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Oncological and Surgical Outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa

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Oncological and Surgical Outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa

WITS
UNIVERSITY

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A dissertation submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Plastic and Reconstructive Surgery

Declaration

I, Njabulo Msizi Dumakude, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Plastic and Reconstructive Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

……

(Signature of candidate)

……02……day of ……August……20……25……in……Johannesburg……

Dedication

I dedicate this work to all the men and women of the Dumakude and Zondi clan that came before me. To my mother and father for their tireless efforts in shaping me to the man that I am today. To my siblings who always encouraged me and celebrated my every achievement. To my friends who stuck with me at the lowest and worst of times. Thank you all for being a part of me, without your prayers and support, none of this would have been possible.

Abstract

Background: Breast cancer remains a significant health burden, particularly in South Africa, with rising prevalence and challenges in access to reconstructive surgery for affected women. The Goldilocks Mastectomy, introduced as a minimally invasive reconstructive procedure following mastectomy, offers a potential solution to address cosmetic and psychological concerns in patients with limited access to formal reconstruction. This study evaluates the oncological adequacy and clinical outcomes of the Goldilocks Mastectomy in a South African cohort, focusing on factors influencing postoperative complications.

Methods: A retrospective review was conducted at Helen Joseph Hospital (2017–2024) on 50 patients (95 breasts) undergoing Goldilocks Mastectomy. Data included demographics, comorbidities, surgical complications (graded by Clavien-Dindo classification), and histopathological margin status. Logistic regression models identified predictors of complications.

Results: The mean age was 45 years (interquartile range [IQR] 39–53), with a mean Body mass index (BMI) of 28.5 (IQR 26.0–35.3). Complications occurred in 20% (n=10), including haematoma (20%), nipple necrosis (20%), and wound dehiscence (10%). Reoperation rate was 14% (n=7). Positive margins were observed in 12% (n=6), with two requiring re-excision. Increased weight (odds ration [OR] 1.09, 95% confidence interval [CI] 1.02–1.21, p=0.036) and positive margins (OR 67.6, 95% CI 4.44–3690, p=0.009) were significant predictors of complications.

Conclusion: Goldilocks Mastectomy demonstrates acceptable oncological safety and complication rates in carefully selected patients. It expands excess to reconstruction in both the obese and comorbid population. Furthermore, the simplicity and use of native tissue makes the Goldilocks Mastectomy inherently more cost effective when compared to flap or implant-based reconstruction. A significant advantage in low-resource environments.

Acknowledgements

I wish to express my heartfelt gratitude to my supervisors, Drs. Adelaide Rooi and Marietha Nel, for their guidance and mentorship during what I could simply call the most challenging period in my life. Thank you for your patience and unwavering support.

Table of contents

Declaration i

Dedication ii

Abstract iii

Acknowledgements iv

Table of contents v

List of Figures ix

List of Tables x

List of abbreviations xi

CHAPTER 1 1

Introduction 1

CHAPTER 2 4

Study design 4

Study site 4

Methodology 4

Data analysis 5

CHAPTER 3: RESULTS 6

General characteristics 6

Comorbidities 6

Surgical Outcomes 7

Surgical complications 7

Involved margins 7

Clavien-Dindo Classification 7

Factors associated with complications 8

Oncological outcomes 9

CHAPTER 4 11

Discussion 11

Conclusion 13

Study limitations 14

References 15

Appendices 17

INTRODUCTION AND BACKGROUND 44

LITERATURE REVIEW 45

The Goldilocks Mastectomy 45

Oncological adequacy 47

Comorbidities 48

Complications 49

PROBLEM STATEMENT 51

Aims 51

Objectives 52

METHODS AND MATERIALS 52

Study design. 52

Study site. 52

Study population. 53

Inclusion criteria 53

Exclusion Criteria 53

Sample size and sampling method 53

Sample size. 53

Sampling method 54

Data sources 54

Data collection 54

Socioeconomic 54

Clinical Information 55

Complications 55

Oncological outcomes 55

Data management 55

Data analysis 56

Oncological outcomes 56

Surgical outcomes 56

Ethical consideration 57

Timeline 58

Funding 59

Study Limitations 60

REFERENCES 60

Appendix A..... 19

Appendix B..... 23

Appendix C..... 27

Appendix D..... 29

Appendix E..... 31

Appendix F..... 33

Appendix G..... 35

Appendix H..... 37

Appendix I…….……..…… 40

List of Figures

Figure 3.1. The association between weight and height, categorized by complications. Points represent individual observations, and regression 9

Figure 3.2. Tumour types 10

List of Tables

Table 1.1. Findings of previous studies……3

Table 2.1. Descriptive statistical analysis…….…. 19

Table 2.2. Logistic regression analysis of factors associated with complications following Goldilocks Mastectomy…… 23

Table 3.1. Comorbidities…….……..……. 7

Table 3.2. Complications……..……. 8

List of abbreviations

AIC	Akaike information criterion
AIDS	Acquired Immunodeficiency Syndrome
CI	Confidence interval
BMI	body mass index
DCIS	ductal carcinoma *in situ*
HIV	human immunodeficiency virus
IQR	interquartile range
LCIS	lobular carcinoma *in situ*
NCCN	National Cancer Care Network
NHLS	National Health Laboratory Services
OR	Odds ratio
Wits	University of the Witwatersrand

CHAPTER 1

Introduction

Breast cancer continues to be a major global health concern for women, representing the most diagnosed malignancy and causing significant mortality worldwide (Bray et al., 2018). The South African context reflects this global pattern, with breast cancer constituting approximately one-fifth of all female cancer cases (O. A. Ayeni et al., 2020). Demographic projections indicate a growing challenge, as the population aged 65 years and older is expected to double by 2024 ((US), 2007). Concurrent improvements in managing infectious diseases such as HIV have contributed to increased life expectancy in South Africa (O. A. Ayeni et al., 2020), resulting in a larger population of older patients who may require breast cancer treatment. This demographic shift presents unique surgical challenges, as older patients are more likely to decline complex reconstructive procedures (Walton, Ommen and Audisio, 2011).

Richardson and Ma introduced the Goldilocks Mastectomy in 2012 as an alternative for patients unsuitable for or declining traditional reconstruction methods (Richardson and Ma, 2012). This innovative approach creates a natural breast contour using preserved skin flaps, offering a simplified yet effective option between no reconstruction and complex reconstructive procedures (Richardson and Ma, 2012).

This study assessed the excision margin and complication profile of the Goldilocks Mastectomy within a South African population, where limited literature exists on Goldilocks Mastectomy, despite the high prevalence of comorbidities.

Research indicates that 80% of breast cancer patients locally, have at least one comorbidity, with over 40% presenting with multiple chronic conditions (Ayeni et al.,

2020). The high prevalence of obesity (52.8% of patients with BMI ≥30) (O. A. Ayeni et al., 2020), further complicates reconstructive options. These factors, combined with resource constraints, highlight the need to incorporate the Goldilocks Mastectomy in our setting.

Both Chaudhry and Schwartz demonstrated its applicability in the patient with an elevated body mass index (BMI) as well as in the morbidly obese (BMI >40) (Chaudhry et al., 2019; Schwartz, 2017).

Several authors have criticised its inferior cosmetic outcomes, compared to other breast reconstructive procedures (Ogawa, 2015; Chaudhry et al., 2019). However, these observations do not represent a consensus though, as a study that reviewed patient reported outcomes using the BREAST-Q score (a validated patient-reported outcome measure assessing satisfaction and quality of life in breast surgery) showed similar pre- and post-operative scores in the breast satisfaction category following Goldilocks Mastectomy (Mohammad, 2023). Technical refinements, such as incorporating lateral intercostal artery perforator flaps, have addressed initial concerns about volume deficiency (Schwartz, 2019). Reported complication rates show considerable variation, from 6% and 9% in early studies (Richardson and Ma, 2012; Chaudhry et al., 2019), to 20% in more recent analyses (Mohammad, 2023). See **Table 1.1.** for comparison of previous studies.

Table 1.1. Findings of previous studies

Study	Sample Size	Mean BMI	Complication Rate	Notable Findings
Richardson & Ma (2012)	32	30.3	6%	Initial description
Chaudhry et al. (2019)	53	33.7	9.38%	High BMI focus
Mohammad (2023)	15	33.1	20%	BEAST-Q results

This study evaluates the oncological adequacy and clinical outcomes of the Goldilocks Mastectomy in a South African cohort. By examining oncological margin status and post-surgical complications, this research seeks to determine whether the procedure provides a safe and effective reconstructive alternative in a setting where access to post-mastectomy reconstruction is constrained. The findings from this study will not only contribute to the scarce research available in this area but may also contribute to surgical decision-making and inform the potential integration of the Goldilocks Mastectomy into standard breast cancer treatment protocols within the wider South African healthcare system.

CHAPTER 2

Study design

This was an eight-year retrospective record review of patients undergoing Goldilocks Mastectomies at a single tertiary public institution in South Africa.

Study site

The study was conducted at Helen Joseph Hospital, a tertiary public institution located in Auckland Park, South Africa.

Methodology

Permission to conduct the study was obtained from both the Helen Jospeh Hospital Research Committee and the University of Witwatersrand (Wits) Human Research Ethics Committee under clearance certificate number M191049. This retrospective qualitative review analysed the oncological and surgical outcomes of the Goldilocks Mastectomy procedures performed at Helen Joseph Hospital between 01 January 2017 and 31 December 2024.

Patients were selected using consecutive sampling of all eligible individuals who underwent the procedure between 2017 and 2024. To identify patients who had undergone Goldilocks Mastectomy, the Plastic and Reconstructive Surgery as well as the Breast Surgery theatre records at the Helen Jospeh Hospital theatre complex were reviewed. After obtaining the relevant permissions, patient hospital records were retrieved and retrospectively reviewed to obtain patient demographics, preoperative consultation, intraoperative notes as well as postoperative course and follow up. Final histopathological reports were reviewed once permission was obtained from the National Health Laboratory Services (NHLS). Data collected from patient records were

used to determine surgical outcomes, and data on margin status was collected from NHLS final histopathology results, in patients undergoing Goldilocks Mastectomy as a form of primary surgery in the treatment of breast cancer. Furthermore, adverse events were graded according to the Clavien-Dindo Classification of surgical complications.

Data analysis

This study investigated the association between patient characteristics and postoperative complications following breast cancer surgery with immediate reconstruction using the Goldilocks Mastectomy procedure. Data were analysed in R version 4.4.1. Descriptive statistics were used to summarise patient characteristics including comorbidities, surgical outcomes, and oncological margin status. Continuous variables such as age, BMI, weight, height and tumour characteristics were expressed as means, ranges and interquartile ranges (IQR). The Wilcoxon rank sum test and Fisher's exact test were performed to assess factors associated with complications. Univariate logistic regression models were utilised to evaluate potential predictors of complications. Variables with a significance level below 0.2 in univariate analysis were considered for the final adjusted model **(Table 2.1, Appendix A)**. To identify significant predictors of postoperative complications while adjusting for confounding factors, stepwise selection based on the Akaike Information Criterion (AIC) was applied to refine the multivariable logistic regression model, considering variables with a p-value less than 0.2 in the univariate analysis **(Table 2.2, Appendix B)**. Scatter plots and tables were used to present the relationships between variables such as weight, height, and complications.

CHAPTER 3: RESULTS

General characteristics

From 01 January 2017 until 31 December 2024 a total of 50 patients (95 breasts) underwent the Goldilocks Mastectomy as the reconstructive method during primary breast cancer surgery. The mean age at the time of the initial presentation was 45 (39-53) years. The mean BMI at presentation was 28.5 (26.0-35.3). Four patients (8%) elected to have a unilateral procedure and, the remaining 46 patients (92%) underwent a bilateral Goldilocks Mastectomy procedure. Of the 46 patients who underwent a bilateral procedure, only one patient had bilateral breast cancer as an indication for bilateral Goldilocks Mastectomy. Smoking was only noted in two patients, which accounted for 4% of the cohort, it is unclear whether smoking was actively assessed in all cases or only noted when documented. The mean sternal notch-to-nipple areolar complex (NAC) distance of the studied breasts was 28.5 cm (IQR 26.0; 31.0) and the accompanying mean NAC-to-inframammary fold distance was 11 cm (IQR 9.0,13.0). These values represent an objective measure of breast size. A descriptive statistical summary is presented in **Table 2 .1 (Appendix A).**

Comorbidities

Comorbidities are presented in **Table 3.1.** A total of 20 (40%) patients presented with at least one medical comorbidity. Of the 20 patients three (15%) patients had more than one medical comorbidity. Hypertension was the most prevalent medical comorbidity observed in 10 (20%) patients and HIV was the second most prevalent, observed in six (12%) patients of the cohort. Other comorbidities included diabetes (4%), asthma (4%) and rheumatoid arthritis (2%).

Table 3.1. Comorbidities

Comorbidities	n=10
Asthma	2 (4%)
Diabetes	2 (4%)
Hypertension	10 (20%)
HIV	6 (12%)
Rheumatoid Arthritis	1 (2%)

Surgical Outcomes

Presented in **Table 3.2.** An overall complication rate of 20% was observed, representing 10 patients. This accounts for both surgical and oncological complications

Surgical complications

Surgical complications occurred in eight patients (16%) and included, haematoma, NAC necrosis, epidermolysis, fat necrosis, and wound dehiscence.

Involved margins

Although six patients had involved margins, only two patients (4%) underwent reoperation for these reasons. Reoperation in these patients involved a total mastectomy in one patient and re-excision of involved margins in another patient.

Clavien-Dindo Classification

When applying the Clavien-Dindo model to quantify complications, we found that seven patients fell into Class 3B complications, representing an overall 14% reoperation rate in our cohort. Indications for surgery were (haematoma= 2, nipple necrosis=2, wound dehiscence=1, margin re-excision=1, and complete mastectomy=1)

Table 3.2. Complications

Complications	n=10
Complete mastectomy	1 (10%)
Fat necrosis	2 (20%)
Haematoma	2 (20%)
Margin excision	1 (10%)
Nipple epidermolysis	1 (10%)
Nipple necrosis	2 (20%)
Wound dehiscence	1 (10%)

Factors associated with complications

The odds of complications increased by 2-21% for every 1 kg increase in weight (odds ratio [OR] 1.09 (95%); confidence interval [CI] 1.02-1.21; p=0.036). For every 1 cm increase in height the odds associated with a complication decreased by 18% (OR 0.82 (95%); CI 0.64-0.98; p=0.055), however, this is not significant at the conventional 5% level, see **Figure 3.1**. The odds of complications associated with marginal excision were 67.6 (95%); CI 4.44-3 690; p=0.009) times higher than those with wide excision.

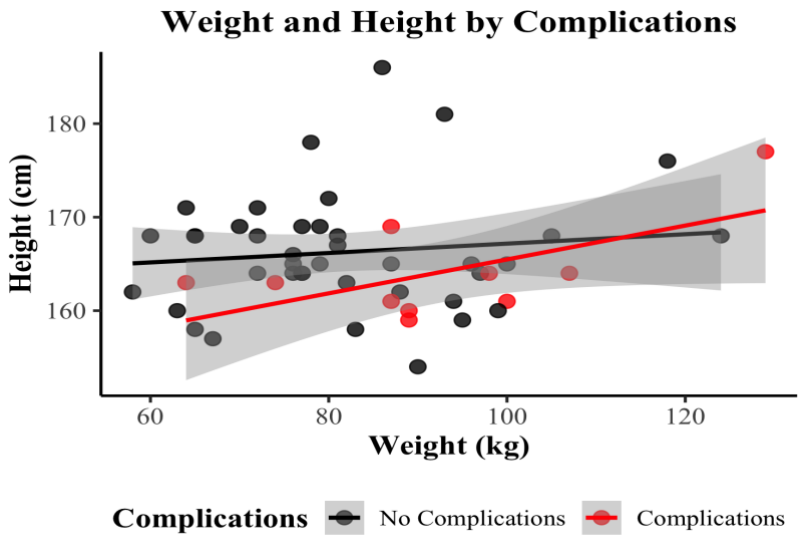

Figure 3.1. The association between weight and height, categorized by complications. Points represent individual observations, and regression lines indicate trends. Shaded areas show 95% confidence intervals.

Oncological outcomes

A total of 51 breasts were reviewed for oncological outcomes. Tumour types according to final histopathological reports are presented in **Figure 3.2.** Surgical excision margins were involved in six (12%) of the breast specimens, with clear surgical excision margins achieved in 45 breasts (88%). Contralateral prophylactic mastectomy was performed in 45 breasts as a matching procedure, none of the 45 breasts were affected by breast cancer as per final histopathological report.

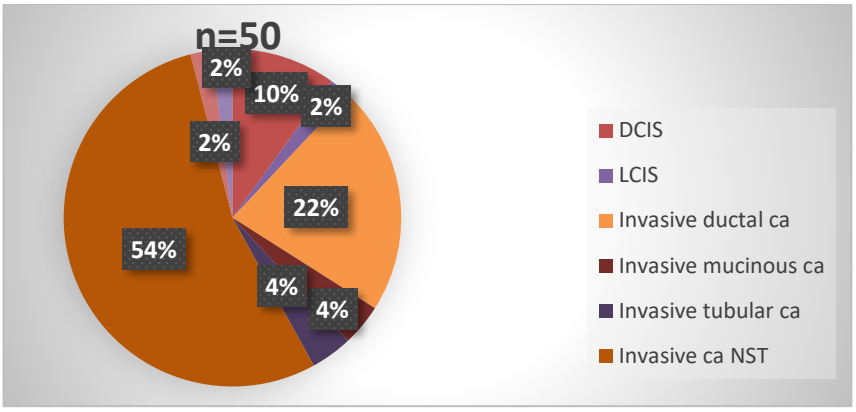

Figure 3.2. Tumour types

CHAPTER 4

Discussion

Although many studies have reported on the surgical outcomes the Goldilocks Mastectomy, we have not been able to identify local or international studies examining the oncological outcomes of the Goldilocks procedure. We compared our findings to those observed in nipple sparing mastectomy studies as the latter were also performed at our institution. This is not a novel concept, as Richardson and Aronowitz in 2018 already presented a case report where they preserved the NAC during the Goldilocks Mastectomy (Richardson and Aronowitz, 2018).

In 2021 Son et al., compared the rate of negative margins in 300 patients undergoing different forms of mastectomies in patients diagnosed with lobular carcinoma *in situ*. In their study they found that the rate of involved margins in radical *versus* skin and nipple sparing mastectomy were 8.4%, 18% and 12.7% respectively (Son et al., 2021). This is comparable to the rate of positive margins observed in our study, where positive margins were noted in six patients (12%) who underwent the Goldilocks Mastectomy as a nipple sparing procedure. In contrast, Woodward et al., found a 5.6% positive margin rate when they studied a cohort of 105 patients undergoing nipple sparing mastectomy (Woodward et al., 2020).

We did not identify any cases of recurrence during the observation period. Of the six patients who had involved margins, only two patients underwent a reoperation. One patient underwent a total mastectomy and the other patient underwent a re-excision of the involved margins. Another patient with chest wall involvement did not have any further surgical intervention as it was not indicated. The remaining three patients were referred for adjuvant radiation therapy and close clinical observation.

The complications of the Goldilocks Mastectomy have been documented in multiple studies. Richardson and Ma reported a 6% complication rate in their cohort of 32 patients (Richardson and Ma, 2012). Similarly, Chaudhry et al., in a study of 58 patients reported a 9.38% complication rate (Chaudhry et al., 2019). At 16% our study showed a higher surgical complication rate than reported by the above-mentioned studies. However, it was still more favourable than the 20% complication rate observed by Mohammad (Mohammad, 2023). Our study also highlighted the role of an increased weight and decreased height in contributing to poor surgical outcomes. Although complications were not directly linked to a high BMI in this study, it supports the notion of an increased overall complication risk with higher BMI (Srinivasa et al., 2020).

In the original description by Richardson and Ma, the primary indication for the Goldilocks Mastectomy was for the older obese patient with severe comorbidities, limiting the use of more formal reconstructive methods (Richardson and Ma, 2012). In our institution we expanded on the indications of this procedure by applying it to a younger population, as the average recorded age was 45 years in our study, compared to an average age of 61.5 by Richardson and Ma (Richardson and Ma, 2012). It is unclear whether this younger population had better tolerance for the procedure, which may explain the acceptable complication profile despite comorbidities.

We also applied the procedure to patients with a lower average BMI of 28.5 compared to Richardson and Chaudhry who recoded an average BMI of 30.3 and 33.7, respectively (Richardson and Ma, 2012; Chaudhry et al., 2019).

In order to improve the cosmesis, we performed the procedure as a nipple sparing mastectomy as described by Richardson and Aronowitz in 2018 (Richardson and

Aronowitz, 2018). This is a significant improvement from the initial description in 2012 by Richardson and Ma as a skin sparing mastectomy procedure (Richardson and Ma, 2012). This technique may raise oncological concerns due to potential for residual tissue. However, our margin involvement rate remained within range of other nipple sparing mastectomy studies.

While short-term safety was demonstrated, long-term oncological adequacy must be validated in future studies. Additionally, given the lower technical demand i.e. elimination of need for microsurgical expertise. The cost-effectiveness of Goldilocks Mastectomy compared to other reconstructive techniques, particularly in resource-constrained settings, merits further exploration.

Conclusion

In our experience, the Goldilocks Mastectomy has similar outcomes to studies examining the margin status of nipple sparing mastectomies. Similarly, we also demonstrated that complication rates were well within range of published data on outcomes of the Goldilocks Mastectomy. It is therefore a safe and cost-effective procedure that can be incorporated into our practise in well selected patients. Although we did not examine the cosmetic outcomes in the current study, it proved to be a significant aesthetic enhancement to the original description by preserving the NAC. We suggest expanding on our study by the addition of patient satisfaction in a follow up study.

Specific training programs and awareness campaigns could enhance the implementation of Goldilocks Mastectomy in similar healthcare systems. Barriers such

as limited patient education and institutional inertia should be addressed to support broader adoption.

Study limitations

As this was a retrospective study, we were not able to interview patients regarding their satisfaction with the cosmetic results of this procedure. This study is also limited by selection bias, and a small sample size, therefore, extreme caution is advised when making any inferences. Additionally, not all patient records may have had uniformly recorded data, which is a common limitation in retrospective reviews

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Appendices

Appendix A: Table 2.1: Descriptive statistical summary

Appendix B: Table 2.2: Logistic regression analysis of factors associated with complications

Appendix C: Data collection sheet

Appendix D: Wits approval of title

Appendix E: Wits HREC approval certificate

Appendix F: Helen Joseph Hospital ethics and research committee approval

Appendix G: NHLS letter of approval

Appendix H: Turn it in report

Appendix I: Submitted proposal

Appendix A: Table 2.1

Table 2.1: Descriptive statistical summary.

Characteristic	Overall N = 50	No N = 40	Yes N = 10	p-value[1]
Age, Median (IQR)	45 (39 – 53)	45 (39 – 53)	46 (41 – 59)	0.58
Race, n (%)				0.86
Black	25 (50)	19 (48)	6 (60)	
Coloured	3 (6.0)	3 (7.5)	0 (0)	
White	22 (44)	18 (45)	4 (40)	
Employment, n (%)				0.72
Employed	20 (40)	17 (43)	3 (30)	
Unemployed	30 (60)	23 (58)	7 (70)	
Smoking Status, n (%)	2 (4.0)	1 (2.5)	1 (10)	0.36
Weight, Median (IQR)	81 (72 – 94)	79 (72 – 92)	89 (87 – 100)	0.060
Height, Median (IQR)	165.0 (162.0 – 168.0)	165.0 (162.5 – 168.5)	163.0 (161.0 – 164.0)	0.16
Bmi, Median (IQR)	28.5 (26.0 – 35.3)	28.1 (25.8 – 33.4)	34.4 (27.9 – 38.6)	0.10
Sternal Notch To Nipple Distance (cm)				
Right, Median (IQR)	28.5 (26.0 – 31.0)	28.5 (25.8 – 30.0)	30.0 (27.0 – 34.5)	0.22
Left, Median (IQR)	28.5 (26.0 – 32.5)	28.0 (25.0 – 31.0)	31.8 (27.0 – 35.0)	0.074
Nipple to inframammary fold (cm)				
Right, Median (IQR)	11.00 (9.00 – 13.00)	11.00 (9.00 – 13.00)	12.75 (10.00 – 14.00)	0.12
Left, Median (IQR)	11.0 (9.0 – 13.0)	10.0 (9.0 – 12.5)	13.0 (10.0 – 17.0)	0.044
Tumour Location, n (%)				>0.99
Right	34 (68)	27 (68)	7 (70)	
Left	16 (32)	13 (33)	3 (30)	

Clavien And Dindo Classification, n (%)				>0.99
1	3 (30)	0 (NA)	3 (30)	
3b	7 (70)	0 (NA)	7 (70)	
Unknown	40	40	0	
Specimen Weight, Median (IQR)	421 (336 – 543)	409 (292 – 527)	463 (369 – 729)	0.15
Excision Margins, n (%)				0.011
Not Involved	44 (88)	38 (95)	6 (60)	
Involved	6 (12)	2 (5.0)	4 (40)	
Tumour Type, n (%)				0.64
DCIS	5 (10)	4 (10)	1 (10)	
Invasive Ca	27 (54)	23 (58)	4 (40)	
Invasive Ductal Ca	11 (22)	8 (20)	3 (30)	
Invasive Mucinous Ca	2 (4.0)	1 (2.5)	1 (10)	
Invasive Tubular Ca	2 (4.0)	1 (2.5)	1 (10)	
LCIS	1 (2.0)	1 (2.5)	0 (0)	
Lobular Carcinoma	1 (2.0)	1 (2.5)	0 (0)	
No Residual Tumour	1 (2.0)	1 (2.5)	0 (0)	
Contralateral, n (%)	44 (90)	34 (87)	10 (100)	0.57
Outcome, n (%)				0.57
N/A	4 (8.2)	4 (10)	0 (0)	
No Tumour	45 (92)	35 (90)	10 (100)	
Comorbidities				
Has Asthma, n (%)	2 (4.0)	2 (5.0)	0 (0)	>0.99
Has Diabetes, n (%)	2 (4.0)	2 (5.0)	0 (0)	>0.99
Has Hypertension, n (%)	10 (20)	7 (18)	3 (30)	0.40

Has HIV, n (%)	6 (12)	4 (10)	2 (20)	0.59
Has Rheumatoid Arthritis, n (%)	1 (2.0)	1 (2.5)	0 (0)	>0.99

[1]Wilcoxon rank sum test; Fisher's exact test

Appendix B: Table 2.2

Table 2.2: Logistic regression analysis of factors associated with complications.

		Univariate			Multivariable with manual selection	
	N	**OR**[1]	**95% CI**[1]	**p-value**	**OR (95% CI)**[1]	**p-value**
Age	50	1.01	0.95, 1.07	0.7	1.05 (0.97 to 1.16)	0.28
Race	50					
Black		—	—			
Coloured		0.00		>0.9		
White		0.70	0.16, 2.88	0.6		
Employment	50					
Employed		—	—			
Unemployed		1.72	0.41, 8.91	0.5		
Smoking Status	50					
No		—	—			
Yes		4.33	0.16, 117	0.3		
Weight	50	1.04	1.00, 1.09	0.069	1.09 (1.02 to 1.21)	0.036
Height	50	0.94	0.81, 1.06	0.3	0.82 (0.64 to 0.98)	0.055
BMI	50	1.12	0.99, 1.28	0.074		
Sternal Notch To Nipple Distance (cm)						
Right	50	1.13	0.98, 1.33	0.10		
Left	50	1.16	1.01, 1.35	0.042		
Nipple to inframammary fold (cm)						
Right	50	1.20	0.98, 1.51	0.087		

Left	50	1.27	1.04, 1.61	0.027		
Tumour Location	50					
Right		—	—			
Left		0.89	0.17, 3.80	0.9		
Specimen Weight	50	1.00	1.00, 1.01	0.046		
Excision Margins	50					
Not Involved		—	—		—	
Involved		12.7	2.04, 108	0.009	67.5 (4.44 to 3,690)	0.011
Tumour Type	50					
DCIS		—	—			
Invasive Ca		0.70	0.07, 15.5	0.8		
Invasive Ductal Ca		1.50	0.13, 35.9	0.8		
Invasive Mucinous Ca		4.00	0.10, 221	0.4		
Invsive Tubular Ca		4.00	0.10, 221	0.4		
LCIS		0.00		>0.9		
Lobular Carcinoma		0.00		>0.9		
No Residual Tumour		0.00		>0.9		
Outcome	49					
N/A		—	—			
No Tumour		12,155,661	0.00, NA	>0.9		
Comorbidities						
Has Asthma	50	0.00		>0.9		
Has Diabetes	50	0.00		>0.9		
Has Hypertension	50	2.02	0.37, 9.50	0.4		
Has HIV	50	2.25	0.28, 13.8	0.4		

Has Rheumatoid Arthritis	50	0.00	>0.9

[1]OR = Odds Ratio, CI = Confidence Interval, OR = Odds Ratio, CI = Confidence Interval

Appendix C: Data collection sheet

1. Study number							

2. Sociodemographic

a) Age

b) Race

c) Employment/ Education

3. Clinical information

a) Comorbidities

b) Smoking status

c) Weight

d) Height

e) Breast size

iii. Nipple-to-sternal notch

iv. Nipple-to-Inframammary fold

d) Tumour location

3. Complications

a) Grading according to Clavien and Dindo Classification of surgical Complications
1) Grade 1
2) Grade 2
3) Grade 3a/b
4) Grade 4a/b
5) Grade 5
- Suffix d

4. Oncological outcomes

a) Specimen weight

b) Excision margins

c) Tumour type

d) Tumour size

Appendix D: Wits HREC clearance certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Njabulo Msizi Dumakude

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M240739

NAME: (Principal Investigator)	Dr Njabulo Msizi Dumakude
STUDENT/STAFF NO:	A0070826/2531517
DEGREE:	Master of Medicine in Plastic and Reconstructive Surgery
DEPARTMENT:	Plastic and Reconstructive Surgeon
STUDY SITE(S):	Helen Joseph Hospital
TITLE:	Oncological and Surgical Outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa
DATE CONSIDERED:	27/09/2024
DECISION:	Approved unconditionally
CONDITIONS:	Retrospective record review study
NOTE:	Original Application Number: MED24-06-542
SUPERVISOR:	Dr M. Nel and Dr A. Rooi
APPROVED BY:	Paul Ruff Paul Ruff (Oct 22, 2024 15:26 GMT+2) Professor P. Ruff, Chairperson, HREC (Medical)

DATE OF APPROVAL: 22/10/2024 **EXPIRY DATE:** 21/10/2029

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATOR(S)

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** in the month date of convened meeting each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Email a signed copy of ethics clearance certificate to HREC-Medical.ResearchOffice@wits.ac.za.

Principal Investigator Signature

23/10/2024

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix E: Wits approval of title

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

28 March 2024
Person No: 2531517
PAG

Dr NM Dumakude
P O Box 1551
Greytown
3250
South Africa

Dear Dr Njabulo Dumakude

Master of Medicine in Plastic and Reconstructive Surgery: Approval of Title

We have pleasure in advising that your proposal entitled *Oncological and Surgical outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

100 1922 2022

Appendix F: Helen Joseph Hospital research committee approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Gauteng Department of Health
Helen Joseph Hospital
Enquiries: Dr. M. Mukansi
Research Committee: Chairperson
Tel :(011) 489-0306/1087
Fax :(011) 489 1038
E mail:Murimisi.mukansi@wits.ac.za

---

24 October 2023

To whom it may concern

Subject: HELEN JOSEPH HOSPITAL RESEARCH COMMITTEE APPLICATION

PROTOCOL TITLE: A retrospective study at Helen Joseph Hospital on the oncological and surgical outcomes of Goldilocks mastectomy at a tertiary public hospital. The profile of the patients, diagnosis, medical history and outcome will be reviewed.

Principal Investigator: Dr N.M Dumakude

Ethics Clearance: Pending

Co- investigator: Dr N.M Dumakude

Department: Helen Joseph Hospital

Committee Recommendations
The Committee is giving you Conditional access while awaiting the final ethical clearance certificate from the University of Witwatersrand.

It is the duty of the researcher to collect the data to the relevant department after the Research Committee approved the study.

Dr. M. Mukansi
Chairperson of HJH Ethic and Research Committee

Appendix G: NHLS Letter of approval

NATIONAL HEALTH LABORATORY SERVICE

Academic Affairs and Research
1 Modderfontein Road, Sandringham, 2031
Tel: +27 (0)11 555 0367/0406
Email: babatyi.kgokong@nhls.ac.za
academic.research@nhls.ac.za
Web: www.nhls.ac.za

20 March 2025

Applicant: Njabulo Dumakude
Institution: University of the Witwatersrand
E-mail Address: ndumakude22@gmail.com
Tel: 011 488 3494 **Cell:** 083 947 1034

Project Title: Oncological and Surgical outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa.

Reference Number: PR2456286

Research Application Type(s):
1. Request for Data

RE: APPROVAL LETTER: REQUEST TO ACCESS NHLS RESOURCES FOR RESEARCH PURPOSES

This letter serves to advise that the application requesting permission to conduct the above-mentioned research using the listed NHLS resources has been reviewed and **"Approved"**. Please note that the approval is granted on the condition that you comply with the NHLS Research Material and Data Access Policy and requirements stated below.

1. All material and data requested shall be used as per the research protocol submitted to the NHLS and as approved by the relevant Health Research Ethics Committee (HREC) in South Africa.
2. Access to the NHLS data shall be limited to the minimum required for successful completion of the approved study and shall be made available with the following identifier(s) for the purposes of data extraction from external records: Episode Numbers. **(This is on the condition that permission to access the records has been obtained from the relevant authorities)**.
3. Confidentiality shall be maintained at the participant and institutional level and there shall be no disclosure of personal information or confidential information.
4. Data and/or material shall not be shared with other parties unless approved by the NHLS
5. The material and/or data obtained from the NHLS shall be anonymised and not, for any reason, be used to track or recruit patients as no pre-approval/consent is obtained from patients.
6. Processes shall be discussed with the relevant NHLS departments (i.e. Corporate Data Warehouse (CDW), NHLS Laboratory Management, Operations Office, etc.) and agreed upon.
7. Any amendments to the study requirements, including the use of the material and/or data for purposes not initially disclosed to the NHLS) shall be cleared by an approved HREC and submitted to the NHLS for approval via the AARMS system – https://aarms.nhls.ac.za.
8. The NHLS shall be acknowledged as a source of material and/or data in any output, such as abstracts and journal articles, emanating from the project.
9. A final report of the research study and any published output resulting from this study shall be submitted to the NHLS via AARMS

Please note that this letter constitutes approval by the NHLS Academic Affairs and Research Office. The NHLS entities tasked with providing the material and/data may have additional requirements for access. Data related queries may be directed to NHLS CDW, email: zarina.sabat@nhls.ac.za; contact number: 011 386 6074.

Dr Babatyi Malope-Kgokong
National Manager: Academic Affairs and Research

Appendix H: Turn it in report

Dumakude FINAL MMed document for submission 13_APRIL_25.docx

ORIGINALITY REPORT

6%	4%	3%	2%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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Exclude quotes	On	Exclude matches	< 8 words
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Appendix I: Submitted proposal

Oncological and Surgical outcomes of Goldilocks Mastectomy at a Tertiary Public Hospital in Johannesburg, South Africa

Research Protocol for Master of Medicine in Plastic and Reconstructive Surgery

Dr Njabulo Msizi Dumakude

Student Number: 2531517

Registrar

Division of Plastic and Reconstructive Surgery

Supervisors

Dr A. Rooi

MBChB (University of Stellenbosch)

FCPS (University of Witwatersrand)

Dr M. Nel

Senior research Scientist (PhD)

Academic Laboratory Manager Department of Surgery

Table of Contents

1 INTRODUCTION AND BACKGROUND 44

2 LITERATURE REVIEW 45

2.1 The Goldilocks Mastectomy 45

2.2 Oncological adequacy 47

2.3 Comorbidities 48

2.4 Complications 49

3 PROBLEM STATEMENT 51

4 Aims 51

5 Objectives 52

6 METHODS AND MATERIALS 52

6.1 Study design 4

6.2 Study site 4

6.3 Study population 53

6.4 Inclusion criteria 53

6.5 Exclusion Criteria 53

7 Sample size and sampling method 53

7.1 Sample size 53

7.2 Sampling method. 54

8 Data sources 54

9 Data collection 54

9.1 Socioeconomic 54

9.2 Clinical Information 55

9.3 Complications 55

9.4 Oncological outcomes 55

10 Data management 55

11 Data analysis 56

11.1 Oncological outcomes 56

11.2 Surgical outcomes 56

12 Ethical consideration 57

13 Timeline 58

14 Funding 59

15 Study Limitations 60

REFERENCES 60

INTRODUCTION AND BACKGROUND

Breast cancer remains the leading cause of cancer among women worldwide, accounting for up to 6.6% of all cancer related deaths (Bray et al., 2018). This is mirrored in South Africa as reported by Ayeni as the most common cancer among women, accounting for 20.8% of all female cancers (O. A. Ayeni *et al.*, 2020b). These numbers are expected to rise as future population projections anticipate a doubling in the number of individuals over the age of 65, from 20 to 40 million by the year 2024 (Hyattsville, 2007). Similarly in South Africa the life expectancy has been extended on account of effective treatment of infectious diseases namely human immunodeficiency virus (HIV) (Ayeni et al., 2020).

Based on the aforementioned, the reconstructive breast surgeon can expect to be faced with a larger number of older patients, who are at the higher risk of comorbidities that preclude prolonged or multiple complex reconstructive procedures. The concept of a skin sparing mastectomy was popularized by Toth and Lappert in the early 1990s, their aim was to improve reconstructive outcomes following mastectomy, by modifying the incisions as well as minimizing the amount of skin excised during mastectomy (Toth and Lappert, 1991).

To date, several modifications to this procedure have since been described. In 2012 Heather Richardson and Grace Ma described the Goldilocks Mastectomy as a means of addressing needs of women who were to undergo mastectomy that either could not have or did not want formal reconstruction (Richardson and Ma, 2012b).

The American Joint Committee on Cancer (AJCC) provides guidelines on the staging of breast cancer using the TNM (Tumour, Nodal Status and Metastasis) system

(Hortobagyi *et al.*, 2017). The AJCC in conjunction with the Union for International Cancer Control recommend skin sparing mastectomy for patients with stage I-II infiltrative breast cancer and Ductal Carcinoma in situ who are candidates for radical mastectomy (González and Rancati, 2015). Some authors have extended the use of this technique to stage III breast cancer in selected cases, with promising results (Foster *et al.*, 2022). However, other authors have cautioned against the use of skin sparing mastectomy in advanced or poorly differentiated tumours as this increases the likelihood of local recurrence (Medina-Franco *et al.*, 2001).

Be it as it may, most crucial to breast cancer management is cancer extirpation, therefore management of these patients should follow strict protocols. Fundamental requirements to successful and oncologically safe skin-sparing mastectomy as set out by the National Cancer Care Network (NCCN) include multidisciplinary evaluation, proper patient selection, an experienced surgical team, and most importantly, obtaining appropriate margins (Kumar *et al.*, 2022)

LITERATURE REVIEW

The Goldilocks Mastectomy

The Goldilocks mastectomy was first described by Richardson and Ma in 2012, a novel concept at the time. It was offered as a last resort to patients who had declined reconstruction by other means and elected for a conventional mastectomy (Richardson and Ma, 2012).

Using the Goldilocks mastectomy technique, the authors present a middle ground between formal reconstruction after mastectomy and the amputated appearance associated with mastectomy without reconstruction (Richardson and Ma, 2012).

As goes the tail of Goldilocks and the three bears, a young lady was presented with options at two extremes, either too hard or too soft, either too hot or too cold. Ultimately, she chose an option that is a compromise of both attributes.

In their study, Richardson and Ma managed 32 women, a total of 50 breasts using this technique, which uses the de-epithelialized skin flaps to create a breast mound following excision of breast parenchyma using an elliptical or circum-areolar incision. The operation is unique in that it uses the lower pole skin to create a breast mound. (Richardson and Ma, 2012b).

Since its conception, it has been widely accepted as a method of oncoplastic breast reconstruction procedure with predominant use in patients with a higher body mass index (BMI) (Chaudhry *et al.*, 2019b). Richardson and Ma proposed that the ideal candidate for the procedure would be a patient with large and ptotic breasts.

As a middle ground, it allows the patient freedom to undertake reconstruction as a delayed procedure. Secondary reconstructive procedures can be autologous, including fat grafting or implant based on patient preference (Richardson and Ma, 2012b).

Additionally, it avoids potential long-term complications associated with implant-based reconstruction, as the mound also acts as a shelf anchor for the pocket, preventing it from migrating superiorly on the chest wall (Richardson and Ma, 2012).

Richardson and Ma reported a 6% post-operative complication rate which included one prolonged seroma and three cases of cellulitis in their study. Another study by Chaudhry *et al.,* recorded a 9.38% complication rate when they analyzed outcomes in Goldilocks Mastectomy. The only major drawback noted was the inferior cosmetic outcome in comparison to other reconstructive methods (Chaudhry *et al.*, 2019b).

To the best of my knowledge, no studies from South Africa exploring outcomes of Goldilocks mastectomy have been published.

Oncological adequacy

> "Consensus guidelines support a negative margin defined as no ink on tumour for invasive carcinoma, for patients with ductal carcinoma in situ (DCIS) a margin of 2 mm has been found to minimize the risk of local recurrence when treated with lumpectomy and radiation therapy"(Pilewskie and Morrow, 2018).

A negative margin is one of the factors associated with a reduction in local recurrence, but increasing these margins has not been shown to result in improved local control (Houssami *et al.*, 2014). Although important to obtain negative margins, tumour biology is considered a more important factor in determining local recurrence (Pilewskie and Morrow, 2018).

It is therefore crucial that orientation of the surgical specimens, description of the gross and microscopic margin status, reporting of the distance, orientation, and type of tumour (invasive or DCIS) in relation to the closest margin are part of the standard evaluation in every breast conservation surgery specimen (Kumar *et al.*, 2022). A study evaluating the quality of histopathological reporting in breast cancer cases from four South African breast units, found that the standard of reporting was generally at a high level, though it sited room for improvement in areas including, but not limited to tumour grade, excision margins and pathological staging (Toma et al., 2021).

Comorbidities

When Ayeni *et al.,* studied 2281 South African women with breast cancer to examine the prevalence of multi-morbidity, they found that 80% of their study cohort had at least one comorbidity and more than 40% had multi-morbidity defined as more than one chronic condition. The authors also noted that obesity (defined as BMI >/= 30) was found in 52,8% of the study population. The former, coupled with an increase in the older age group as per United States population projections (Hyattsville, 2007), present a special subset of patients who are less than ideal candidates for complex reconstruction.

Obese patients are also at higher risk of reconstructive failure, making them poor candidates for autologous and prosthetic based reconstruction(Schwartz, 2017)

The Goldilocks Mastectomy in its initial description was indicated for obese, elderly patients with comorbidities who were not candidates or those who cannot have formal breast reconstruction (Richardson and Ma, 2012b)

Complications

The complications will be graded according to the Clavien Classification of surgical outcomes, this model was first described by Clavien Sanabria and Strasberg in 1992, here the authors proposed a classification consisting of four grades, Grade I complications are alterations from the ideal postoperative course, are not-threatening, and without lasting disability. Grade II complications are potentially life-threatening although without residual disability. Within grade II complications a subdivision is made according to the requirement for invasive procedures. Grade III complications are those with residual disability, including organ resection or persistence of life-threatening conditions. Grade IV complications are deaths occurring because of complications (Clavien PA, 1992).

In 2004 Dindo and colleagues proposed a modification to the previously described classification, the number of grades was increased from five to seven, with two subgroups added to grades three and four the suffix “d” for disability is added to any of the grades if a patient suffers a complication at discharge, indicating a need for follow up to completely evaluate the complication (Dindo, Demartines and Clavien, 2004). The classification is presented on Table 1.

Table 1: Classification of Surgical Complications

Grade	Definition
Grade 1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade 2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade 3	Requiring surgical, endoscopic or radiological intervention. a) Intervention not under anaesthesia b) Intervention under anaesthesia
Grade 4	Life-threatening complication (including CNS complications)* requiring Immediate care or Intensive care unit management a) Single organ dysfunction b) Multiple organ dysfunction
Grade 5	Death of a patient

*Includes subarachnoid bleeding, brain haemorrhage, and ischaemic stroke. Excludes transient ischaemic attacks	

PROBLEM STATEMENT

In South Africa, a large number of patients do not qualify for formal reconstruction as described in the original paper by Richardson and Ma on Goldilocks Mastectomy. This includes but not limited to patients with multiple comorbidities, poor socioeconomic circumstances preventing patients from undergoing implant based reconstruction as well as a high rate of obesity among women presenting with breast cancer, therefore the applicability of this safe and minimally invasive procedure need to be investigated.

Aims

The study aims to determine the oncological adequacy of the Goldilocks mastectomy, defined by the NCCN guidelines as no ink on tumour for invasive carcinoma and a 2 mm margin for Ductal Carcinoma in situ, as a reconstructive procedure following breast cancer extirpation and to review the surgical outcomes in a cohort of woman from a south African tertiary institution.

Objectives

I. To assess Goldilocks Mastectomy procedures performed at Helen Joseph Hospital between 2017 and 2023 were oncologically adequate according to local and international standards.
II. To describe surgical outcomes in patients undergoing Goldilocks mastectomy at Helen Joseph Hospital between 2017 and 2023 including complications and reoperation rates
III. To compare patient and disease factors in a cohort of Goldilocks mastectomy patients at Helen Joseph Hospital to determine if the procedure was applied according to indications descried in the original description by Richardson and Ma (2012)
IV. To analyse whether patient sociodemographic and disease factors are associated with an increased risk of complications

METHODS AND MATERIALS

Study design.

An Eight-year retrospective analysis that compares outcomes of Goldilocks Mastectomies performed in South Africa to international studies.

Study site.

The study will be conducted at Helen Joseph Hospital, a tertiary public institution located in Auckland Park Johannesburg, South Africa. The hospital is affiliated to the University of the Witwatersrand's Medical School and comprises of 23 wards, 11 clinics and 11 theatres.

Study population.

All patients who underwent Goldilocks Mastectomy as a means of cancer extirpation and immediate autologous breast reconstruction.

Inclusion criteria

- Adult patients > 16 years of age
- Female
- Positive breast cancer diagnosis
- Undergoing Goldilocks mastectomy as a means of primary reconstruction.

Exclusion Criteria

- Patients undergoing other immediate forms of breast reconstruction not specified as Goldilocks Mastectomy on theatre records.
- Patients undergoing Goldilocks mastectomy procedure for non-oncological indications (i.e., risk reduction)
- Incomplete records
- Patients undergoing combined Goldilocks mastectomy and implant-based reconstruction as an immediate form of breast reconstruction.

Sample size and sampling method

Sample size.

Based on surgical records reviewed at Helen Joseph Hospital an estimated number of 38 patients will be included in the study.

Sampling method.

I. Review of final histopathology reports sourced from the National Health Laboratory Services to assess if adequate excision margins were achieved according to the NCCN Guidelines.

II. Patient files will be sourced and reviewed to obtain patient demographics, preoperative assessment, and post operative course in line with the data collection tool. (see Appendix 1)

Data sources

- The theatre operation registers at HJH are classified according to discipline. Goldilocks Mastectomy procedures are performed as combined cases and are recorded in either the Breast or Plastic and Reconstructive surgery register. Both registers will be sourced to identify patients who meet the inclusion criteria.
- National Health Laboratory Services- definitive histopathology reports on patient cohort will be sought from the NHLS database.
- Patient files will be retrieved from the hospital archives, to review details of pre- and postoperative consultations, as well as theatre notes.

Data collection

Socioeconomic

a) Age

b) Race

c) Employment/ Education

Clinical Information

a) Comorbidities
b) Smoking status
c) Weight
d) Height
a) Breast size
    i. Nipple-to-sternal notch
    ii. Nipple-to-Inframammary fold

Complications

a) Will be classified according to the Clavien classification of surgical complications.

Oncological outcomes

a) NHLS histopathology tracking number
b) Specimen weight
c) Excision margins,
d) Tumour type
e) Tumour size

[See appendix 1- DATA COLLECTION SHEET]

Data management

Data will be stored securely in the primary investigator's computer, which requires a password or biometric finger recognition which only the primary investigator has access to. Patients' identities will be protected by using a unique study number

assigned to each patient. The relevant data will be exported into a Microsoft Excel spreadsheet (Microsoft, Redmond, USA).

Data analysis

This is a descriptive pairwise comparison study between actual surgical outcomes and the expected based on the international standard adjusted for the risk profile

- R will be the statistical software used
- Package to be used: tidyverse, ggplot2

<u>Tests: for surgical outcomes</u>

Hypothesis test one sample t-test will be used to assess the significance of differences between the actual and expected surgical outcomes

Oncological outcomes

1. Review final histopathology report.
2. Quantify clear margins obtained.

Surgical outcomes

1. Complications
2. Reoperation rate will be further subdivided according to indication i.e., complications, re-excision and or reconstruction.

3. Review procedure indications as initially described by Richardson and Ma, evaluating its application as a reconstructive option in the South African context.

Objective	Variables	Data analysis
Determine oncological adequacy of Goldilocks Mastectomy procedure	Described international and local standards breast cancer margins	Analyze final NHLS histology reports to determine compliance
Determine surgical outcomes of GM procedure	Patient factors Disease factors	Review patient files, determine pre- and postoperative course
Determine initial procedure indications	Applicability to South African context	Review patient files to determine preoperative consultation

Ethical consideration

- Approval from the Wits Human Research Ethics Committee (HREC medical) will be applied for.
- Permission From Wits Human Research Ethics Committee (HREC medical) to perform the study will be sought.
- Permission to do the study will be obtained from the HJH CEO.

- The study will be registered on the National Health Research database.
- Study participant confidentiality will be upheld and maintained by using only study numbers on data sheets.
- There will be no deviation from standards of care as this is a retrospective quantitative analytic case series.
- No data will be collected before an official ethics clearance number is issued by the HREC.

Timeline

Year	**2024**					**2024**					**2025**		
	2023	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
Literature Review													
Preparing Protocol													
Protocol Assessment													

Ethics Application													
Collecting Data													
Data Analysis													
Writing up Thesis													
Writing up Paper													

Funding

The study is self-funded by the author, cost estimation is insubstantial and will be covered by the author.

Item	**Price (ZAR)**

Petrol	**R500**
Stationery	**R300**
Printing and photocopying	**R200**
TOTAL	**R1000**

Study Limitations

- Missing patient files.
- Incomplete relevant information on patient files.
- Single center study

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Appendix 1 DATA COLLECTION SHEET

1. <u>Study number</u>							

2. <u>Sociodemographic</u>

a) Age

b) Race

c) Employment/ Education

3. <u>Clinical information</u>

a) Comorbidities

b) Smoking status

c) Weight

d) Height

e) Breast size

iii. Nipple-to-sternal notch

iv. Nipple-to-Inframammary fold

d) Tumour location

3. <u>Complications</u>

a) Grading according to Clavien and Dindo Classification of surgical Complications
   1) Grade 1
   2) Grade 2
   3) Grade 3a/b
   4) Grade 4a/b
   5) Grade 5
      - Suffix d

4. <u>Oncological outcomes</u>

a) NHLS histopathology tracking number

b) Specimen weight

c) Excision margins

d) Tumour type

e) Tumour size