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
2016

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

Coordenadora do Mestrado Profissional: Prof.ª Dr.ª Ana Maria de Faria Nunes Stamm
Professora Orientadora: Prof.ª Dr.ª Janaína Luz Narciso Schiavon
Professora Co-orientadora: Prof.ª Dr.ª Rosemeri Maurici da Silva

Florianópolis
Universidade Federal de Santa Catarina
2016

Ficha de identificação da obra elaborada pelo autor,
através do Programa de Geração Automática da Biblioteca Universitária da UFSC.

Seidel, William
Reconstrução mamária após mastectomia por neoplasia de mama: análise comparativa entre reconstrução precoce e tardia : Reconstrução mamária precoce vs. tardia após mastectomia / William Seidel ; orientadora, Janaína Luz Narciso Schiavon ; coorientadora, Rosemeri Maurici Silva.
Florianópolis, SC, 2016.
35 p.

Dissertação (mestrado profissional) - Universidade Federal de Santa Catarina, Centro de Ciências da Saúde. Programa de Pós-Graduação em Cuidados Intensivos e Paliativos.

Inclui referências

1. Cuidados Intensivos e Paliativos. 2. Cuidados Intensivos e Paliativos. 3. Neoplasias da Mama. 4. Mamoplastia. 5. Qualidade de Vida. I. Schiavon, Janaína Luz Narciso. II. Silva, Rosemeri Maurici. III. Universidade Federal de Santa Catarina. Programa de Pós-Graduação em Cuidados Intensivos e Paliativos. IV. Título.

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.

AGRADECIMENTOS

Agradeço principalmente à minha orientadora Dra. Janaina Luz Narciso-Schiavon que desde o início me incentivou muito e ao longo de todo trabalho teve paciência e persistência que muitas vezes não a tive para prosperar na pesquisa, por todas as orientações e revisões além de ajuda em todas as etapas do projeto. Aos meus colegas Daniel Barazzetti, Gustavo Palmeiro Walter, Thiago Alessandro Ferri e Renata Della Giustina por ajudar na coleta de dados, revisões de prontuários e aplicação de entrevistas assim como revisão de literatura. À Dra. Rosemeri Maurici pelo suporte científico e revisões. Ao chefe da residência de cirurgia plástica Dr. Jorge Bins Ely pelo incentivo ao estudo, pesquisa e teor científico. Ao meu staff Dr. Arthur Koerich, Dr. Conrado D'Ávila e Dr. João Francisco do Vale Pereira, pelos valiosos ensinamentos e oportunidade profissional. Ao Hospital Universitário da UFSC, como instituição, por permitir a realização da pesquisa. Às nossas pacientes do ambulatório que se voluntariaram a participar da pesquisa. À minha noiva Mariana Saideles Martins, com quem divido tudo, agradeço o apoio, incentivo e suporte emocional em todas as etapas.

SUMÁRIO

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

AUTORES:

William Seidel[1,2]; Jorge Bins Ely[1]; Daniel Ongaratto Barazzetti[1]; Renata Della Giustina[3]; Gustavo Palmeiro Walter[1,2]; Thiago Alessandro Ferri[1,2]; Rosemeri Maurici[2]; Janaína Luz Narciso-Schiavon[2,3]

[1]. Serviço de Cirurgia Plástica e Queimados – Hospital Universitário Polydoro Ernani de São Thiago - Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.
[2]. Mestrado Profissional em Cuidados Intensivos e Paliativos, Centro de Ciências da Saúde, Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.
[3]. Núcleo de Estudos em Gastroenterologia e Hepatologia, Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.

AUTOR PARA CORRESPONDÊNCIA:
William Seidel
Serviço de Cirurgia Plástica/Hospital Universitário Polydoro Ernani de São Thiago/UFSC. Rua Professora Maria Flora Pausewang s/nº, 4º andar, Trindade, 88040-900, Florianópolis, SC, Brasil.
Phone: 55 48 37219052
e-mail: williamseidel86@gmail.com

Suporte financeiro: não houve suporte financeiro.
Conflitos de interesse: os autores declaram que não há conflito de interesse.

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 ± 10,6 anos e 98,3% eram mulheres. Oitenta porcento 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%), expansor 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

Backgroud: 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 timming 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

REFERÊNCIAS BIBLIOGRÁFICAS

1. Justo N, Wilking N, Jonsson B, et al. A review of breast cancer care and outcomes in Latin America. Oncologist 2013;18:248-56.
2. Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer 2015;136:E359-86.
3. Freitas Jr R, Freitas NM, Curado MP, et al. Incidence trend for breast cancer among young women in Goiania, Brazil. Sao Paulo Med J 2010;128:81-4.
4. Lee BL, Liedke PE, Barrios CH, et al. Breast cancer in Brazil: present status and future goals. Lancet Oncol 2012;13:e95-e102.
5. Ng SK, Hare RM, Kuang RJ, et al. Breast Reconstruction Post Mastectomy: Patient Satisfaction and Decision Making. Ann Plast Surg 2016;76:640-4.
6. Mora LD. História do Tratamento Cirúrgico do Cancro da Mama: Empirismo e Ciência History of Surgical Treatment of Breast Cancer: Empiricism and Science. Revista Portuguesa de Cirurgia 2013:41-58.
7. Plesca M, Bordea C, El Houcheimi B, et al. Evolution of radical mastectomy for breast cancer. J Med Life 2016;9:183-6.
8. Veronesi U, Saccozzi R, Del Vecchio M, et al. Comparing Radical Mastectomy with Quadrantectomy, Axillary Dissection, and Radiotherapy in Patients with Small Cancers of the Breast. New England Journal of Medicine 1981;305:6-11.
9. Gerber B, Krause A, Dieterich M, et al. The oncological safety of skin sparing mastectomy with conservation of the nipple-areola complex and autologous reconstruction: an extended follow-up study. Ann Surg 2009;249:461-8.
10. Uroskie TW, Colen LB. History of Breast Reconstruction. Seminars in Plastic Surgery 2004;18:65-69.
11. Hartrampf CR, Scheflan M, Black PW. Breast reconstruction with a transverse abdominal island flap. Plast Reconstr Surg 1982;69:216-25.
12. Petit JY, Gentilini O, Rotmensz N, et al. Oncological results of immediate breast reconstruction: long term follow-up of a large series at a single institution. Breast Cancer Res Treat 2008;112:545-9.
13. Bezuhly M, Temple C, Sigurdson LJ, et al. Immediate postmastectomy reconstruction is associated with improved breast cancer-specific survival: evidence and new challenges from the Surveillance, Epidemiology, and End Results database. Cancer 2009;115:4648-54.
14. Gieni M, Avram R, Dickson L, et al. Local breast cancer recurrence after mastectomy and immediate breast reconstruction for invasive cancer: a meta-analysis. Breast 2012;21:230-6.
15. Nedumpara T, Jonker L, Williams MR. Impact of immediate breast reconstruction on breast cancer recurrence and survival. Breast 2011;20:437-43.

16. Cardoso MJ, Santos AC, Cardoso J, et al. Choosing observers for evaluation of aesthetic results in breast cancer conservative treatment. Int J Radiat Oncol Biol Phys 2005;61:879-81.
17. Kuroda F, Urban C, Zucca-Matthes G, et al. Evaluation of Aesthetic and Quality-of-Life Results after Immediate Breast Reconstruction with Definitive Form-Stable Anatomical Implants. Plast Reconstr Surg 2016;137:278e-286e.
18. Minayo MCdS, Hartz ZMdA, Buss PM. Qualidade de vida e saúde: um debate necessário. Ciência & Saúde Coletiva 2000;5:7-18.
19. Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976) 2000;25:3186-91.
20. Fleck MP, Louzada S, Xavier M, et al. Aplicação da versão em português do instrumento abreviado de avaliação da Qualidade de vida "WHOQOL-bref". Revista de Saúde Pública 2000;34:178-183.
21. Oliveira IS, Costa LC, Manzoni AC, et al. Assessment of the measurement properties of quality of life questionnaires in Brazilian women with breast cancer. Braz J Phys Ther 2014;18:372-83.
22. Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group. Psychol Med 1998;28:551-8.
23. Cortes-Flores AO, Morgan-Villela G, Zuloaga-Fernandez del Valle CJ, et al. Quality of life among women treated for breast cancer: a survey of three procedures in Mexico. Aesthetic Plast Surg 2014;38:887-95.
24. Claro Jr F, Costa DVd, Pinheiro AdS, et al. Complicações em reconstrução mamária total em pacientes mastectomizadas por câncer de mama: análise comparativa de longo prazo quanto a influência de técnica, tempo de cirurgia, momento da reconstrução e tratamento adjuvante Complications in total breast reconstruction in patients treated for breast cancer: long-term comparative analysis of the influence of the technique, operative time, timing of reconstruction, and adjuvant treatment. Revista Brasileira de Cirurgia Plástica 2013:85-91.
25. Kim MK, Kim T, Moon HG, et al. Effect of cosmetic outcome on quality of life after breast cancer surgery. Eur J Surg Oncol 2015;41:426-32.
26. Kim KD, Kim Z, Kuk JC, et al. Long-term results of oncoplastic breast surgery with latissimus dorsi flap reconstruction: a pilot study of the objective cosmetic results and patient reported outcome. Ann Surg Treat Res 2016;90:117-23.
27. Cosac OM, Camara Filho JPP, Cammarota MC, et al. Reconstrução mamária de resgate: a importância dos retalhos miocutâneos. Salvage breast reconstruction: the importance of myocutaneous flaps. Revista Brasileira de Cirurgia Plástica 2013:92-99.
28. Albornoz CR, Matros E, McCarthy CM, et al. Implant breast reconstruction and radiation: a multicenter analysis of long-term health-related quality of life and satisfaction. Ann Surg Oncol 2014;21:2159-64.

29. Schain WS, Wellisch DK, Pasnau RO, et al. The sooner the better: a study of psychological factors in women undergoing immediate versus delayed breast reconstruction. Am J Psychiatry 1985;142:40-6.
30. Chevray PM. Timing of breast reconstruction: immediate versus delayed. Cancer J 2008;14:223-9.
31. Jeevan R, Cromwell DA, Browne JP, et al. Findings of a national comparative audit of mastectomy and breast reconstruction surgery in England. J Plast Reconstr Aesthet Surg 2014;67:1333-44.
32. Albornoz CR, Bach PB, Mehrara BJ, et al. A paradigm shift in U.S. Breast reconstruction: increasing implant rates. Plast Reconstr Surg 2013;131:15-23.
33. D'Souza N, Darmanin G, Fedorowicz Z. Immediate versus delayed reconstruction following surgery for breast cancer. Cochrane Database Syst Rev 2011:CD008674.
34. Dean C, Chetty U, Forrest AP. Effects of immediate breast reconstruction on psychosocial morbidity after mastectomy. Lancet 1983;1:459-62.
35. Al-Ghazal SK, Sully L, Fallowfield L, et al. The psychological impact of immediate rather than delayed breast reconstruction. Eur J Surg Oncol 2000;26:17-9.
36. Sanati-Mehrizy P, Massenburg BB, Rozehnal JM, et al. A Comparison of Postoperative Outcomes in Immediate Versus Delayed Reconstruction After Mastectomy. Eplasty 2015;15:e44.
37. Tseng JF, Kronowitz SJ, Sun CC, et al. The effect of ethnicity on immediate reconstruction rates after mastectomy for breast cancer. Cancer 2004;101:1514-23.
38. Flitcroft K, Brennan M, Costa D, et al. An evaluation of factors affecting preference for immediate, delayed or no breast reconstruction in women with high-risk breast cancer. Psychooncology 2016.
39. Roth RS, Lowery JC, Davis J, et al. Quality of life and affective distress in women seeking immediate versus delayed breast reconstruction after mastectomy for breast cancer. Plast Reconstr Surg 2005;116:993-1002; discussion 1003-5.
40. Schmauss D, Machens H-G, Harder Y. Breast Reconstruction after Mastectomy. Frontiers in Surgery 2016;2.
41. Sullivan SR, Fletcher DR, Isom CD, et al. True incidence of all complications following immediate and delayed breast reconstruction. Plast Reconstr Surg 2008;122:19-28.
42. Alderman A, Gutowski K, Ahuja A, et al. ASPS clinical practice guideline summary on breast reconstruction with expanders and implants. Plast Reconstr Surg 2014;134:648e-55e.
43. Chang DW, Ferguson RE. Primary versus secondary postmastectomy reconstruction. Handchir Mikrochir Plast Chir 2008;40:225-9.
44. Kronowitz SJ. Immediate versus delayed reconstruction. Clin Plast Surg 2007;34:39-50; abstract vi.

45. Gassman AA, Yoon AP, Festekjian J, et al. Comparison of immediate postoperative pain in implant-based breast reconstructions. J Plast Reconstr Aesthet Surg 2016;69:604-16.
46. Parabkaharan S, Melody M, Trotta R, et al. Comparison of Reconstructive Outcomes in Breast Cancer Patients With Preexisting Subpectoral Implants: Implant-Sparing Mastectomy With Delayed Implant Exchange Versus Immediate Tissue Expander Reconstruction. Ann Plast Surg 2016;76 Suppl 4:S332-5.
47. Paredes CG, Pessoa SGdP, Peixoto DTT, et al. Impacto da reconstrução mamária na Qualidade de vida de pacientes mastectomizadas atendidas no Serviço de Cirurgia Plástica do Hospital Universitário Walter Cantídio. The impact of breast reconstruction on the quality of life of patients after mastectomy at the Plastic Surgery Service of Walter Cantídio University Hospital. Revista Brasileira de Cirurgia Plástica 2013:100-104.
48. Huguet PR, Morais SS, Osis MJ, et al. [Quality of life and sexuality of women treated for breast cancer]. Rev Bras Ginecol Obstet 2009;31:61-7.

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 data

William Seidel

Janaína Luz Narciso Schiavon

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:
Conflicts of Interest and Source of Funding: A has received honoraria from Company Z. B is currently receiving a grant (#12345) from Organization Y, and is on the speakers' bureau for Organization X – the CME organizers for Company A. For the remaining authors none were declared.
In addition, each author must complete and submit the journal's copyright transfer agreement, which includes a section on the disclosure of potential conflicts of interest based on the recommendations of the International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (www.icmje.org/update.html).
A copy of the form is made available to the submitting author within the Editorial Manager submission process. Co-authors will automatically receive an e-mail with instructions on completing the form upon submission.
Compliance with NIH and Other Research Funding Agency Accessibility Requirements
A number of research funding agencies now require or request authors to submit the post-print (the article after peer review and acceptance but not the final published article) to a repository that is accessible online by all without charge. As a service to our authors, Wolters Kluwer will identify to the National Library of Medicine (NLM) articles that require deposit and will transmit the post-print of an article based on research funded in whole or in part by the National Institutes of Health, Wellcome Trust, Howard Hughes Medical Institute, or other funding agencies to PubMed Central. The Copyright Transfer Agreement provides the mechanism.
Permissions
Authors must submit written permission from the copyright owner (usually the publisher) to use direct quotations, tables, or illustrations that have appeared in copyrighted form elsewhere, along with complete details about the source. Any permissions fees that might be required by the copyright

owner are the responsibility of the authors requesting use of the borrowed material, not the responsibility of Wolters Kluwer.

Clinical Trials

Manuscripts based on a prospective clinical trial should document the registration of the clinical trial. If the trial is not registered, the authors should provide reasons for this omission. The final decision of the relevance of trial registration to any manuscript will be made by the editor.

Manuscript Submission

Online manuscript submission

All manuscripts must be submitted on line through the Web site: **http://sap.edmgr.com**. **First-time users:** Please click the Register button from the menu and enter the requested information. On successful registration, you will be sent an e-mail indicating your user name and password. Print a copy of this information for future reference. Note: If you have received an e-mail from us with an assigned user ID and password, or if you are a repeat user, do not register again; simply log in. Once you have an assigned ID and password, you do not have to re-register, even if your status changes (that is, author, reviewer, or editor). **Authors:** Please click the log-in button from the menu at the top of the page and log into the system as an Author. Submit your manuscript according to the author instructions. You will be able to track the progress of your manuscript through the system. If you experience any problems, please contact: Jane Wood, Managing Editor, Annals of Plastic Surgery, e-mail: willhermyone@aol.com, or William C. Lineaweaver, MD, FACS, Editor-in-Chief, *Annals of Plastic Surgery*, e-mail: william.lineaweaver@jmsburncenters.com

Preparation of Manuscript

Manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review.

Articles submitted to the journal must be written with a solid basis of English language. If you need assistance in this area, listed below are a few companies who provide language and copyediting services. Use of an editorial service is at the discretion and cost of the authors, and will not guarantee acceptance for publication in the journal.

Please note: Appearance in the list of vendors does not represent endorsement by the publisher. Authors are encouraged to investigate each service on their own, as well as seek out additional vendors offering similar services.

- American Journal Experts (Discount available for Wolters Kluwer journal authors)
- The Medical Editor
- Text Check
- Bio Science Writers
- Boston BioEdit
- ScienceDocs

In addition, Annals of Plastic Surgery adheres to the SAMPL guidelines for statistical information. A link to the SAMPL guidelines may be found at http://www.equator-network.org/wp-content/uploads/2013/03/SAMPL-Guidelines-3-13-13.pdf

Each of the following should be submitted as a separate document within the submission file:

Cover letter: The cover letter should state the authors' intent to submit the article to Annals of Plastic Surgery, state the title of the article and authors' names, and contain any other information pertinent to the submission of the manuscript.

Title page: Include on the title page (a) complete manuscript title and a brief title for use as a running head; (b) authors' full names, highest academic degrees, and affiliations (limit of two); (c) name and address for correspondence, including fax number, telephone number, and e-mail address; (d) address for reprints if different from that of corresponding author; and (e) sources of support that require acknowledgment.

The title page must also include disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); RCUK; and other(s).

Structured or unstructured abstract and key words: Limit the abstract to 350 words. It must be factual and comprehensive. Limit the use of abbreviations and acronyms, and avoid general statements (eg,

"the significance of the results is discussed"). The abstract should summarize the problem presented, studies undertaken, results, and conclusions; it replaces a summary at the end of the article.
Text: Provide succinct internal headings to clarify the paper's organization. Cite all tables and illustrations in the text. Define abbreviations at first mention in text and in each table and figure. If a brand name is cited, supply the manufacturer's name and address (city and state/country). Acknowledge all forms of support, including pharmaceutical and industry support, in an Acknowledgments paragraph.
Abbreviations: For a list of standard abbreviations, consult the Council of Biology Editors Style Guide (available from the Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814) or other standard sources. Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.
References: The authors are responsible for the accuracy of the references. Key the references (double-spaced) at the end of the manuscript. Cite the references in text in the order of appearance. Cite unpublished data, such as papers submitted but not yet accepted for publication or personal communications, in parentheses in the text. If there are more than three authors, name only the first three authors and then use et al. Refer to the List of Journals Indexed in *Index Medicus* for abbreviations of journal names, or access the list at http://www.nlm.nih.gov/tsd/serials/lji.html. Sample references are given below:
Journal article
1. Lin S-D, Tsai C-C, Lai C-S, et al. Endoscope-assisted parotidectomy for benign partoid 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

Supplemental Digital Content

Supplemental Digital Content (SDC): Authors may submit SDC via Editorial Manager to Wolters Kluwer journals that enhance their article's text to be considered for online posting. SDC may include standard media such as text documents, graphs, audio, video, etc. On the Attach Files page of the submission process, please select Supplemental Audio, Video, or Data for your uploaded file as the Submission Item. If an article with SDC is accepted, our production staff will create a URL with the SDC file. The URL will be placed in the call-out within the article. SDC files are not copy-edited by Wolters Kluwer staff; they will be presented digitally as submitted. For a list of all available file types and detailed instructions, please visit http://links.lww.com/A142.
SDC Call-outs: Supplemental Digital Content must be cited consecutively in the text of the submitted manuscript. Citations should include the type of material submitted (Audio, Figure, Table, etc.), be clearly labeled as "Supplemental Digital Content," include the sequential list number, and provide a description of the supplemental content. All descriptive text should be included in the call-out as it will not appear elsewhere in the article.
Example:

We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

List of Supplemental Digital Content: A listing of Supplemental Digital Content must be submitted at the end of the manuscript file. Include the SDC number and file type of the Supplemental Digital Content. This text will be removed by our production staff and not be published.

Example:

Supplemental Digital Content 1. wmv

SDC File Requirements: All acceptable file types are permissible up to 10 MBs. For audio or video files greater than 10 MBs, authors should first query the journal office for approval. For a list of all available file types and detailed instructions, please visit http://links.lww.com/A142.

Digital figures:

A) Creating Digital Artwork

1. Learn about the publication requirements for Digital Artwork: http://links.lww.com/ES/A42
2. Create, Scan and Save your artwork and compare your final figure to the Digital Artwork Guideline Checklist (below).
3. Upload each figure to Editorial Manager in conjunction with your manuscript text and tables.

B) Digital Artwork Guideline Checklist

Here are the basics to have in place before submitting your digital artwork:

- Artwork should be saved as TIFF, EPS, or MS Office (DOC, PPT, XLS) files. High resolution PDF files are also acceptable.
- Crop out any white or black space surrounding the image.
- Diagrams, drawings, graphs, and other line art must be vector or saved at a resolution of at least 1200 dpi. If created in an MS Office program, send the native (DOC, PPT, XLS) file.
- Photographs, radiographs and other halftone images must be saved at a resolution of at least 300 dpi.
- Photographs and radiographs with text must be saved as postscript or at a resolution of at least 600 dpi.
- Each figure must be saved and submitted as a separate file. Figures should not be embedded in the manuscript text file.

Remember:

- Cite figures consecutively in your manuscript.
- Number figures in the figure legend in the order in which they are discussed.
- Upload figures consecutively to the Editorial Manager web site and enter figure numbers consecutively in the Description field when uploading the files.

Figure legends: Legends must be submitted for all figures. They should be brief and specific, and they should appear on a separate manuscript page after the references. Use scale markers in the image for electron micrographs, and indicate the type of stain used.

Color figures: The journal accepts for publication color figures that will enhance an article. Authors who submit color figures will receive an estimate of the cost for color reproduction. If they decide not to pay for color reproduction, they can request that the figures be converted to black and white at no charge.

Tables: Cite tables consecutively in the text, and number them in that order. Key each on a separate sheet, and include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used). Do not embed tables within the body of the manuscript. They should be self-explanatory and should supplement, rather than duplicate, the material in the text.

Style: Pattern manuscript style after the *American Medical Association Manual of Style* (10th edition). *Stedman's Medical Dictionary* (27th edition) and *Merriam Webster's Collegiate Dictionary* (11th edition) should be used as standard references. Refer to drugs and therapeutic agents by their accepted generic or chemical names, and do not abbreviate them. Use code numbers only when a generic name is not yet available. In that case, supply the chemical name and a figure giving the chemical structure of the drug. Capitalize the trade names of drugs and place them in parentheses after the generic names. To comply with trademark law, include the name and location (city and state in USA; city and country outside USA) of the manufacturer of any drug, supply, or equipment mentioned in the manuscript. Use the metric system to express units of measure and degrees Celsius to express temperatures, and use SI units rather than conventional units.

After Acceptance

Open access

Wolters Kluwer's hybrid open access option is offered to authors whose articles have been accepted for publication. With this choice, articles are made freely available online immediately upon publication. Authors may take advantage of the open access option at the point of acceptance to ensure that this choice has no influence on the peer review and acceptance process. These articles are subject to the journal's standard peer-review process and will be accepted or rejected based on their own merit.

Open access articles are published under the terms of the Creative Commons License: Attribution-Non-Commercial-No Derivative (CC-BY-NC-ND) (http://creativecommons.org/licenses/by-nc-nd/4.0). This license gives the publisher the right to publish the article, create derivatives, and sell reprints. The authors retain the copyright and anyone can use the article for non-commercial purposes, but it does not permit commercial exploitation or the creation of derivative works without specific permission.

Gold OA for authors funded by RCUK and Wellcome Trust: For authors funded by RCUK, Wellcome Trust, World Bank, Gates Foundation, or Austrian Science Foundation, open access articles may be published under the terms of the Creative Commons License: Attribution (CC-BY) (http://creativecommons.org/licenses/by/4.0). This license gives the publisher the right to publish the article. The authors retain copyright but anyone may reuse the article and create derivatives, even for commercial purposes, with proper attribution to the author and links to the original article. Only authors with the above-mentioned funding may choose this option.

Green OA for authors funded by RCUK and Wellcome Trust: Authors funded by RCUK, Wellcome Trust, World Bank, Gates Foundation, or Austrian Science Foundation may opt to publish open access under the terms of the Creative Commons License: Attribution Noncommercial (CC BY-NC) (http://creativecommons.org/licenses/by-nc/4.0). This license gives the publisher the right to publish the article. The authors retain copyright but anyone may reuse the article and create derivatives with proper attribution. With Green OA, however, authors do not pay an article processing charge (APC), and their articles are deposited into PMC with an embargo period of at least 6 months. Only authors with the above-mentioned funding may choose this option.

All authors who choose an OA option will have their final published article deposited into PMC upon publication, or for Green OA, the manuscript will be made available after an embargo of at least six months.

Authors of accepted peer-reviewed articles have the choice to pay a fee to allow perpetual unrestricted online access to their published article to readers globally, immediately upon publication. The article processing charge for *Annals of Plastic Surgery* is $2,600. The article processing charge for authors funded by the Research Councils UK (RCUK) is $3,275. The publication fee is charged on acceptance of the article and should be paid within 30 days by credit card by the author, funding agency or institution. Payment must be received in full for the article to be published open access.

Authors retain copyright

Authors retain their copyright for all articles they opt to publish open access. Authors grant Wolters Kluwer a license to publish the article and identify itself as the original publisher.

Creative Commons licenses

Articles opting for open access will be freely available to read, download and share from the time of publication. Articles are published under the terms of the Creative Commons License Attribution-NonCommerical No Derivative 4.0 which allows readers to disseminate and reuse the article, as well as share and reuse of the scientific material. It does not permit commercial exploitation or the creation of derivative works without specific permission. To view a copy of this license visit: http://creativecommons.org/licenses/by-nc-nd/34.0.

Compliance with NIH, WT, RCUK and other research funding agency accessibility requirements

A number of research funding agencies now require or request authors to submit the post-print (the article after peer review and acceptance but not the final published article) to a repository that is accessible online by all without charge. As a service to our authors, Wolters KluwerLWW identifies to the National Library of Medicine (NLM) articles that require deposit and transmits the post-print of an article based on research funded in whole or in part by the National Institutes of Health, Howard Hughes Medical Institute, or other funding agencies to PubMed Central. The revised Copyright Transfer Agreement provides the mechanism. Wolters Kluwer LWW ensures that authors

can fully comply with the public access requirements of major funding bodies worldwide. Additionally, all authors who choose the open access option will have their final published article deposited into PubMed Central.
Wellcome Trust- and RCUK- funded authors can may choose to publish their paper as open access with the payment of an article process charge, or opt for their accepted manuscript to be deposited (green route) into PMC with an embargo.
With both the gold and green open access options, the author will continue to sign the Copyright Transfer Agreement (CTA) as it provides the mechanism for Wolters Kluwer LWW to ensure that the author is fully compliant with the requirements. After signature of the CTA, the author will then sign a License to Publish where they will then own the copyright.
It is the responsibility of the author to inform the Editorial Office and/or LWW that they have RCUK PMC-relevant funding. LWW will not be held responsible for retroactive deposits to PMC if the author has not completed the proper forms.
FAQ for open access
http://links.lww.com/LWW-ES/A48
Page proofs and corrections: Corresponding authors will receive electronic page proofs to check the copyedited and typeset article before publication. Portable document format (PDF) files of the typeset pages and support documents (eg, reprint order form) will be sent to the corresponding author by e-mail. Complete instructions will be provided with the e-mail for downloading and printing the files and for faxing the corrected page proofs to the publisher. Those authors without an e-mail address will receive traditional page proofs. It is the author's responsibility to ensure that there are no errors in the proofs. Changes that have been made to conform to journal style will stand if they do not alter the authors' meaning. Only the most critical changes to the accuracy of the content will be made. Changes that are stylistic or are a reworking of previously accepted material will be disallowed. The publisher reserves the right to deny any changes that do not affect the accuracy of the content. Authors may be charged for alterations to the proofs beyond those required to correct errors or to answer queries. Proofs must be checked carefully and corrections faxed within 24 to 48 hours of receipt, as requested in the cover letter accompanying the page proofs.
Reprints: Authors will receive a reprint order form and a price list with the page proofs. Reprint requests should be faxed with the corrected proofs, if possible. Reprints are normally shipped 6 to 8 weeks after publication of the issue in which the item appears. Contact the Reprint Department, Lippincott Williams & WilkinsWolters Kluwer, 351 W. Camden Street, Baltimore, MD 21201, fax: 410-528-4434, e-mail: reprints@wolterskluwer.com with any questions.

Publisher's contact: Fax corrected page proofs, reprint order form, and any other related materials to the Production Editor, at 877-705-1375.

ANEXO 2 – PARECER DO COMITÊ DE ÉTICA

UNIVERSIDADE FEDERAL DE SANTA CATARINA - UFSC

Plataforma Brasil

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 Paliativos 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 à técnica cirúrgica empregada.

Objetivo Secundário:

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

Endereço: Universidade Federal de Santa Catarina, Prédio Reitoria II (Edifício Santa Clara), R: Desembargador Vitor Lima,
Bairro: Trindade **CEP:** 88.040-400
UF: SC **Município:** FLORIANOPOLIS
Telefone: (48)3721-6094 **E-mail:** cep.propesq@contato.ufsc.br

UNIVERSIDADE FEDERAL DE SANTA CATARINA - UFSC

Continuação do Parecer: 1.183.132

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 beneficios 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 aprovaçao 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)

Endereço: Universidade Federal de Santa Catarina, Prédio Reitoria II (Edifício Santa Clara), R: Desembargador Vitor Lima,
Bairro: Trindade **CEP:** 88.040-400
UF: SC **Município:** FLORIANOPOLIS
Telefone: (48)3721-6094 **E-mail:** cep.propesq@contato.ufsc.br