

WILLIAM SEIDEL

**RECONSTRUÇÃO MAMÁRIA APÓS MASTECTOMIA
POR NEOPLASIA DE MAMA: ANÁLISE COMPARATIVA
ENTRE RECONSTRUÇÃO PRECOCE E TARDIA**

**Dissertação apresentada à Universidade
Federal de Santa Catarina, como
requisito para a conclusão do Mestrado
Profissional em Cuidados Intensivos e
Paliativos**

**Florianópolis
Universidade Federal de Santa Catarina
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DEDICATÓRIA

Dedico à Deus, meus pais Gervásio José Seidel e Jaci Luft Seidel, minha irmã Angélica Seidel e, minha noiva Mariana Saideles Martins que sempre me incentivaram e deram suporte em todos os sentidos para prosperar na vida.

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TÍTULO: Reconstrução mamária após mastectomia por neoplasia de mama: análise comparativa entre reconstrução precoce e tardia

TITLE: Breast reconstruction after mastectomy for breast cancer: comparative analysis of early and late reconstruction

Título curto: Reconstrução mamária precoce vs. tardia após mastectomia

Brief title: Early vs. late breast reconstruction after mastectomy

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RESUMO

Introdução: A reconstrução precoce com implantes definitivos pós-mastectomia por neoplasia de mama tem sido amplamente empregada, especialmente com a evolução dos tratamentos cirúrgicos do câncer de mama cada vez mais conservadores. **Objetivos:** Identificar diferentes características associadas à cirurgia plástica de acordo com o tempo de reconstrução: precoce ou tardio, e avaliar Qualidade de vida em pacientes submetidas a mastectomia por câncer. **Métodos:** Estudo analítico transversal, que avaliou indivíduos adultos submetidos a mastectomia por neoplasia de mama e reconstrução mamária no Serviço de Cirurgia Plástica de um hospital terciário. **Resultados:** Entre março de 2011 e novembro de 2015, 58 indivíduos submetidos à mastectomia foram incluídos, com média de idade de $51,6 \pm 10,6$ anos e 98,3% eram mulheres. Oitenta por cento dos pacientes foi submetida a mastectomia radical e 20% à segmentectomia. Reconstrução cirúrgica precoce ocorreu em 22,4% e tardia em 77,6% dos casos: reconstrução imediata com retalho local (15,5%); reconstrução imediata com implante de silicone gel (6,9%); retalho músculo-cutâneo transverso do reto abdominal (TRAM) (6,9%); reconstrução tardia com retalho local (8,6%), expensor e implante (39,7%); e reconstrução com retalho do grande dorsal e implante (22,4%). Quando se comparou os indivíduos submetidos à cirurgia de reconstrução precoce àqueles submetidos à reconstrução tardia, se observou que entre os indivíduos submetidos à cirurgia de reconstrução tardia das mamas, havia uma maior proporção de mastectomia radical (90,7% vs. 41,7%; $p = 0,001$), de duas ou mais intervenções cirúrgicas (64,1% vs. 20,0%; $p = 0,029$). Não se observou diferenças na Qualidade de vida, avaliada por meio do questionário WHOQoL-Bref, de acordo com o tempo de reconstrução. **Conclusões:** As características que se associam ao tempo de reconstrução pós-mastectomia relacionam-se a fatores pré-operatórios, como a cirurgia empregada e o número de intervenções realizado e não têm influência nas complicações ou na Qualidade de vida.

Palavras-chave: Cuidados intensivos e Paliativos; Neoplasias da Mama; Mamoplastia; Cirurgia Plástica

ABSTRACT

Background: Early reconstruction after mastectomy for breast cancer with definitive implants has been widely used, especially with the evolution of conservative surgical breast cancer treatments. We aimed to identify different characteristics associated with plastic surgery according to reconstruction time: immediate or delayed, and evaluate quality of life in patients undergoing mastectomy for cancer. **Methods:** Cross-sectional analytical study, which evaluated adult patients undergoing mastectomy for breast cancer and breast reconstruction in Plastic Surgery Service in a tertiary hospital. **Results:** Between March 2011 and November 2015, 58 patients who underwent mastectomy were included with a mean age of 51.6 ± 10.6 years and 98.3% were women. Eighty percent of the patients underwent a radical mastectomy and 20% to segmentectomies. Immediate surgical reconstruction occurred in 22.4% and delayed reconstruction was reported in 77.6% of cases: immediate reconstruction with the local flap trade (15.5%); immediate reconstruction with prosthesis (6.9%); TRAM (transverse flap myocutaneous rectus abdominis) (6.9%); delayed reconstruction with local flap (8.6%), expander and prosthesis (35.7%); and reconstruction with latissimus dorsi flap and prosthesis (22.4%). When comparing individuals undergoing reconstructive surgery according to timing of reconstruction, it was observed that patients undergoing delayed breast reconstruction surgery presented a higher proportion of radical mastectomy (90.7% vs. 41.7%; $p = 0.001$), two or more surgical interventions (64.1% vs 20.0%; $p = 0.029$). There was no difference in the quality of life according to reconstruction time. **Conclusions:** The characteristics that are associated with post-mastectomy reconstruction timing are related to preoperative factors, such as the procedure employed and the number of interventions performed and have no influence on complications or quality of life.

Keywords: Intensive and Palliative Care; Breast Neoplasms; Mammoplasty; Plastic Surgery

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APÊNDICE 1

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

O (a) senhor (a) está sendo convidado a participar de uma pesquisa **RECONSTRUÇÃO MAMÁRIA POR MEIO DE RETALHO GRANDE DORSAL COM PRÓTESE E COM USO DE EXPANSORES: ANÁLISE COMPARATIVA ENTRE AS TÉCNICAS E QUALIDADE DE VIDA PÓS-OPERATÓRIO DE MASTECTOMIA POR CÂNCER DE MAMA**, que fará avaliação dos dados contidos em seu prontuário médico, tendo como objetivo determinar grau de satisfação em relação ao tratamento oferecido e o processo e o detalhamento em relação ao seu tratamento. . A partir de sua autorização os dados sobre o seu tratamento serão colhidos de seu prontuário. Esta pesquisa será realizada no Hospital Universitário.

Este impresso contém as informações para sua participação voluntária neste estudo, que visa comparar a Qualidade de vida depois de mastectomia e se há diferença na Qualidade de vida dependendo da técnica cirúrgica utilizada. Os pacientes que forem selecionados para o estudo, incluindo você, deverão fornecer, ao entrevistador, informações como: idade, cor da pele, tempo de cirurgia, e responder ao questionário WOQOL-BREF sobre Qualidade de vida.

O maior benefício para o participante da pesquisa seria o benefício indireto advindo do melhor entendimento do resultado da cirurgia sobre a Qualidade de vida do paciente. Além disso,

a divulgação dos resultados pode estimular outros pesquisadores do mundo a realizar estudos maiores.

Esta pesquisa está submetida à Resolução CNS nº 466/12. Nós pesquisadores declaramos que cumpriremos as exigências contidas na Resolução CNS nº 466/12 (especialmente nos itens IV.3 e IV.4). Em qualquer etapa do estudo, você terá acesso aos profissionais responsáveis pela pesquisa para esclarecimento de eventuais dúvidas sobre o trabalho. Os principais investigadores são o Dr. William Seidel e a Professora Janaína Luz Narciso Schiavon, que podem ser encontradas no Departamento de Clínica Médica, 3º andar Hospital Universitário ou pelos e-mails williamseidel86@gmail.com e gastro.hu@uol.com.br, respectivamente. Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com os pesquisadores por e-mail ou no telefone 3721-9014. O Comitê de Ética e Pesquisa em Seres Humanos dessa Universidade localiza-se no Prédio Reitoria II (Edifício Santa Clara), R: Desembargador Vitor Lima, nº 222, sala 401, Trindade, Florianópolis/SC. CEP 88.040-400. E-mail: cep.propesq@contato.ufsc.br. Telefone: (48) 3721-6094.

É garantida a liberdade da retirada de consentimento a qualquer momento e deixar de participar do estudo, sem qualquer prejuízo à continuidade de seu tratamento na Instituição. As informações obtidas serão analisadas em conjunto com outros pacientes, não sendo divulgado a identificação de nenhum paciente. Você tem o direito de ser mantido atualizado sobre os resultados parciais das pesquisas, quando em estudos abertos, ou de resultados que sejam do conhecimento dos pesquisadores, inclusive considerando benefícios e acompanhamentos posteriores ao encerramento e/ ou a interrupção da pesquisa. Também não há compensação financeira relacionada à sua participação. Não há despesas pessoais para o participante em qualquer fase do estudo, incluindo exames e consultas. No entanto, caso ocorram, há garantia de ressarcimento das despesas tidas pelos participantes da pesquisa e dela decorrentes; e há garantia de indenização diante de eventuais danos decorrentes da pesquisa. Considera-se que toda pesquisa envolvendo seres humanos envolve risco em tipos e gradações variados. O dano eventual poderá ser imediato ou tardio, comprometendo o indivíduo ou a coletividade. Deve levar-se em consideração a possibilidade de danos à dimensão física, psíquica, moral, intelectual, social, cultural ou espiritual do ser humano. No caso desse estudo, o risco é mínimo e envolveria a exposição dos dados de coletados no laboratório do HU e de seu prontuário. No entanto, os pesquisadores se comprometem a manter o sigilo e confidencialidade dos dados dos participantes e utilizá-los unicamente para as finalidades previstas na pesquisa, ou seja, divulgação em evento científico e publicação em periódico científico. O pesquisador tem o compromisso de utilizar os dados e o material coletado somente para esta pesquisa.

Este termo de consentimento livre e esclarecido é fornecido em duas vias, que serão assinadas também pelo pesquisador responsável pelo projeto, sendo que uma cópia se destina ao participante e a outra ao pesquisador.

Segue abaixo os termos da declaração para poder participar do estudo:

Acredito ter sido suficientemente informado a respeito do estudo **“RECONSTRUÇÃO MAMÁRIA POR MEIO DE RETALHO GRANDE DORSAL COM PRÓTESE E COM USO DE EXPANSORES: ANÁLISE COMPARATIVA ENTRE AS TÉCNICAS E QUALIDADE DE VIDA PÓS-OPERATÓRIO DE MASTECTOMIA POR CÂNCER DE MAMA”**. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também

que minha participação é isenta de despesas e que tenho garantia do acesso a tratamento hospitalar, caso seja necessário. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento: antes ou durante o mesmo; sem penalidades, prejuízo, perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.

Paciente ou representante legal

data

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste paciente ou representante legal para a participação neste estudo.

Responsável pelo estudo

William Seidel

Janaína Luz Narciso Schiavon

data

ANEXO 1 - NORMAS ADOTADAS

Annals of Plastic Surgery

Online Submission and Review System

Ethical/Legal Considerations

A submitted manuscript must be an original contribution not previously published (except as an abstract or preliminary report); must not be under consideration for publication elsewhere; and must, if accepted, not be published elsewhere in similar form, in any language, without the consent of Wolters Kluwer. Each person listed as an author is expected to have participated in the study to a significant extent. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the Journal, its editors, or the publisher. The editorial office will acknowledge receipt of your manuscript and will give you a manuscript number for reference. Address all inquiries regarding manuscripts not yet accepted or published to the Journal's editorial office. **All manuscripts must be submitted online through the journal's website at <http://sap.edmgr.com>.** See submission instructions under "Online manuscript submission."

Patient anonymity and informed consent

It is the author's responsibility to ensure that a patient's anonymity be carefully protected and to verify that any experimental investigation with human subjects reported in the manuscript was performed with informed consent and following all the guidelines for experimental investigation with human subjects required by the institution(s) with which all the authors are affiliated. The protocol of the study must be approved by the Institutional Review Board (IRB) or the equivalent (eg, Research Ethics Board) where the study is conducted. Written releases from patients must accompany photographs in which the identity of the patient can be recognized. In the absence of such a release, an image must be cropped or partially obscured to the extent that the patient cannot be identified. Covering the eyes in a full-face photograph is not sufficient.

Conflicts of Interest and Copyright Transfer

Authors must state all possible conflicts of interest in the manuscript, including financial, consultative, institutional, and other relationships that might lead to bias or conflict of interest. If there is no conflict of interest, this should also be explicitly stated as "none declared." All sources of funding should be acknowledged in the manuscript. All relevant conflicts of interest and sources of funding should be included on the title page of the manuscript under the heading, "Conflicts of Interest and Source of Funding." For example:

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Sample references are given below:

Journal article

1. Lin S-D, Tsai C-C, Lai C-S, et al. Endoscope-assisted parotidectomy for benign parotid tumors. *Ann Plast Surg* 2000;45:269-273

Book chapter

2. Todd VR. Visual information analysis: frame of reference for visual perception. In: Kramer P, Hinojosa J., eds. *Frames of Reference for Pediatric Occupational Therapy*. Philadelphia: Lippincott Williams & Wilkins; 1999:205-256

Entire book

3. Kellman RM, Marentette LJ. *Atlas of Craniomaxillofacial Fixation*. Philadelphia: Lippincott Williams & Wilkins; 1999

Software

4. Epi Info [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention; 1994

Online journals

5. Friedman SA. Preeclampsia: a review of the role of prostaglandins. *Obstet Gynecol* [serial online]. January 1988;71:22-37. Available from: BRS Information Technologies, McLean, VA. Accessed December 15, 1990

Database

6. CANCERNET-PDQ [database online]. Bethesda, MD: National Cancer Institute; 1996. Updated March 29, 1996

World Wide Web

7. Gostin LO. Drug use and HIV/AIDS [*JAMA HIV/AIDS* web site]. June 1, 1996. Available at: <http://www.ama-assn.org/special/hiv/ethics>. Accessed June 26, 1997

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ANEXO 2 – PARECER DO COMITÊ DE ÉTICA

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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: RECONSTRUÇÃO MAMÁRIA POR MEIO DE RETALHO GRANDE DORSAL COM PRÓTESE E COM USO DE EXPANSORES: ANÁLISE COMPARATIVA ENTRE AS TÉCNICAS E QUALIDADE DE VIDA NO PÓS-OPERATÓRIO DE MASTECTOMIA POR CÂNCER DE MAMA

Pesquisador: JANAINA LUZ NARCISO SCHIAVON

Área Temática:

Versão: 2

CAAE: 46208215.2.0000.0121

Instituição Proponente: Universidade Federal de Santa Catarina

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.183.132

Data da Relatoria: 10/08/2015

Apresentação do Projeto:

Trata o presente de um projeto de pesquisa do Mestrado Profissional associado à Residência Médica em Cuidados Intensivos e Palliativos que será desenvolvido por William Seidel em coautoria com Gustavo Palmeiro Walter, sob orientação de Rosemeri Maurici da Silva e orientação de Janaina Luz Narciso Schiavon, que assina a folha de rosto como pesquisador responsável, junto com Carlos Alberto Justo da Silva, Diretor Geral do HU UFSC.

O projeto prevê a inclusão de 150 participantes, submetidas à mastectomia por câncer de mama e cirurgia reparadora atendidas no HU entre janeiro de 2014 e dezembro de 2015, mediante a aplicação de questionário WHOQOL-BREF e coleta de dados clínicos e epidemiológicos (pelo prontuário)

Objetivo da Pesquisa:

Objetivo Primário:

Identificar as variáveis associadas a melhor qualidade de vida e avaliar se há diferença com relação a técnica cirúrgica empregada.

Objetivo Secundário:

- Descrever as características clínicas de mulheres submetidas à cirurgia reparadora pós-

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mastectomia por câncer de mama.

-Realizar análise comparativa entre as técnicas do "retalho grande dorsal associado à prótese" com "uso de expansores teciduais mamários".

-Aplicar o questionário de satisfação pessoal denominado WHOQOL-BREF nas mulheres submetidas à cirurgia reparadora pós-mastectomia por câncer de mama.

-Identificar se houve diferença entre o grau de qualidade de vida e a técnica operatória empregada.

Avaliação dos Riscos e Benefícios:

Os riscos e benefícios foram descritos devidamente

Comentários e Considerações sobre a Pesquisa:

Informações adicionais sobre a pesquisa estão devidamente descritas nos campos do presente Parecer e nos documentos submetidos do processo

Considerações sobre os Termos de apresentação obrigatória:

Constam na Plataforma os documentos solicitados para a submissão do projeto:

- 1) Folha de rosto devidamente assinada;
- 2) Formulário Projeto da Pesquisa - PB;
- 3) Projeto de Pesquisa estruturado na íntegra;
- 4) Anuência da Instituição

Recomendações:

Não há

Conclusões ou Pendências e Lista de Inadequações:

Considerando que todas as recomendações foram satisfatoriamente atendidas sou de parecer favorável à aprovação deste processo

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

FLORIANOPOLIS, 13 de Agosto de 2015

Assinado por:
Washington Portela de Souza
(Coordenador)

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