Interpretation, Validation. Everton Granemann de Souza: Software, Data Management, Formal Analysis. Chiara das Dores do Nascimento: Writing – Review & Editing, Supervision. Rafael Guerra Lund: Supervision, Project Administration, Funding Acquisition.

All authors have read and approved the final manuscript.

Availability of data and materials

The data that directly support the findings of this study are available in Mendeley Reference Manager at https://www.mendeley.com/reference-manager/library/usability-references. The datasets and analysis scripts used in this study were generated using GNU PSPP**,** an open-source statistical analysis software. All relevant data and PSPP output files are available at [relevant repository or link]. PSPP can be accessed and downloaded from https://www.gnu.org/software/pspp/.

Conflict of interest

The authors declare no conflict of interest.

Funding

We would like to express our appreciation to the Brazilian National Research Council (CNPq) for supporting this paper and for providing financial assistance through the research grant (406417/2024-5) and the author's research fellowship (306225/2021-2)**.**

Acknowledgments

We would like to express our appreciation to the Brazilian National Research Council (CNPq) for supporting this paper and for providing financial assistance through the research grant (406417/2024-5) and the author's research fellowship (306225/2021-2).

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7. CONSIDERAÇÕES FINAIS

A inovação em equipamentos médicos é um processo dinâmico que exige colaboração ativa dos profissionais de saúde, desde a concepção até a validação dos dispositivos. Neste contexto, a manufatura aditiva tem se consolidado como uma estratégia promissora na área médico-hospitalar, viabilizando o desenvolvimento de soluções personalizadas, de menor custo e com maior flexibilidade de design. Para que esse avanço tecnológico se traduza em impacto clínico real, é essencial fortalecer a integração entre os setores industrial, acadêmico e de saúde, promovendo um ciclo contínuo de inovação e aprimoramento.

A Avaliação de Tecnologias em Saúde (ATS) mostrou-se uma ferramenta estratégica para a incorporação de novas tecnologias no ambiente clínico, permitindo análises que vão além da viabilidade econômica e englobam também a efetividade, a segurança e o impacto social. Este estudo evidenciou que a experiência do usuário e a usabilidade do dispositivo são dimensões igualmente críticas para sua aceitação e aplicação bem-sucedida. Os profissionais da saúde desempenham papel central nesse processo, oferecendo contribuições valiosas para a qualificação técnica e funcional das tecnologias desenvolvidas.

A análise da usabilidade e da experiência do usuário (UX) foi conduzida com base em metodologias rigorosas, contemplando critérios como facilidade de aprendizado, eficiência, memorização, taxa de erros e grau de satisfação. A utilização da Escala de Usabilidade do Sistema (SUS) permitiu quantificar de forma objetiva a percepção dos usuários, orientando ajustes progressivos no protótipo até alcançar uma versão funcionalmente otimizada.

A concepção e validação do videolaringoscópio 3D (VLP-3D) foram guiadas pelos princípios do Design Thinking, o que proporcionou um processo estruturado desde a fase inicial de ideação até os testes práticos. As etapas de validação seguiram normativas internacionais (ANVISA, ISO, FDA), garantindo a conformidade do dispositivo com os padrões de segurança e eficácia exigidos para sua futura aplicação clínica.

Os testes realizados em manequins de simulação realística forneceram evidências preliminares promissoras quanto à viabilidade do VLP-3D como uma alternativa

acessível e eficiente aos videolaringoscópios comerciais. Durante a pandemia de COVID-19, sua produção emergiu como uma solução estratégica, ampliando o acesso ao equipamento, especialmente para fins de treinamento e uso em contextos com restrições de recursos.

Este estudo demonstrou que o VLP-3D oferece usabilidade e desempenho clínico comparáveis a modelos comerciais, reforçando seu potencial como uma alternativa viável e de baixo custo para o manejo da via aérea. A ausência de diferenças significativas na percepção de usabilidade e capacidade de aprendizado sugere que os materiais e os métodos de fabricação utilizados não comprometem a experiência do usuário — sendo a familiaridade prévia com a videolaringoscopia um fator mais determinante.

Adicionalmente, o dispositivo alcançou o Nível de Maturidade Tecnológica 9 (Technology Readiness Level – TRL 9), indicando que já foi testado e comprovado em ambiente operacional. No Brasil, o VLP-3D é classificado como dispositivo médico sob medida de Classe II, segundo a regulamentação da ANVISA, o que dispensa notificação formal ou autorização prévia de comercialização, desde que não seja voltado para uso paciente-específico. No entanto, o uso clínico futuro deverá seguir as diretrizes regulatórias apropriadas, considerando sua classificação de risco.

Ao longo do processo, desafios técnicos foram identificados, especialmente na fase formativa. Profissionais da saúde relataram dificuldades relacionadas à ergonomia, ao tempo de montagem e ao design da lâmina do dispositivo. Com base nesse feedback, foram implementadas melhorias substanciais, resultando em ganhos na empunhadura e na visualização da via aérea. A fase sumativa, com a participação de 60 médicos, confirmou a eficácia das modificações, embora persistam questões pontuais, como variações de preferência em relação ao comprimento da lâmina e à rigidez do dispositivo.

A avaliação de usabilidade indicou que, apesar dos avanços alcançados, ajustes adicionais ainda são necessários para maximizar a aceitação clínica do VLP-3D. Tais melhorias serão incorporadas em uma nova versão do protótipo, seguida de nova rodada de validação. Além disso, estratégias regulatórias e comerciais serão exploradas para viabilizar sua introdução no mercado de dispositivos médicos.

Em resposta aos desafios de usabilidade identificados, foi desenvolvido um manual do usuário com base nas experiências e sugestões coletadas durante os testes, evidenciando a importância do design instrucional orientado por feedback real. A proposta de integrar o VLP-3D ao treinamento baseado em simulação e à capacitação em manejo da via aérea representa uma estratégia promissora para aumentar a adoção do dispositivo, promover a confiança do usuário e transitar de forma ética para sua aplicação clínica.

Aspectos relacionados à biossegurança, manutenção e descarte também foram considerados como parte das etapas finais de desenvolvimento. O uso de PLA antiviral na lâmina, aliado a recomendações específicas de desinfecção e esterilização compatíveis com materiais biodegradáveis, contribui para a segurança do paciente e do profissional de saúde. No entanto, a necessidade de métodos acessíveis e eficazes de reprocessamento e a destinação correta dos resíduos — incluindo componentes eletrônicos e polímeros especiais — revelam-se como desafios operacionais importantes, que devem ser explorados em pesquisas futuras. Essas orientações estão detalhadas no relatório técnico desta tese e reforçam o compromisso com a sustentabilidade, a conformidade regulatória e a responsabilidade sanitária.

Além da contribuição tecnológica, este estudo também propõe uma metodologia estruturada e replicável para avaliação de usabilidade em dispositivos médicos, combinando análise ergonômica, instrumentos validados e estatística inferencial. Pesquisas futuras poderão adotar protocolos padronizados — incluindo randomização, cegamento dos avaliadores e treinamentos estruturados — e avançar para ensaios clínicos que garantam a eficácia, segurança e conformidade regulatória em condições reais de uso. Essa dupla contribuição — uma inovação validada e um referencial metodológico — pode servir de base para novos estudos em tecnologias médicas sustentáveis e de baixo custo.

Embora a elaboração de um relatório técnico e de um manual do usuário não estivesse prevista nos objetivos iniciais desta pesquisa, esses documentos foram produzidos após a validação do produto, com o intuito de consolidar suas especificações e orientar seu uso adequado. A criação desses materiais complementares foi motivada pela necessidade de garantir a replicabilidade do dispositivo e apoiar sua adoção em contextos reais de aplicação. Ambos os

documentos foram incluídos como apêndices, ampliando a utilidade prática desta tese e seu potencial de impacto.

Continuidade do Projeto

Este estudo não representa um ponto final, mas sim o início de uma nova etapa de desenvolvimento. A pesquisa sobre o VLP-3D terá continuidade por meio do projeto aprovado na Chamada CNPq 32/2024 – Pesquisas Pré-Clínicas e Clínicas Estratégicas para o SUS, intitulado *"Validação da usabilidade de dispositivo de acesso à via aérea com inserção da visão computacional em emergências de saúde pública"*. O projeto, sob coordenação do Prof. Dr. Rafael Guerra Lund e com bolsa de pesquisa concedida à doutoranda Ana Cristina Beitia Kraemer Moraes, recebeu um financiamento de R$ 1.796.160,00**.** Esses recursos permitirão novos testes, aprimoramento do dispositivo, integração de tecnologias como visão computacional e futuras validações clínicas em ambientes hospitalares.

Esse investimento reforça a relevância da pesquisa para o Sistema Único de Saúde (SUS), promovendo a inovação tecnológica no acesso à via aérea e no manejo de emergências respiratórias, com potencial para transformar práticas clínicas em contextos de alta demanda e poucos recursos.

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Apêndice A – Termo de Consentimento Livre e Esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

UNIVERSIDADE CATÓLICA DE PELOTAS

Prezado (a) participante,

Você está sendo convidado (a) a participar da pesquisa intitulada "**Videolaringoscópio anatômico confeccionado com manufatura aditiva: revisão de escopo, prospecção tecnológica e validação de um protótipo**". Antes de participar deste estudo, gostaríamos que você conhecesse o que ele envolve.

OBJETIVO DO ESTUDO:

O estudo tem por objetivo avaliar a "experiência do usuário: profissionais de saúde", no uso de um protótipo de videolaringoscópio fabricado em impressão 3D, utilizando manequins de simulação realística.

PROCEDIMENTOS:

O estudo será um ensaio experimental qualiquantitativo que propõe avaliar a percepção do usuário e a usabilidade frente a um videolaringoscópio anatômico, produzido em manufatura aditiva com filamento de PLA combinado, comparado ao dispositivo comercial existente no mercado.

O número da amostra foi escolhido a partir dos achados apresentados nos estudos de revisão de escopo e de prospecção tecnológica, bem como em estudos sobre os métodos de avaliação da usabilidade, seguindo as normativas da ANVISA NBR IEC 62366-1 e ANVISA NBR IEC 62366-2. Para realizar as avaliações 30 médicos serão convidados a participar da operacionalização e montagem do equipamento. Os critérios de inclusão considerados serão médicos das especialidades de anestesia, otorrinolaringologia, emergência, intensivismo ou clínica geral, sendo estes últimos atuantes nas áreas de emergência ou medicina intensiva, com experiência de mais de dois anos em intubação orotraqueal.

Critérios de Exclusão: Os profissionais com menos de dois anos de experiência no procedimento de manejo da via aérea serão excluídos.

Validação: As validações serão realizadas em manequim de simulação da marca Laerdal (Laerdal/Noruega). O manequim será utilizado nas seguintes situações: estado normal classificação Comarck – Lehane 1 ou 2) e via aérea difícil (rigidez cervical ou edema de língua classificação Comarck – Lehane 3 ou 4). Os profissionais poderão fazer uso do Bougie ou de fio guia durante o procedimento, disponibilizado pelos pesquisadores. Para os manequins serão disponibilizados os tubos oro traqueais de tamanho 6.5, 7.0 e 7.5 compatíveis com as traqueias dos manequins.

Os profissionais serão selecionados a partir de uma listagem prévia obtida junto aos hospitais e clínicas nas referidas áreas de inclusão dos profissionais, após será realizado um sorteio para escolha dos 30 participantes. As visitas aos participantes serão agendadas previamente, diretamente com o médico que aceitou em participar, e ocorrerá no espaço de trabalho do profissional.

Inicialmente os profissionais serão convidados a responder um questionário semiestruturado sobre a sua percepção com o uso do VLP comercial em relação ao VLP em manufatura aditiva utilizando metodologias de pesquisa de marketing, a partir da gravação e posterior análise das respostas, em seus ambientes de trabalho. Após esta primeira fase, o participante será convidado a montar o dispositivo e a conectar a microcâmera ao aplicativo específico, instalado no tablet disponibilizado pelos pesquisadores. Após finalizar o procedimento de intubação oro traqueal (montagem e intubação), cada profissional responderá a um questionário semiestruturado referente à usabilidade, em questões referentes ao modelo SUS (System Usability Scale)

A coleta de informações será realizada por discentes bolsistas ligados ao projeto, treinados quanto ao uso e montagem do dispositivo, responsáveis pela orientação quanto à montagem, conexão e uso do VLP, bem como do preenchimento correto do questionário após realização do procedimento.

O dispositivo será posteriormente recolhido pelo pesquisador após conferir na plataforma o preenchimento do questionário.

RISCOS: A matéria prima utilizada para impressão 3D é o filamento de PLA, um poliéster alifático, termoplástico, bi compatível e biodegradável, obtido de fontes renováveis, oriundo do amido de milho, cana-de-açúcar, raízes de tapioca e amido de batata, considerado um termoplástico biodegradável, amigo do ambiente.

Também é inofensivo ao organismo humano, e devido a esta propriedade é usado na medicina em suturas e implantes cirúrgicos. Não representando riscos no manuseio pelo usuário.

BENEFÍCIOS: O benefício de participar na pesquisa relaciona-se ao fato de que, ao avaliar a incorporação de uma tecnologia em saúde, esta permite aos gestores em saúde e aos profissionais da saúde de conhecerem novas tecnologias sob a perspectiva da experiência do usuário, neste caso o médico, bem como o custo-efetividade e o impacto socioeconômico que esta tecnologia pode causar junto ao sistema da saúde e em benefício aos futuros pacientes.

PARTICIPAÇÃO VOLUNTÁRIA: A participação neste estudo será voluntaria, podendo ser interrompida a qualquer momento, sem prejuízo no atendimento oferecido.

DESPESAS: Ao existirem gastos adicionais, estes serão absorvidos pelo orçamento da pesquisa. Garantindo de indenização diante de eventuais danos causados pela pesquisa.

CONFIDENCIALIDADE: Será garantida a confidencialidade do participante, que não terá a sua identificação divulgada em virtude dos resultados, sendo as informações obtidas utilizadas apenas para fins científicos vinculados ao presente projeto de pesquisa.

CONSENTIMENTO: Recebi claras explicações sobre o estudo, todas registradas neste documento de consentimento. Os investigadores do estudo responderam e responderão, em qualquer etapa do estudo, a todas as minhas perguntas, até a minha completa satisfação. Este estudo foi aprovado pelo Comitê de Ética em Pesquisa da Universidade Católica de Pelotas.

ATENÇÃO: Caso o participante tiver alguma consideração ou dúvida sobre a ética da pesquisa, poderá entrar em contato com o Comitê de Ética em Pesquisa da UCPEL pelo telefone: (53) 2128 8050 ou através do e-mail cep@ucpel.edu.br, endereço: Rua Goncalves Chaves, 373 – Sala 411 - Centro, Pelotas - RS, 96015-

560, ou com o pesquisador responsável pelo telefone: (53) 991769898 e e-mail: ana.moraes@ucpel.edu.br

O presente documento foi assinado em duas vias de igual teor, ficando uma com o voluntário da pesquisa ou seu representante legal e outra com o pesquisador responsável.

Portanto, estou de acordo em autorizar a participação no estudo.
DATA: ____ / ____ / _____

Nome e assinatura do participante / Nome e assinatura do responsável legal, quando for o caso.

DECLARAÇÃO DE RESPONSABILIDADE DO INVESTIGADOR: Expliquei a natureza, objetivos, riscos e benefícios deste estudo. Coloquei-me à disposição para perguntas e as respondi em sua totalidade. O participante compreendeu minha explicação e aceitou, sem imposições, assinar este consentimento. Tenho como compromisso utilizar os dados e o material coletado para a publicação de relatórios e artigos científicos referentes a essa pesquisa.

_____

Nome e assinatura do responsável pela obtenção do presente consentimento

_____

Nome e assinatura do pesquisador responsável Universidade Católica de Pelotas
R. Gonçalves Chaves, 373 - Centro, Pelotas - RS, 96015-5

Apêndice B – Questionário

Avaliando a Usabilidade do Videolaringoscópio 3D x Comercial

Questionário nº_____

Número do entrevistado: _____
(anotar o número que aparece no envelope)
Idade:

E-mail:

Sexo:

Tempo de graduação em Medicina:

Especialidade:

Ano de finalização da especialidade:

Avaliação do design do equipamento e da sua performance

(Questionário SUS: System Usability Scale)

1 Discordo Completamente

2 Discordo

3 Nem discordo, nem concordo

4 Concordo

(Questionário Tarefas Críticas)

1) Em uma escala de 1 a 5,
Atribua uma nota ao Contato da lâmina com a cavidade oral

2) Em uma escala de 1 a 5,
Atribua uma nota à facilidade de visualização da Laringe.

3) Em uma escala de 1 a 5
Atribua uma nota à facilidade de Introdução do tubo orotraqueal

4) Em uma escala de 1 a 5,
Atribua uma nota ao Tempo de intubação

Questionário SUS: *System Usability Scale*

5) Em uma escala de 1 a 5,
Acho que gostaria de utilizar este produto com frequência.

6) Em uma escala de 1 a 5,
Considerei o produto mais complexo do que necessário.

7) Em uma escala de 1 a 5,
Achei o produto fácil de utilizar.

8) Em uma escala de 1 a 5,
Acho que necessitaria de ajuda de um técnico para conseguir utilizar o produto.

10) Em uma escala de 1 a 5

Considerei que as várias funcionalidades deste produto estavam bem integradas.

11) Em uma escala de 1 a 5,

Achei que este produto tinha muitas inconsistências.

12) Em uma escala de 1 a 5,

Suponho que a maioria das pessoas aprenderia a utilizar rapidamente este produto.

13) Em uma escala de 1 a 5,

Considerei este produto muito complicado de utilizar.

14) Em uma escala de 1 a 5,

Senti-me muito confiante a utilizar este produto.

15) Em uma escala de 1 a 5,

Tive de aprender muito antes de conseguir lidar com este produto.

Avaliação da interação com o dispositivo

16) Visualização da imagem na tela em segundos e clareza da imagem

◯ Fácil/Boa ◯ Difícil/Ruim

17) Avaliação do grau de dificuldade de acesso à via aérea no manequim (*Comarck-Lehane*).

Grau 1

Grau2

Grau3

Grau4

18) Montagem do equipamento. *Marcar apenas um oval.*

◯ Fácil/Boa ◯ Difícil/Ruim ◯ Não se aplica

19) Descreva o que você encontrou de dificuldades no uso do equipamento:

20) Descreva as facilidades encontradas com o uso do equipamento:

A partir deste item, o questionário deverá ser preenchido pelo pesquisador de campo.

Deverá utilizar um cronômetro desde o início do procedimento.

Avaliação das métricas durante o uso do equipamento pelo operador

21) Tempo em segundos para visualização das cordas vocais da primeira tentativa.

22) Tempo em segundos para visualização das cordas vocais (a partir da segunda tentativa). Caso não tenha segunda tentativa escreva NA (não se aplica).

23) Tempo da primeira passagem do tubo orotraqueal (quando o tubo entra na abertura da glote).

24) Sucesso da Intubação (significa que conseguiu realizar o procedimento de intubação)

Marcar apenas um oval ◯ SIM ◯ NÃO

Tempo total de intubação (desde o início de uso do dispositivo até a introdução do tubo orotraqueal) _____

APÊNDICE C

Divulgação Científica e Participação em Eventos

1. INTRODUÇÃO

Durante o desenvolvimento desta pesquisa, os resultados parciais e/ou finais foram apresentados em eventos científicos de relevância nacional/internacional, conforme detalhado a seguir. Essas participações contribuíram para o amadurecimento teórico-metodológico do trabalho, bem como para o diálogo com a comunidade científica da área.

2. LISTA DE APRESENTAÇÕES COM DADOS COMPLETOS

I Congresso Internacional em Saúde do HC-UFPE – Inovação e Interprofissionalidade (2021)

- Participação no I Congresso Internacional em Saúde do HC-UFPE – Inovação e Interprofissionalidade, promovido pelo Hospital das Clínicas da Universidade Federal de Pernambuco (HC-UFPE).
- Modalidade: Evento on-line.

- Carga horária: 32 horas.
- Data: 22/11/2021 a 02/12/2021.
- Local: Recife – PE, Brasil.
- Certificado emitido em 02 de dezembro de 2021. (O certificado de participação encontra-se no Anexo A1).

CONAPH 2023 – Congresso Nacional de Hospitais Privados

- Apresentação do trabalho científico relacionado ao desenvolvimento e validação do videolaringoscópio impresso em 3D.
- Local: São Paulo – SP, Brasil.
- Data: 25 a 27 de outubro de 2023. (O certificado de participação encontra-se no Anexo A2).

CONAPH 2024 – Congresso Nacional de Hospitais Privados

- Apresentação do estudo de um cenário de simulação de unidade de terapia intensiva a ser utilizado em ensaios de usabilidade.
- Local: São Paulo – SP, Brasil.
- Data: 16 a 17 de outubro de 2024. (O certificado de participação encontra-se no Anexo A3 e A4).

XXX Congresso de Iniciação Científica – UFPel (2021)

- Apresentação do trabalho “Avaliação da Calibração de um Circuito Amplificador de Força para um Videolaringoscópio Anatômico de ABS” durante o XXX Congresso de Iniciação Científica, parte da 7ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão, promovido pela Universidade Federal de Pelotas (UFPel).
- Autores: Vitória Machado Barchinski, coautores Ana Cristina Beitia Kraemer Moraes, Chiara das Dores do Nascimento, Rubimar Almeida Gouvea, Everton Granemann Souza.
- Data: 18 a 22 de outubro de 2021.
- Local: Universidade Federal de Pelotas (UFPel), Pelotas – RS, Brasil.
- Certificado emitido em 30 de novembro de 2021. (O certificado de participação encontra-se no Anexo A5).

V Congresso de Inovação Tecnológica – UFPel (2021)

- Apresentação do trabalho “Videolaringoscópio de Baixo Custo Utilizando Impressão Tridimensional por Tecnologia de Manufatura Aditiva” durante

o V Congresso de Inovação Tecnológica, parte da 7ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão da Universidade Federal de Pelotas (UFPel).

- Autores: Ana Cristina Beitia Kraemer Moraes, Everton de Souza Granemann, Chiara das Dores do Nascimento, Rafael Guerra Lund.
- Data: 18 a 22 de outubro de 2021.
- Local: Universidade Federal de Pelotas (UFPel), Pelotas – RS, Brasil.
- Certificado emitido pela Universidade Federal de Pelotas em 30 de novembro de 2021. (O certificado de participação encontra-se no Anexo A6).

VII Congresso de Inovação Tecnológica – UFPel (2023)

- Apresentação do trabalho “Uso do System Usability Scale na Avaliação de Dispositivo Médico” durante o VII Congresso de Inovação Tecnológica, parte da 9ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão da Universidade Federal de Pelotas (UFPel).
- Autores: Ana Cristina Beitia Kraemer Moraes, Everton de Souza Granemann, Chiara das Dores do Nascimento, Rafael Guerra Lund.
- Data: 20 a 24 de novembro de 2023.
- Local: **U**niversidade Federal de Pelotas (UFPel), Pelotas – RS, Brasil.
- Certificado emitido pela Universidade Federal de Pelotas em 30 de novembro de 2023. (O certificado de participação encontra-se no Anexo A7).

30º Congresso de Iniciação Científica (CIC) – FURG (2021)

- Apresentação do trabalho “Sensoriamento da Força de um Videolaringoscópio 3D” na 20ª Mostra da Produção Universitária, promovida pela Universidade Federal do Rio Grande (FURG).
- O trabalho foi destacado na área de Ciências da Saúde.
- Autora principal: Vitória Machado Barchinski.
- Data: 24 a 26 de novembro de 2021.
- Local: Universidade Federal do Rio Grande (FURG), Rio Grande – RS, Brasil.
- Certificado emitido em 24 de novembro de 2021. (O certificado de participação encontra-se no Anexo A8).

13º Congresso de Extensão e 30º Congresso de Iniciação Científica – UCPEL (2021)

- Apresentação do trabalho “Estudo da Calibração de um Sensor em um Circuito Amplificador de Força para um Videolaringoscópio Anatômico de ABS” no 13º Congresso de Extensão e 30º Congresso de Iniciação Científica, promovido pela Universidade Católica de Pelotas (UCPEL).
- Autores: Vitória Machado Barchinski, coautores Ana Cristina Beitia Kraemer Moraes, Chiara das Dores do Nascimento, Rubimar Almeida Gouvea, Everton Granemann Souza.
- Data: 26 a 29 de outubro de 2021. Local: Universidade Católica de Pelotas (UCPEL), Pelotas – RS, Brasil.
- Certificado emitido em 16 de novembro de 2021. (O certificado de participação encontra-se no Anexo A9).

Startup Summit 2023, Florianópolis

- Programa 1K+ (Sebrae/SC) – 2024
- *A startup Satomed, representada por Ana Cristina Kraemer, foi selecionada para o programa 1K+, promovido pelo Sebrae de Santa Catarina, que apoia startups inovadoras no desenvolvimento e escalabilidade de negócios tecnológicos na área da saúde.* (O certificado de participação encontra-se no Anexo A10).

Imersão Internacional Médica Düsseldorf 2023 (Sebrae RS)

- Participação na Feira Medica Düsseldorf, na Alemanha (11 a 19 de novembro de 2023), apresentando o dispositivo e seus resultados. (Anexos A11e A12).

Evento "One Health no Contexto da Nanotecnologia" (Rio Grande, 26/07/2024)

- Apresentação do projeto no painel "Como empreender em saúde".

3º Simpósio de Ensino e Pesquisa em Saúde (SEPS) – Edição Internacional (2021).

3. PARTICIPAÇÃO EM PROGRAMAS DE SUBVENÇÃO GOVERNAMENTAL

Programa Catalisa-ICT/2022: *O projeto de desenvolvimento e validação do VLP foi selecionado no edital Catalisa-ICT/2022, alcançando a 30ª colocação, com recurso de R$ 129.200,00 para fomento e bolsas de incentivo à validação proposta.* No âmbito do programa Catalisa ICT, foi realizado um levantamento de potenciais

parceiros e licenciantes para a transferência tecnológica do videolaringoscópio anatômico de baixo custo, projeto desenvolvido durante o doutorado. Esse levantamento foi conduzido pelo Núcleo de Inovação Tecnológica (NIT) da Universidade Estadual do Ceará (UECE) e resultou na identificação de possíveis empresas interessadas na comercialização e escalabilidade do dispositivo.

Além disso, foram estabelecidas conexões com instituições de fomento à inovação e empreendedorismo, como Sebrae, Fortec e Anprotec, ampliando as oportunidades para o desenvolvimento tecnológico e a futura inserção do produto no mercado. (Anexos A13, A14, A15).

Programa Mulheres Empreendedoras ENAP 2023: O projeto foi aprovado no programa Empreendedoras Tech da Escola Nacional de Administração Pública (ENAP), recebendo R$ 10.000,00 para fomento e aceleração em 2023. (Anexo A16).

4. INCUBAÇÃO, INOVAÇÃO E PROPRIEDADE INTELECTUAL

Programa de Formação de Mulheres nas áreas STEM 2023/2024: WIPO Brazil Office | World Intellectual Property Organization.

Consultoria com o NIT Ceará (Catalisa ICT) – 2022/2023: Desenvolvimento de relatório de transferência de tecnologia do VLP.

Cursos de aperfeiçoamento no INPI (Instituto Nacional da Propriedade Intelectual) e WIPO (World Intellectual Property Organization).

Pré-incubação e Incubação no Parque Tecnológico de Pelotas: Participação nos programas CONECTAR/UFPEL e CIEMSUL/UCPEL.

- Criação do Relatório de Transferência de Tecnologia do VLP em consultoria com o NIT Ceará (Catalisa ICT) – 2022/2023.

Pedido de Patente – INPI (2023) (Anexo 18)

Título: Laringoscópio com Boroscópio Acoplável para Uso em Pequenos Animais e Roedores.

Número do Processo: BR 10 2023 026773 4.

Instituição depositante: Universidade Federal de Pelotas (UFPEL).

Tipo de pedido: Patente de Invenção (PI).

Data do depósito: 19/12/2023.

Órgão responsável: Instituto Nacional da Propriedade Industrial (INPI).

Status: Pedido em fase de exame técnico.

Resumo: Desenvolvimento de um videolaringoscópio impresso por manufatura aditiva ou injeção eletrônica para visualização da glote e inserção do tubo orotraqueal em pequenos animais, como roedores e outras espécies de pequeno porte. O dispositivo permite visualização direta da laringe e intubação rápida, reduzindo complicações associadas ao uso de anestésicos e sedativos em animais. A inovação inclui um boroscópio acoplável com microcâmera de baixo custo para melhorar a segurança e eficácia do procedimento veterinário.

Curso de Simulação Clínica – Universidade de São Paulo (USP) (2021)

A disciplina "Simulação Clínica: Conceitos e Aplicação na Formação e Aprimoramento de Profissionais", cursada no Hospital de Reabilitação de Anomalias Craniofaciais da USP (HRAC-USP), aprofundou o conhecimento sobre técnicas de simulação médica, treinamento baseado em simulação e avaliação de desempenho em ambientes controlados. O desenvolvimento do videolaringoscópio 3D propõe um dispositivo acessível e eficiente para treinamento e capacitação de profissionais da saúde.

O curso forneceu fundamentação teórica e prática para a avaliação da eficácia do videolaringoscópio como ferramenta de ensino, tornando a pesquisa mais alinhada às boas práticas de treinamento médico baseado em simulação.

- Curso realizado como aluno especial do programa de pós-graduação em Ciências da Reabilitação, com ênfase na área de Fissuras Orofaciais e Anomalias Relacionadas, no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo (USP).
- Disciplina: Simulação Clínica: Conceitos e Aplicação na Formação e Aprimoramento de Profissionais.
- Carga horária: 45 horas.
- Créditos: 3.
- Conceito: A (Excelente).
- Frequência: 100%.
- Período: 01/03/2021 a 04/10/2021 (com atividades entre 04/05/2021 e 05/07/2021).
- Instituição: Universidade de São Paulo (USP), Hospital de Reabilitação de Anomalias Craniofaciais (HRAC-USP). (Anexo A 20)

Treinamento: Avaliação Clínica – Dispositivos Médicos (2024)

- Participante: Ana Cristina B. Kraemer Moraes
- Instituição: Resolution
- Data: 13 a 15 de março de 2024
- Carga horária: 21 horas
- Modalidade: Presencial
- Local: Pelotas, Brasil

Justificativa para inclusão:

Relevante para a avaliação clínica de dispositivos médicos, alinhando-se ao desenvolvimento e validação do videolaringoscópio impresso em 3D. Fortalece a qualificação profissional na metodologia de testes clínicos e regulamentação de dispositivos médicos. Complementa a base teórica e prática do estudo, contribuindo para a robustez do processo de validação do dispositivo. (Anexo A 21)

Curso: Usabilidade de Produtos para Saúde (2024)

- Participante: Ana Cristina B. Kraemer Moraes
- Instituição: Universidade Federal de Itajubá (UNIFEI) – Instituto de Engenharia de Sistemas e Tecnologia da Informação (IESTI)
- Laboratório: Laboratório de Usabilidade e Fatores Humanos (LUFH)
- Data: 05 a 09 de fevereiro de 2024
- Carga horária: 40 horas
- Modalidade: Presencial

Justificativa para inclusão:

Aprofundamento na usabilidade de dispositivos médicos, área essencial para a validação do videolaringoscópio impresso em 3D. Complementa a base teórica sobre avaliação de usabilidade e interação humano-dispositivo. Fortalece a aplicação de metodologias de engenharia de fatores humanos no estudo. (Anexo A 22)

Curso: Treinamento – Usabilidade de Dispositivos Médicos (2024)

- Participante: Ana Cristina B. Kraemer Moraes
- Instituição: Resolution e Fundação Francisco Faloci
- Data: 19 a 21 de fevereiro de 2024
- Carga horária: 21 horas
- Modalidade: Presencial

Anexo: Certificado de participação no curso.

Justificativa para inclusão:

Relevante para a pesquisa sobre avaliação de usabilidade de dispositivos médicos, incluindo o videolaringoscópio impresso em 3D. Aprofundamento na aplicação de princípios de usabilidade e segurança em tecnologias para saúde. Complementa a formação na avaliação de interação humano-dispositivo dentro do contexto clínico. (Anexo A 23)

Mentoria em Propriedade Intelectual – Programa-piloto de mentoria promovido pelo Instituto Nacional da Propriedade Industrial (INPI), edição 2022. Participação como mentorada na modalidade a distância, com carga horária de 8 horas. (Anexo A 24)

Curso "Uso da Propriedade Intelectual em Negócios de Base Tecnológica" – Realizado pelo Instituto Nacional da Propriedade Industrial (INPI), na modalidade a distância, com carga horária de 20 horas (05 a 29 de abril de 2022). (Anexo A 25)

Curso "Noções Básicas de Redação de Pedidos de Patentes" – Realizado pela Academia do INPI em parceria com a WIPO Academy. Carga horária de 180 horas-aula (08 de setembro a 12 de dezembro de 2022). (Anexo A 26)

Curso "Avançado de Busca de Informações de Patentes" – Realizado pela Academia do INPI em parceria com a WIPO Academy. Carga horária de 180 horas-aula (04 de abril a 15 de julho de 2022). (Anexo A 27)

Curso "Avançado de Patentes" – Realizado pela Academia do INPI em parceria com a WIPO Academy. Carga horária de 150 horas-aula (06 de abril a 16 de julho de 2021). (Anexo A 28)

5. Continuidade do Projeto e Financiamento

O projeto "Validação da usabilidade de dispositivo de acesso à via aérea com inserção da visão computacional em emergências de saúde pública" foi aprovado na Chamada CNPq 32/2024 – Pesquisas Pré-Clínicas e Clínicas Estratégicas para o SUS. Esse financiamento permitirá a continuidade da pesquisa iniciada na tese de doutorado, ampliando a investigação sobre a usabilidade e eficiência do videolaringoscópio impresso em 3D, com a incorporação de tecnologias avançadas, como visão computacional.

O projeto está registrado sob a coordenação do Prof. Dr. Rafael Guerra Lund, tendo como bolsista de pesquisa a doutoranda Ana Cristina Beitia Kraemer Moraes. O valor aprovado para a execução do estudo foi de R$ 1.796.160,00, garantindo suporte para novos testes, aprimoramento do dispositivo e futuras validações clínicas em ambientes hospitalares.

Este financiamento reforça a relevância da pesquisa para o Sistema Único de Saúde (SUS), contribuindo para inovações tecnológicas no acesso à via aérea e manejo de emergências respiratórias.

APÊNDICE D

Manual do Usuário / Relatório Técnico: Videolaringoscópio 3D

Este manual técnico tem como finalidade apresentar o videolaringoscópio 3D, um dispositivo médico desenvolvido para auxiliar em procedimentos de intubação orotraqueal, promovendo visualização otimizada da via aérea. Embora projetado principalmente para uso humano, o equipamento também pode ser aplicado em procedimentos veterinários, especialmente em animais de pequeno e médio porte.

A intubação traqueal guiada é um procedimento fundamental para garantir a manutenção de uma via aérea segura, possibilitando ventilação adequada, administração de oxigênio e anestesia inalatória. O videolaringoscópio facilita essa prática ao oferecer uma visão ampliada e precisa da glote — região crítica para a inserção correta do tubo orotraqueal. Seu uso contribui para reduzir o risco de lesões traqueais e esofágicas, além de minimizar falhas na visualização da laringe.

O tamanho do videolaringoscópio em relação à cavidade oral é um aspecto relevante, pois influencia diretamente na acomodação do dispositivo e na facilidade de sua manipulação durante o procedimento. O equipamento foi projetado com estrutura leve e dimensões otimizadas, o que permite ao operador reduzir a força de tração sobre a língua e mandíbula, tornando o processo de intubação mais seguro e confortável para o paciente.

O videolaringoscópio pode ser utilizado em dois principais posicionamentos anatômicos: orientação crânio-dorsal e orientação crânio-ventral, adaptando-se à técnica e às necessidades clínicas do operador.

Este manual tem como objetivo orientar o usuário no uso correto do equipamento, promovendo segurança, eficiência e qualidade na assistência prestada, além de minimizar riscos e complicações durante a intubação.

Descrição da Produção do Manual Técnico do Videolaringoscópio 3D (VLP-3D):

O manual técnico do videolaringoscópio 3D (VLP-3D) foi desenvolvido com base em dados empíricos obtidos durante as fases de avaliação formativa e somativa de usabilidade, realizadas com profissionais da saúde em ambientes clínicos e simulados. A coleta de dados incluiu observação direta, registro de dificuldades durante a montagem e operação do dispositivo, entrevistas semiestruturadas e aplicação da System Usability Scale (SUS).

As informações obtidas permitiram identificar os principais pontos de dúvida, hesitação ou erro durante o uso do dispositivo. A partir dessas evidências, foram definidos os conteúdos essenciais para o manual, incluindo:

- instruções claras de montagem e desmontagem,
- posicionamento adequado para intubação,
- cuidados com a câmera e iluminação,
- medidas de segurança,
- limpeza e conservação,
- orientações para uso veterinário.

O objetivo do manual é fornecer suporte prático e direto ao usuário, promovendo maior autonomia e reduzindo o risco de erro em contextos clínicos e educacionais. A versão final do manual incorporou também sugestões dos participantes, refletindo uma abordagem centrada no usuário e iterativa.

O documento está incluído neste dataset em formato PDF, e sua estrutura segue os princípios de design instrucional com foco em clareza, simplicidade e aplicabilidade.

O manual completo e os dados técnicos estão disponíveis para consulta no link: Lund, Rafael; Kraemer Moraes, Ana Cristina (2025), “Manual do usuário / Relatório Técnico do Videolaringoscópio em PLA”, Mendeley Data, V1, doi: 10.17632/9mj4g728pr.1

ANEXOS

ANEXO – A1

CERTIFICADO

Certificamos que **ANA CRISTINA B KRAEMER MORAES**, participou com êxito do evento I CONGRESSO INTERNACIONAL EM SAÚDE DO HC-UFPE - INOVAÇÃO E INTERPROFISSIONALIDADE realizado de 22/11/2021 a 02/12/2021, em plataforma on line, contabilizando carga horária total de 32 horas.

Recife, 02/12/2021

Filipe Carrilho de Aguiar
Superintentendente do Hospital das Clínicas da UFPE

Claudia Diniz Lopes Marques
Presidente do Congreseso

Raquel Wilner da Silveira
Presidente do Comissão Científica

UFPE

EBSERH
É MEC

ANEXO – A2

CONAHP 2023 Congresso Nacional de Hospitais Privados
PESSOAS QUE TRANSFORMAM A SAÚDE

Certificamos que

ANA CRISTINA KRAEMER MORAES

teve seu trabalho científico selecionado e aprovado para a **Sessão Pôster do Congresso Nacional de Hospitais Privados – Conahp 2023**, com o trabalho científico sobre o tema:

A EXPERIÊNCIA DO USUÁRIO NA VALIDAÇÃO DE UM VIDEOLARINGOSCÓPIO EM IMPRESSÃO 3D

O congresso foi promovido pela Anahp – Associação Nacional de Hospitais Privados, nos dias 18 e 19 de outubro de 2023, em São Paulo (SP).

António Britto
Diretor-executivo da Anahp

Denise Santos
Presidente da Comissão Científica do Conahp 2023

Realização: anahp

ANEXO – A3


CONAHP Congresso Nacional de Hospitais Privados 2024

Certificamos que

ANA CRISTINA B KRAEMER MORAES

teve seu trabalho científico selecionado e aprovado para a **Sessão Pôster do Congresso Nacional de Hospitais Privados – Conahp 2024**, com o trabalho científico:

VALIDAÇÃO DE CENÁRIO SIMULADO NA AVALIAÇÃO DE RISCO DE EQUIPAMENTOS ELETROMÉDICOS

O congresso foi promovido pela Anahp – Associação Nacional de Hospitais Privados, nos dias 16 e 17 de outubro de 2024, em São Paulo (SP).

Antônio Britto
Diretor-executivo da Anahp

Paulo Chapchap
Presidente da Comissão Científica do Conahp 2024

Realização: anahp Há 23 anos promovendo qualidade e ética na saúde

ANEXO – A4


CONAHP Congresso Nacional de Hospitais Privados 2024

Certificamos que

ANA CRISTINA BEITIA KRAEMER MORAES

teve seu trabalho científico selecionado e aprovado para a **Sessão Pôster do Congresso Nacional de Hospitais Privados – Conahp 2024**, com o trabalho científico:

VALIDAÇÃO DE USABILIDADE PARA EQUIPAMENTOS MÉDICOS: INTEGRANDO UNIVERSIDADE X INDÚSTRIA

O congresso foi promovido pela Anahp – Associação Nacional de Hospitais Privados, nos dias 16 e 17 de outubro de 2024, em São Paulo (SP).

Antônio Britto
Diretor-executivo da Anahp

Paulo Chapchap
Presidente da Comissão Científica do Conahp 2024

Realização: anahp Há 23 anos promovendo qualidade e ética na saúde

ANEXO – A5


MINISTÉRIO DA EDUCAÇÃO
UNIVERSIDADE FEDERAL DE PELOTAS

A Universidade Federal de Pelotas, certifica que

VITÓRIA MACHADO BARCHINSKI

Apresentou o trabalho **"AVALIAÇÃO DA CALIBRAÇÃO DE UM CIRCUITO AMPLIFICADOR DE FORÇA PARA UM VIDEOLARINGOSCÓPIO ANATÔMICO DE ABS"** no **XXX Congresso de Iniciação Científica**, da 7ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão, realizado na UFPel, no período de 18 a 22 de outubro de 2021. O referido trabalho possui o(s) seguinte(s) autor(es): **BARCHINSKI, Vitória Machado; MORAES, Ana Cristina Beitia Kraemer; NASCIMENTO, Chiara das Dores do; GOUVEA, Rubimar Almeida; SOUZA, Everton Granemann**, sob orientação do(a) Prof.(a) **Everton Granemann Souza**.

Pelotas, 30 de novembro de 2021.

A autenticidade deste documento pode ser verificada através da URL:
https://cobalto.ufpel.edu.br/autenticacao/documento/ e informe o código de validação IE33421V22

ANEXO – A6

MINISTÉRIO DA EDUCAÇÃO
UNIVERSIDADE FEDERAL DE PELOTAS

A Universidade Federal de Pelotas, certifica que

ANA CRISTINA B KRAEMER MORAES

Apresentou o trabalho **"VIDEOLARINGOSCÓPIO DE BAIXO CUSTO UTILIZANDO IMPRESSÃO TRIDIMENSIONAL POR TECNOLOGIA DE MANUFATURA ADITIVA"** no **V Congresso de Inovação Tecnológica**, da 7ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão, realizado na UFPel, no período de 18 a 22 de outubro de 2021. O referido trabalho possui o(s) seguinte(s) autor(es): **MORAES, Ana Cristina B Kraemer; GRANEMANN, Everton de Souza; NASCIMENTO, Chiara das Dores do; LUND, Rafael Guerra** , sob orientação do(a) Prof.(a) **Rafael Guerra Lund**.

Pelotas, 30 de novembro de 2021.

A autenticidade deste documento pode ser verificada através da URL:
https://cobalto.ufpel.edu.br/autenticacao/documento/ e informe o código de validação QT165222E9

ANEXO – A7

MINISTÉRIO DA EDUCAÇÃO
UNIVERSIDADE FEDERAL DE PELOTAS

A Universidade Federal de Pelotas, certifica que

ANA CRISTINA BEITIA KRAEMER MORAES

Apresentou o trabalho **"USO DO SYSTEM USABILITY SCALE NA AVALIAÇÃO DE DISPOSITIVO MÉDICO"** no **VII Congresso de Inovação Tecnológica**, da 9ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão, realizado na UFPel, no período de 20 a 24 de novembro de 2023. O referido trabalho possui o(s) seguinte(s) autor(es): **MORAES, Ana Cristina Beitia Kraemer; GRANEMANN, Everton de Souza; NASCIMENTO, Chiara das Dores do; LUND, Rafael Guerra.**, sob orientação do(a) Prof.(a) **RAFAEL GUERRA LUND**.

Pelotas, 30 de novembro de 2023.

A autenticidade deste documento pode ser verificada através da URL:
https://cobalto.ufpel.edu.br/autenticacao/documento/ e informe o código de validação X4038240QO

ANEXO – A8

24 a 26 de novembro de 2021

20ª MOSTRA DA PRODUÇÃO UNIVERSITÁRIA

Entre memórias e reinvenções: resistências que transformam

30º Congresso de Iniciação Científica
24ª Seminário de Extensão
23º Encontro de Pós-Graduação
16º Seminário de Ensino
8º Simpósio de Cultura
4º Salão de Indissociabilidade

CERTIFICADO

Certificamos que o trabalho **SENSORIAMENTO DA FORÇA DE UM VIDEOLARINGOSCÓPIO 3D** apresentado por **VITÓRIA MACHADO BARCHINSKI** foi escolhido como destaque na área de **CIÊNCIAS DA SAÚDE** no 30º Congresso de Iniciação Científica (CIC) realizado na 20ª Mostra da Produção Universitária, realizada de 24 a 26 de novembro de 2021, na Universidade Federal do Rio Grande - FURG.

Rio Grande, 24 de novembro de 2021.

Chave de autenticidade: **6224637A-3923-6B74-E124-1744E4C9B17B**
A autenticidade deste certificado poderá ser comprovada através do site www.furg.br

Sibele da Rocha Martins
PRÓ-REITORA DE GRADUAÇÃO

Daniel Nonnenmacher Prado
PRÓ-REITOR DE EXTENSÃO E CULTURA

Eduardo Resende Secchi
PRÓ-REITOR DE PESQUISA E PÓS-GRADUAÇÃO

Daiane Teixeira Gutierrez
PRÓ-REITORA DE ASSUNTOS ESTUDANTIS

Prodocência · CAPES · Pibid · CNPq · FAPERGS · FURG

ANEXO – A9

#SALÃO UNIVERSITÁRIO 2021

A situação da Universidade - ensino, pesquisa e extensão no período tardio e pós-pandemia

CERTIFICADO

Certificamos que **VITORIA MACHADO BARCHINSKI** participou do **13º Congresso de Extensão/20º Mostra de Pós-Graduação/ 30º Congresso de Iniciação Científica/6ª Mostra de Trabalhos de Pesquisas produzidas por profissionais e a 6ª Mostra de Iniciação Científica e Extensão promovida para alunos das Escolas de Pelotas e da Região Sul**, realizado de 26 a 29 de Outubro de 2021, promovido pela Pró-Reitoria Acadêmica da UCPel, apresentando o trabalho **ESTUDO DA CALIBRAÇÃO DE UM SENSOR EM UM CIRCUITO AMPLIFICADOR DE FORÇA PARA UM VIDEOLARINGOSCÓPIO ANATÔMICO DE ABS**, de autoria de **Vitória Machado Barchinski**, coautores **Ana Cristina Beitia Kraemer Moraes; Chiara das Dores do Nascimento; Rubimar Almeida Gouvea; Everton Granemann Souza**, sob orientação do(a)(s) Prof.(a)(s) **EVERTON GRANEMANN SOUZA**.

Pelotas, 16 de novembro de 2021

Profª Dr.ª Patrícia Haertel Giusti
Pró-Reitora Acadêmica

Prof. Dr. Ricardo Tavares Pinheiro
Coordenador de Pesquisa e Pós-Graduação Stricto Sensu

Tiago Abeijon Gadret
Coordenador de Serviços Acadêmicos

Realização: CATÓLICA DE PELOTAS

Apoio: CNPq FAPERGS

Registrado na SDRA sob nº 5501 - 21

ANEXO – A10

TERMO DE COMPROMISSO DE PARTICIPAÇÃO - PROGRAMA 1K+
Satomed
46.034.956/0001-05

QUADRO RESUMO

1. ANUENTE: 49 EDUCACAO LTDA, pessoa jurídica de direito privado, inscrita no CNPJ/MF sob o no 35.611.694/0001-88, com sede na Rodovia João Paulo, 2608 - 502A. João Paulo, Florianópolis - SC, 88030-300.

2. ORGANIZADORA: SERVIÇO DE APOIO ÀS MICRO E PEQUENAS EMPRESAS DE SANTA CATARINA - SEBRAE/SC, sociedade civil sem fins lucrativos, transformado em serviço social autônomo pelo Decreto nº 99.570, de 09 de outubro de 1990, inscrito no CNPJ sob o nº 82.515.859/0001-06, com sede na SC 401, Km 01, lote 02, Parque Tecnológico Alfa, em Florianópolis, SC, doravante denominado **PATROCINADO,** neste ato representado pelo analista técnico, Alexandre Souza, brasileiro, casado, portador da carteira de identidade n.º 2.063.092, expedida pela SSP/SC, e do CPF n.º 785.018.819-53

3. STARTUP SELECIONADA:
Nome Startup: Satomed
CNPJ: 46.034.956/0001-05
Nome Representante: Ana Cristina Kraemer
CPF: 906875150-68
E-mail: anacristinabkmoraes@gmail.com
Telefone: (53) 99176-9898

ANEXO – A11

ANEXO – A12

ANEXO – A13

CATALISA ICT

Resultado do Edital CATALISA ICT de Planos de Inovação

Lista de selecionados por ordem alfabética dos proponentes

PROPONENTE	PLANO DE INOVAÇÃO	UF
Abel de Oliveira Costa Filho	MÉTODO ENZIMÁTICO ACELERADOR DE RESÍDUO ORGÂNICO	AM
Adalberto Rezende Santos	Método de cultivo unidimensional de microrganismos	RJ
Adamo Ferreira Gomes do Monte	Simuladores calibrados para colorimetria	MG
Admilson Marin	Expector - Remove Secreções dos Pulmões - IOT	SP
Adriana e Silva da Costa	INSERTO DE CORTE DE COMPÓSITOS Al2O3-ZrO2-TiN	SC
Adriano Rodrigues de Paula	MataAedes: uma armadilha que controla mosquitos	RJ
Ailton Pereira	Biopigmentos bacterianos para aplicação industrial	SP
Alan Lugarini de Souza	MVP de um Túnel de Vento Virtual	PR
Alana Elza Fontes Da Gama	PocketFisio: fisioterapia segura onde você estiver	PE
ALEXANDRE MIRANDA PIRES DOS ANJOS	DESIDRATAÇÃO DE ALIMENTOS POR ENERGIAS RENOVÁVEIS	PI
Alexandre ten Caten	Sensor Green: Smart Soil Testing	SC
Aline Teixeira Carolino	Bioinseticida para agricultura sustentável	RJ
Alisson Marcos Fogaça	Conversão de resíduos em bioprodutos por pirólise	PR
Alvaro Eduardo Eiras	Calçados e acessórios repelentes contra mosquitos	MG
Ana Cristina Beitia Kraemer Moraes	Videolaringoscópio Anatômico de Baixo Custo	RS
Ana Maria Frattini Fileti	Medidor ultrassônico de vazão bifásica	SP
Ana Maria Mazotto de Almeida	TexKera: fibras têxteis biotecnológicas	RJ

ANEXO – A14

FUNDEP

Projeto 29083-269 - AjvFD3YwmgvR8e3Qu

TERMO DE OUTORGA E APOIO AO PLANO DE INOVAÇÃO

Pelo presente instrumento, a FUNDAÇÃO DE DESENVOLVIMENTO DA PESQUISA - FUNDEP, com sede à Avenida Antonio Carlos, 6627, Pampulha, Belo Horizonte, Minas Gerais, inscrita no CNPJ sob o nº. 18.720.938/0001-41, neste ato representada pelo seu Presidente, doravante denominada OUTORGANTE, concede ao OUTOGARDO, a seguir qualificado, apoio financeiro para a realização do Plano de Inovação intitulado Videolaringoscópio Anatômico De Baixo Custo, selecionado por meio do Edital CATALISA ICT – Planos de Inovação, de acordo com as especificações, cláusulas e condições descritas a seguir:

OUTORGADO (A): ANA CRISTINA BEITIA KRAEMER MORAES, inscrito (a) no CPF nº 90687515068, RG 2067527776, residente e domiciliado à Rua Santos Dumont, 555. Centro. CEP:96020380, Pelotas-RS, endereço eletrônico anacristinabkmoraes@gmail.com

CLÁUSULA PRIMEIRA – DO OBJETO

O presente instrumento tem por objeto à concessão de benefícios de apoio financeiro ao (s) OUTORGADO (S), por parte da OUTORGANTE, destinado à adequada execução do Plano de Inovação intitulado ***Videolaringoscópio Anatômico De Baixo Custo***.

ANEXO – A15

Núcleo de Inovação Tecnológica (NIT) –
Universidade Estadual do Ceará (UECE)

Relatório de Atendimento de Mecanismo - Levantamento de potenciais parceiros/licenciantes Catalisa ICT

Dezembro, 2022

ANEXO – A16

G°NOVA Uma iniciativa ENAP

Certificado

A Escola Nacional de Administração Pública - Enap certifica que

SATOMED

No âmbito do **Programa de apoio a empreendedoras na tecnologia - Empreendedoras.Tech ,** *obteve projeto aprovado para integrar ao programa de aceleração de 2023.*

Betânia Lemos
Presidenta

Certificado registrado na Secretaria Escolar da Enap sob código a4245c8, em 27/11/2023. O presente certificado pode ter a sua validade comprovada acessando o QRCode à esquerda, ou, caso desejar, informando código acima na página da Enap (https://www.escolavirtual.gov.br/documentos/validacao), opção "Validar certificado"

ENAP Escola Nacional de Administração Pública

CNPJ: 00.627.612/0001-09

ANEXO – A17

INPI INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

870230111881
19/12/2023 09:53
29409161951428934

Pedido nacional de Invenção, Modelo de Utilidade, Certificado de Adição de Invenção e entrada na fase nacional do PCT

Número do Processo: BR 10 2023 026773 4

Dados do Depositante (71)

Depositante 1 de 1

Nome ou Razão Social: UNIVERSIDADE FEDERAL DE PELOTAS
Tipo de Pessoa: Pessoa Jurídica
CPF/CNPJ: 92242080000100
Nacionalidade: Brasileira
Qualificação Jurídica: Instituição de Ensino e Pesquisa
Endereço: Rua Gomes Carneiro, 01 - Ed. Delfim Mendes Silveira - Campus Porto/Reitoria - 4º Andar - PRPPG
Cidade: Pelotas
Estado: RS
CEP: 96010-610
País: Brasil
Telefone: (53) 3284 4086
Fax:
Email: epitte@ufpel.edu.br

Dados do Pedido

Natureza Patente: 10 - Patente de Invenção (PI)
Título da Invenção ou Modelo de Utilidade (54): LARINGOSCÓPIO COM BOROSCÓPIO ACOPLÁVEL PARA USO EM PEQUENOS ANIMAIS E ROEDORES
Resumo: A presente invenção tem como finalidade o desenvolvimento de um videolaringoscópio em impressão por manufatura aditiva ou injeção eletrônica com o objetivo de permitir a visualização facilitada da região da glote, na inserção do tubo orotraqueal no acesso a' via aérea inferior em pequenos animais, para uso na medicina veterinária. A sua indicação esta' nos procedimentos cirúrgicos realizados sob uso de anestesia geral e sedativos em animais de pequeno porte (roedores e outros animais). Atualmente o acesso às vias aéreas destes pequenos animais é realizada de maneira intuitiva, o que requer o manuseio rápido e manejo delicado para evitar complicações relacionadas ao uso dos anestésicos e sedativos em animais. O grande benefício desta invenção é a visualização direta da laringe e intubação rápida, com preservação da via respiratória e garantindo um procedimento cirúrgico seguro para animais de pequeno porte. Sendo assim, identificamos a necessidade de criação de um modelo de laringoscópio acoplado a microcâmera, com baixo custo de aquisição, com medidas específicas e adaptáveis, cujo design permita acesso e visualização indireta da glote de pequenos roedores com pesos diferentes, considerados abaixo de 1,0Kg e superior ou igual a 1,0-2,5Kg, para tornar mais seguros os procedimentos sob anestesia geral e sedação.
Figura a publicar: 1

ANEXO – A18

PELOTAS
PARQUE TECNOLÓGICO

DECLARAÇÃO

Declaramos para os devidos fins que a empresa Satomed Fabricação de Produtos Médicos LTDA, CNPJ nº 46.034.956/0001-05, está situada no Pelotas Parque Tecnológico, na Av. Domingos de Almeida, 1785, Areal-Pelotas/RS na sala 20 N, espaço destinado à Incubadora de Base Tecnológica da CIEMSUL vinculada a Universidade Católica de Pelotas ,

Pelotas, 30 de setembro de 2022

Assinado de forma digital por TECNOSUL PARQUE CIENTIFICO E TECNOLOGICO:24073235000171
TECNOSUL PARQUE CIENTIFICO E TECNOLOGICO:24073235000171
Dados: 2022.09.30 15:10:30 -03'00'

Rosâni Boeira Ribeiro

Diretora Executiva

Tecnosul Parque Científico e Tecnológico

ANEXO – A19

ANEXO – A20

USP Universidade de São Paulo Brasil

Janus
Sistema administrativo da Pós-graduação

Hospital de Reabilitação de Anomalias Craniofaciais

ATESTADO

Atestamos, para os devidos fins que, no período entre 01/03/2021 e 04/10/2021, o(a) senhor(a) Ana Cristina Beitia Kraemer Moraes, de número USP 12734895, cursou a(s) disciplina(s) abaixo na qualidade de aluno(a) especial no programa de pós-graduação em Ciências da Reabilitação, área de concentração Fissuras Orofaciais e Anomalias Relacionadas.

Disciplina: Simulação Clínica: Conceitos e Aplicação na Formação e Aprimoramento de Profissionais
Sigla: HRB4095-1/3 **Carga Horária:** 45 **Conceito:** A **Frequência:** 100 **Créditos:** 3
Início: 04/05/2021 **Término:** 05/07/2021

Conceito a partir de 02/01/1997:
A - Excelente, com direito a crédito; B - Bom, com direito a crédito; C - Regular, com direito a crédito; R - Reprovado; T - Transferência.
Um(1) crédito equivale a 15 horas de atividade programada.

Este documento eletrônico dispensa carimbo e assinatura. Sua autenticidade pode ser comprovada fornecendo-se o código de controle na seguinte página da Universidade de São Paulo: **https://uspdigital.usp.br/iddigital**

ANEXO – A21

CERTIFICADO

Treinamento: Avaliação Clínica – Dispositivos médicos

Certifica-se que

Ana Cristina B. Kraemer Moraes

participou do treinamento supracitado realizado nos dias 13 a 15 de março de 2024, modalidade presencial, com carga horária de 21 horas.

Pelotas, 18 de março de 2024.

Francisco Falci

Resolution

Conteúdo:
- Ver arquivo "Avaliação Clínica de Dispositivos Médicos - Mar_2024", formato pdf, conteúdo completo.

ANEXO – A22

IESTI

Certificado

Certificamos que **Ana Cristina B. Kraemer Moraes**, CPF **906.875.150-68**, participou do curso "**USABILIDADE DE PRODUTOS PARA SAÚDE**", ministrado pelo professor doutor Rodrigo Maximiano Antunes de Almeida. Promovido pelo Laboratório de Usabilidade e Fatores Humanos (LUFH) do Instituto de Engenharia de Sistemas e Tecnologia da Informação (IESTI) da Universidade Federal de Itajubá. Com um total de 40 (quarenta) horas, realizado no período de 05 a 09 de fevereiro de 2024.

Prof. Dr. Egon Luiz Müller Júnior
Coordenador do LUFH

Prof. Dr. Robson Luiz Moreno
Diretor do IESTI

ANEXO – A23

CERTIFICADO

Treinamento: Usabilidade – Dispositivos médicos

Certifica-se que

Ana Cristina B. Kraemer Moraes

participou do treinamento supracitado realizado nos dias 19 a 21 de fevereiro de 2024, modalidade presencial, com carga horária de 21 horas.

Pelotas, 21 de fevereiro de 2024.

Francisco Falci

Elaine Koda

Resolution

Conteúdo:
- Ver arquivo "Usabilidade de Dispositivos Médicos", formato pdf, conteúdo completo.

ANEXO – A24

CERTIFICADO

Certificamos que

Ana Cristina B Kraemer Moraes

participou, como mentorando(a),
do Programa-piloto de Mentoria em Propriedade Intelectual,
em sua edição 2022,
na modalidade a distância, com carga horária de 8 h.

VINICIUS BOGÉA CÂMARA
COORDENADOR-GERAL DA COORDENAÇÃO-GERAL DE DISSEMINAÇÃO PARA INOVAÇÃO
INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

3rdggAG9fj

INPI INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL CGDI Coordenação-Geral de Disseminação para Inovação

ANEXO – A25

CERTIFICADO

Certificamos que

Ana Cristina B Kraemer Moraes

participou do curso "Uso da Propriedade Intelectual
em Negócios de Base Tecnológica"
realizado no período de 05 a 29 de abril de 2022
na modalidade ensino a distância, com carga horária de 20h/a.

RICARDO CARVALHO RODRIGUES
COORDENADOR DA ACADEMIA DA PROPRIEDADE INTELECTUAL, INOVAÇÃO E DESENVOLVIMENTO
INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

DEUPY6NWCJ

ACAD Academia da Propriedade Intelectual, Inovação e Desenvolvimento INPI INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

ANEXO – A26

INPI INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL
BRAZILIAN NATIONAL INDUSTRIAL PROPERTY INSTITUTE

WIPO WORLD INTELLECTUAL PROPERTY ORGANIZATION

ACADEMIA DO INPI WIPO ACADEMY

CERTIFICADO

Certificamos que

ANA CRISTINA BEITIA KRAEMER MORAES

Concluiu com êxito o curso DL 320P BR
Com carga-horária de 180 horas-aula

CURSO NOÇÕES BÁSICAS DE REDAÇÃO DE PEDIDOS DE PATENTES

Realizado no período de 08 de setembro a 12 de dezembro de 2022.

Ricardo C. Rodrigues
Coordenador
Academia do INPI

Sherif Saadallah
Diretor Executivo
Academia da OMPI

Anexo - A27

ACADEMIA DO INPI ACADEMIA DA OMPI

CERTIFICADO

Certificamos que

ANA CRISTINA BEITIA KRAEMER MORAES

Concluiu com êxito o Curso DL 318º BR
Com Carga Horária de 180 horas-aula

CURSO AVANÇADO DE BUSCA DE INFORMAÇÕES DE PATENTES

Realizado no período de 04 de abril a 15 de julho de 2022.

Beatriz C. Rodrigues
Coordenador
Academia do INPI

Sherif Saadallah
Diretor Executivo
Academia da OMPI

Anexo - A28

ACADEMIA DO INPI WIPO ACADEMY

CERTIFICADO

Certificamos que

ANA CRISTINA BEITIA KRAEMER MORAES

Concluiu com êxito o Curso DL 301º BR
Com Carga Horária de 150 horas-aula

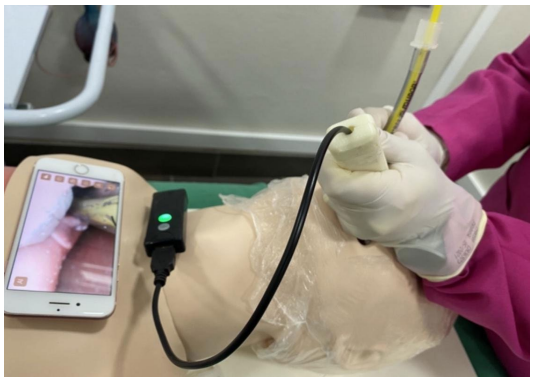
CURSO AVANÇADO DE PATENTES

Realizado no período de 06 de abril a 16 de julho de 2021

Beatriz C. Rodrigues
Coordenador
Academia do INPI

Sherif Saadallah
Diretor Executivo
Academia da OMPI

Anexo - A29



Avaliação e testes iniciais no processo de desenvolvimento do protótipo, incluindo análises de usabilidade, ergonomia e desempenho funcional.

Anexo – A30

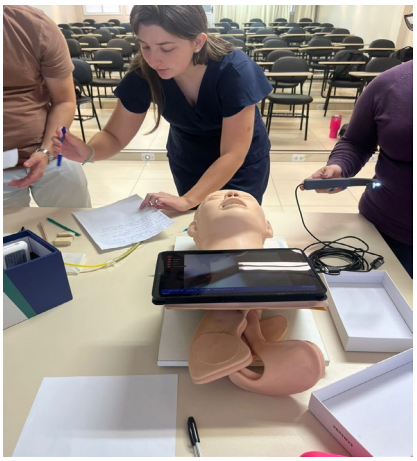
Na imagem, ao centro, estão três versões da evolução do protótipo impresso em 3D. Os dois primeiros modelos foram utilizados nos testes de ***avaliação de prototipagem, heurística, análise de tarefas e avaliação formativa****. O terceiro modelo, refinado com base nos feedbacks anteriores, foi empregado na* ***avaliação sumativa****.*

À ***extremidade esquerda****, observa-se um* ***laringoscópio tradicional do tipo Macintosh****, enquanto na* ***extremidade direita****, está um* ***videolaringoscópio comercial****, utilizado como referência para comparação de desempenho e usabilidade.*

Anexo – A31

Materiais utilizados nos testes de usabilidade com o protótipo modificado. À esquerda, observa-se o modelo comercial de videolaringoscópio da marca. À direita, o modelo desenvolvido por manufatura aditiva, conectado a um tablet para visualização das imagens capturadas durante o procedimento.

Anexo – A32



Treinamento dos entrevistadores.

Anexo – A33