Striving to Do No Harm and yet Respect Patient Autonomy: Ontario Plastic Surgeons’ Perspectives of the Consultation for Breast Reconstruction with Women Who Have Early Stage Breast Cancer

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
Institute of Health Policy, Management and Evaluation
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Abstract

**Background:** The rate of contralateral prophylactic mastectomy (CPM) has doubled over the previous decade in women with early-stage breast cancer. Despite the strong association between CPM and breast reconstruction, little is known about the clinical encounter between patients and plastic surgeons.

**Purpose:** A qualitative study aligned with the constructivist paradigm was conducted to understand how plastic surgeons describe their roles in the decision-making process through their consultations with women who have early-stage breast cancer.

**Methods:** Semi-structured interviews were conducted with Ontario plastic surgeons. An inductive and interpretive thematic approach was used to analyze the data. The four principles of biomedical ethics were used as the conceptual lens to interpret the findings.

**Results:** Four themes were identified: maintaining non-maleficence, supporting patient autonomy, delivering (un)equal healthcare, and providing care to enhance well-being.
Conclusions: Plastic surgeons must balance competing responsibilities to do no harm and support a patient’s right to autonomous healthcare decisions.
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<td>CBC</td>
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Chapter 1
Introduction, Background and Study Objectives

1.1 Introduction

Breast cancer is a pervasive disease that accounts for 13% of all cancers in Canada and is the second leading cause of cancer related deaths among women across the country (Canadian Cancer Statistics Advisory Committee, 2018). Within the province of Ontario, it is the most common cancer in women, with an estimated 10,100 new diagnoses in 2017 (Canadian Cancer Statistics Advisory Committee, 2018; Cancer Care Ontario, 2015). Breast cancer usually presents at an early stage with a favourable prognosis; however, decision making for early stage breast cancer can be challenging, as patients are faced with a number of complex and time-sensitive choices regarding their treatment options (Katz & Morrow, 2012).

Prior to the 1980s, the standard surgical treatment for primary breast cancer was mastectomy, which involves removing the entire index breast and axillary lymph nodes (Kleinman, Machlin, Madans, Makuc, & Feldman, 1983). A newer breast surgical technique, lumpectomy (i.e., breast conserving surgery), was studied during the 1970s and 1980s. This operation involves resecting the tumour containing portion of the breast, along with a margin of normal tissue and is usually followed by radiotherapy (National Comprehensive Cancer Network, 2016). After the publication of a number of key clinical trials demonstrating no differences in overall survival rates between these procedures (Fisher et al., 1985; Fisher et al., 1989; Sarrazin et al., 1989), a consensus statement issued by the National Institutes of Health (NIH) in 1991 established breast conserving surgery as the preferred treatment for women with early stage breast cancer, as it is a less extensive surgical option with oncologic outcomes equivalent to those of mastectomy (NIH consensus conference, 1991). In the years following this NIH treatment recommendation, the number of lumpectomies rose accordingly (Lazovich, Solomon, Thomas, Moe, & White, 1999).

Over the previous decade, however, a surprising trend towards more aggressive treatment has been observed, such that the rates of contralateral prophylactic mastectomy (CPM), (i.e., resection of the opposite, non-cancerous breast either simultaneously with a therapeutic mastectomy or sequentially), have more than doubled in North America (Tuttle, Habermann,
Grund, Morris, & Virnig, 2007; Yao, Stewart, Winchester, & Winchester, 2010). For instance, Tuttle et al. examined trends in the use of CPM in the United States using Surveillance, Epidemiology and End Results data and determined that the CPM rate for patients undergoing mastectomy significantly increased from 4.2% in 1998 to 11.0% in 2003 (Tuttle et al., 2007). A more recent single-institution retrospective cohort study conducted at a Canadian academic breast cancer centre found the CPM rate to be around 6.4% (range: 2.6% to 10.7%) between 2004-2010 (Roberts, Sandhu, Cil, Hofer, & Zhong, 2016). Although CPM decreases the likelihood of developing a contralateral breast cancer (CBC), the incidence of CBC is already extremely low, ranging from 0.1% to 0.6% per year, depending on the tumour biology and the patient’s age at the time of diagnosis (Kurian et al., 2009). Furthermore, CPM does not completely eliminate the risk of CBC altogether, nor does it guarantee that a recurrent breast cancer won’t develop on the ipsilateral side (Herrinton et al., 2005) or that the patient will avoid metastatic disease from the index cancer. A Cochrane meta-analysis from 2010, together with more recently published guidelines, have concluded that there is a lack of evidence indicating that CPM provides any survival advantage over breast conserving surgery (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Landercasper, Lemaine, MacNeill, Song, et al., 2016; Lostumbo, Carbine, & Wallace, 2010; Wright et al., 2018).

Complications associated with CPM are significantly higher relative to lumpectomy or unilateral mastectomy, particularly among individuals who undergo immediate breast reconstruction (Barton et al., 2005; Pinell-White, Kolegraff, & Carlson, 2014) and can significantly impact patients on both a physical and psychological level (Osman, Saleh, Jackson, Corrigan, & Cil, 2013). For instance, evidence shows that patients who have CPM are at increased risk of short-term issues including bleeding, infections, tissue necrosis and sepsis, as well as long-term outcomes, such as chronic pain, sexual dysfunction and decisional regret (Montgomery et al., 1999; Rosenberg et al., 2013).

Interestingly, CPM rates are on the rise among women with no family history or genetic predisposition towards CBC (i.e., non BRCA1/2 mutation carriers), thus illustrating an increasing disparity between recommended care and the actual care patients receive (Brewster & Parker, 2011; Tuttle et al., 2007; Yao et al., 2010). Given that removing the
unaffected breast does not provide any oncologic benefit, coupled with a greater likelihood of both short and long-term complications, the role of CPM in the average newly diagnosed breast cancer patient is controversial (Barton et al., 2005; Fayanju, Stoll, Fowler, Colditz, & Margenthaler, 2014; Lostumbo et al., 2010; Pesce et al., 2014). Accordingly, an extensive and growing body of research seeks to better understand this paradoxical shift towards more aggressive surgical management (Agarwal et al., 2015; Brewster & Parker, 2011; Buchanan et al., 2016; Covelli, Baxter, Fitch, McCready, & Wright, 2015; Covelli, Baxter, Fitch, & Wright, 2014; Tracy, Rosenberg, Dominici, & Partridge, 2013).

Decision making in this cohort of patients is particularly challenging, as the treatments (i.e., lumpectomy plus radiation versus mastectomy) are equally effective in terms of survival. This means that patients and healthcare providers must consider other issues, such as the effects of radiation or the impact of surgery on body image and sexuality, when determining which treatment approach to take. Recent evidence suggests that the upward CPM trend is predominantly motivated by patients, reflecting the increasingly active role they adopt when it comes to surgical decision making (Rosenberg et al., 2013; Yao, Sisco, & Bedrosian, 2016). The growing awareness, availability and advancements in reconstructive breast procedures have also added to the complexity of this choice (King et al., 2011; Yao et al., 2010).

In Ontario, women contemplating mastectomy will typically consult with a general surgeon to discuss oncologic treatments for their breast cancer and potentially a plastic surgeon regarding their reconstructive preferences after mastectomy and less commonly, lumpectomy. Although CPM decision making has been previously investigated among women who have early stage breast cancer (Buchanan et al., 2016; Covelli et al., 2015), little is known about the perspectives and experiences of reconstructive surgeons during their consultations with women who are considering their treatment options. Therefore, the aim of this study was to explore how plastic surgeons describe their roles in patient’s decision making processes regarding breast reconstruction with a view toward advancing our understanding of the rise in CPM rates.
1.2 Background: Literature Review

With the continual increase of CPM among patients who lack familial or genetic risk factors, attention has been focused on uncovering the drivers of this controversial treatment approach. A background review of the literature was undertaken, which identified numerous oncologic and patient demographic factors to be independent predictors of CPM. These include: earlier cancer stage and ductal carcinoma in situ (DCIS), smaller tumour size, node negative status, younger age of diagnosis, white race, higher income and higher education level (Arrington, Jarosek, Virnig, Habermann, & Tuttle, 2009; Brewster & Parker, 2011; King et al., 2011; Tracy et al., 2013; Tuttle et al., 2007; Yao et al., 2016). However, the frequency of CPM procedures over the previous decade cannot be fully explained by these characteristics alone.

1.2.1 Diagnostic Imaging

Rising rates of both unilateral and bilateral mastectomy among women with early stage breast cancer have been observed alongside the introduction of more sensitive diagnostic tools such as magnetic resonance imaging (MRI) for breast cancer treatment planning. This has led some researchers to suggest that the increasing use of preoperative MRI may be a contributing factor in the decision to undergo more aggressive surgery, since MRI is associated with high false positive rates (Miller, Abbott, & Tuttle, 2012). Sorbero et al demonstrated that as the use of preoperative MRI grew from 4.1% in 1998 to 23.7% in 2005, CPM procedures also increased by more than 50% (Sorbero, Dick, Beckjord, & Ahrendt, 2009). Furthermore, the same study found that women newly diagnosed with breast cancer who received an MRI were nearly two times as likely to undergo CPM compared with women who did not have an MRI (Sorbero et al., 2009).

Miller et al speculated that the association between MRI and mastectomy could possibly be explained by its ability to detect additional disease, however, their group also found that patients who received negative MRI results still chose mastectomy over breast conserving surgery significantly more than patients with no MRI (Miller et al., 2012). Although the authors did not explore the reasons behind these findings, they suggested that preoperative MRI may enhance patient anxiety, thus prompting the choice to pursue aggressive surgical
management (Miller et al., 2012). A recent meta-analysis similarly identified a significant association between breast MRI and increased odds of CPM operations (Houssami, Turner, & Morrow, 2017). On the other hand, conflicting evidence from several other studies found no relationship between MRI use and the decision to undergo CPM (Arrington et al., 2009; Guilfoyle et al., 2014), indicating that these findings should be interpreted with caution.

1.2.2 Psychosocial Influences

In addition to the above mentioned factors, psychosocial and cognitive characteristics have also been strongly linked to rising rates of CPM in women who have early stage breast cancer. Concerns surrounding survival, CBC and developing a recurrence are among the most common reasons underpinning this treatment choice, as illustrated in a cross-sectional survey involving patients from both American and Canadian cancer centres. In this study, 98% of women reported the “desire to reduce the risk of developing contralateral breast cancer” to be an extremely or very important factor in their decision to have CPM and 94% also indicated they chose CPM to increase their chance of survival (Rosenberg et al., 2013). Paradoxically, many of these same women also responded correctly to questions about the lack of association between CPM and improved survival rates (Rosenberg et al., 2013).

Fear-based misperceptions and counterfactual thinking are often the impetus behind requests for CPM. For instance, Covelli et al conducted qualitative interviews in women with breast cancer and found that patients are significantly motivated by anxiety and fear, which leads to inaccurate perceptions of their true risks and ultimately, the decision to undergo more radical surgery (Covelli et al., 2015). Further evidence demonstrates that patients believe they will avoid developing a recurrence, prevent cancer in the unaffected breast and live longer by choosing the most aggressive surgical procedure, despite being educated on the survival equivalence of the treatment options (Covelli et al., 2015; Liu et al., 2011). Similarly, research has also shown that the psychological predictors most frequently associated with the decision to undergo CPM include fear of the cancer returning, a desire to do everything possible to cure their disease and to achieve greater peace of mind (Angelos et al., 2015; Parker et al., 2016; Soran et al., 2015). In the high-anxiety environment surrounding breast cancer decision making, it is important for physicians to allay patients’ concerns and ensure
they fully understand the risks and benefits of available treatments in order to make informed choices.

1.2.3 Surgeon Factors

Comparatively little research has examined the influence of physician characteristics on CPM decision making. A survey of surgeons practicing in the United States demonstrated that CPM rates were significantly higher among female surgeons than among male surgeons; however, this study included a very small sample size making it challenging to draw any meaningful gender-based conclusions (Arrington et al., 2009). Research conducted out of Australia found physician demographics, including age and year of graduation to be unrelated to the CPM trend (Musiello, Bornhammar, & Saunders, 2013). On the other hand, a more recent study from the United States determined that treating surgeons explained greater variation in receipt of CPM among women diagnosed with unilateral breast cancer over and above patient clinical factors (Katz et al., 2018). They found surgeons’ attitudes towards CPM, along with their reactions to direct patient requests for CPM, accounted for approximately 25% of this surgeon effect (Katz et al., 2018).

Additional research has suggested that a direct treatment recommendation from the treating physician significantly influences the actual procedure that patients choose. For instance, Jagsi et al found that only 1.9% of patients who recalled receiving a specific recommendation against CPM from their surgeon ultimately chose it, compared to 19% of patients who perceived there to be no clear recommendation with respect to CPM (Jagsi et al., 2017). Notably, only half of the women surveyed in a separate study reported that their surgeon outlined reasons not to undergo CPM (Parker et al., 2016). Together, these findings suggest that physician attitudes and communication in relation to treatment options have an impact on surgical decision making in patients who have breast cancer.

1.2.4 The Role of Breast Reconstruction

Access to breast reconstruction and reconstructive options also appear to play an important role in a patient’s choice for CPM. For instance, Agarwal et al explored the relationship between CPM and breast reconstruction and noted that CPM rates increased from 7.7% to 28.3% over a 10-year period and during that time, the proportion of reconstructed patients
who had CPM also increased from 19% to 46% (Agarwal et al., 2015). Moreover, evidence has demonstrated that women with unilateral breast cancer and DCIS were three times more likely to have CPM if they underwent immediate breast reconstruction (Ashfaq et al., 2014). Relatedly, a desire to achieve breast symmetry was reported to be either extremely or very important to patients in a cross-sectional survey of young women (Rosenberg et al., 2013), and close to 60% of patients surveyed in another study indicated that having the option of reconstructive surgery impacted their decision to have CPM (Soran et al., 2015).

A recent qualitative study exploring CPM decision making in women with non-high-risk early stage breast cancer described how many of the participants regarded CPM as an opportunity to improve the appearance of their breasts through bilateral reconstruction (Greener, Bass, & Lepore, 2018). Some researchers have concluded that the combination between wanting to obtain an ideal aesthetic result, together with a desire for greater peace of mind are the primary deciding factors for patients contemplating CPM (Hieken & Boughey, 2016).

1.2.5 Reconstruction Complications and Decisional Regret

CPM in women with early stage breast cancer is polemic in part due to concerns related to over-treatment and the increased chance of complications or other adverse outcomes. These risks are amplified with the addition of breast reconstruction, as this adds to the complexity of both the surgery and patient recovery. Research investigating the morbidity associated with breast reconstruction indicates that women who undergo CPM and immediate reconstruction experience 40% more complications overall and have almost four times as many severe complications requiring readmission or reoperation compared with patients who have unilateral mastectomies (Pinell-White et al., 2014). Additionally, a large population-based retrospective study conducted in Ontario confirmed that breast cancer patients who received post-mastectomy reconstructions experienced an average of two reoperations following their initial procedure over the course of a 5-year follow-up period and 10% of patients in the overall study cohort had a minimum of three or more unanticipated major reoperations during that time (Roberts, Baxter, Camacho, Lau, & Zhong, 2015).
Although the majority of women who have prophylactic surgery and breast reconstruction tend to report long-term satisfaction with their decision (Kathy, Meagan, & Andrew, 2018; Rosenberg et al., 2013), this treatment approach has the potential to negatively impact quality of life and may lead to decisional regret. For instance, Rolnick et al surveyed women who underwent CPM and showed that nearly 70% of their concerns were directly linked to breast reconstructions, including the look and feel of the implants, as well as scarring, numbness and pain (Rolnick et al., 2007). Additionally, many of the women indicated that they would have liked to view photographs prior to their procedure in order to gain a more realistic expectation toward the aesthetic outcome. They also revealed that they wished they were better informed ahead of time regarding the negative emotions associated with the permanent changes to their body (Rolnick et al., 2007). Furthermore, Boughey et al demonstrated that satisfaction with CPM was lower in women who had breast reconstruction and significantly more patients with reconstruction indicated that they would be less likely to choose CPM again (Boughey et al., 2015). The increased reoperation rate experienced by those who underwent reconstruction was reported to be the main reason for these lower satisfaction scores. Hieken et al caution that since CPM is permanent and may possibly lead to decisional regret or other negative sequelae, delaying the decision to have CPM and breast reconstruction until after the oncologic treatment has concluded may be beneficial for patients experiencing any reservations over this choice (Hieken & Boughey, 2016).

1.2.6 The Role of the Plastic Surgeon

The evidence involving plastic surgeons and their perspectives on CPM is relatively limited. A cross-sectional survey of Maryland surgeons conducted in the mid-nineties showed significant differences in practice patterns across physician specialties such that plastic surgeons recommended proportionately more CPMs compared with their general surgery colleagues (Houn, Helzlsouer, Friedman, & Stefanek, 1995). The authors suggested that plastic surgeons may view the role of prophylactic mastectomy in a dissimilar way to other surgeons and thus, counsel patients in a manner that makes the procedure more acceptable to them (Houn et al., 1995). Current evidence supports this perspective by illustrating that some women who initially select less aggressive surgery subsequently opt for CPM following a preoperative consultation with a plastic surgeon (Covelli et al., 2014). Furthermore, research
published by Nahabedian stated that one of the primary aims of plastic surgeons when treating patients with unilateral breast cancer is to obtain optimal symmetry and a contralateral operation may be regarded as necessary to achieve this goal (Nahabedian, 2008). Despite the fact that breast reconstruction is significantly associated with CPM, the interaction and decision making process between the reconstructive surgeon and the patient has not been well described in the current literature.

1.3 Study Objectives and Rationale

How patients and surgeons communicate with each other in relation to treatment options for breast cancer has been established as a primary driving force behind a patient’s final treatment choice (Parker et al., 2016). As the complexity of surgical decision making has grown in recent years, understanding the clinical encounter and communication between the patient-surgeon dyad is more important than ever. Previous studies are limited due to their quantitative designs and do not improve our understanding of the experiences and challenges faced by plastic surgeons during the reconstructive consultation. Accordingly, this study utilized qualitative methods to perform an in-depth exploration of the knowledge, attitudes, perspectives and experiences of plastic surgeons to better understand how they describe their roles in the treatment decision making process during their consultations with women who have non-high-risk early stage breast cancer.
2 Methods

This chapter includes the rationale for using a qualitative study design, the philosophical underpinnings of the research approach, a brief section on research ethics issues and reflexivity, as well as a detailed description of the methods, coding and analysis. The chapter concludes with a discussion of theoretical considerations and a description of the four principles comprising the biomedical ethics framework that were used to inform the analysis.

2.1 Brief Study Overview

A qualitative research study aligned with the constructivist paradigm was conducted (Charmaz, 2006; Guba & Lincoln, 1994). The study aimed to understand how plastic surgeons describe their roles in the surgical decision making process through their consultations with women who have non-high-risk early stage breast cancer (i.e., non BRCA1/2 carriers with no family history of breast cancer). A combination of purposive and snowball sampling strategies were used to recruit participants from both academic and community hospitals across the province of Ontario, Canada. Overall, 18 plastic surgeons participated in one-on-one semi-structured telephone interviews that were audio recorded and transcribed verbatim. An inductive and interpretive thematic approach was initially used to analyze the data (Braun & Clarke, 2006; Pope, Ziebland, & Mays, 2000; Thomas, 2006). The four principles depicted in Beauchamp and Childress’s biomedical ethics framework – non-maleficence, autonomy, justice and beneficence – were used as the conceptual lens to structure and interpret the findings (Beauchamp & Childress, 2007).

2.2 Justification for a Qualitative Study Design

The primary purpose of qualitative research is to generate knowledge that is based in real-world human experiences (Sandelowski, 2004). Quantitative techniques that use deductive methods of inquiry in controlled research settings are not appropriate when investigating the complexities of lived experiences (Polkinghorne, 2005). Qualitative approaches, on the other hand, represent research strategies specifically designed to enable the exploration of
multifaceted social issues by identifying patterns and trends communicated through the subjective perspectives of study participants (Hunt, 2009). In this way, qualitative research provides a deeper and richer understanding of real world phenomena that cannot be adequately captured or measured in a numerical fashion (Pope & Mays, 1995). Qualitative research is directed towards uncovering the meaning that particular events hold for the individuals experiencing them, as well as the interpretation and representation of those meanings by the investigator (Hoepfl, 1997). Qualitative inquiries are thus well suited for addressing compelling and contextually embedded questions relevant to the health services research domain, which can be used to inform clinical practice and ultimately improve the care that patients receive (Thorne, Reimer Kirkham, & O'Flynn-Magee, 2004).

Although considerable research has investigated rising CPM rates and many quantitative studies have established a significant connection between breast reconstruction and the choice to undergo CPM, the reasons underlying these decisions remain unclear (Agarwal et al., 2015; Ashfaq et al., 2014). We currently have a very limited understanding of the clinical interaction between plastic surgeons and breast cancer patients, as there are no published studies to-date that have explored this patient-physician relationship, particularly within the context of the CPM trend. Given that CPM and breast reconstruction does not provide an oncologic advantage in non-high-risk cohorts, yet increases the likelihood of surgical harms, it is important for the medical community to better understand the factors impacting this treatment choice.

Quantitative inquiries are constrained by their adherence to numerically based data, making them inadequate to capture the nuanced perspectives and motivations behind those involved in the decision making process. Accordingly, a qualitative design was selected for this study since it is capable of moving our current knowledge of the CPM phenomenon beyond the statistical associations provided by previous research. This approach is beneficial in that it makes visible the meaning that plastic surgeons give to their role in the treatment decision making process for breast cancer. It also enables an examination of the patient-physician interaction from the plastic surgeon’s viewpoint, thus resulting in an in-depth understanding of the clinical encounter.
Qualitative studies have explored increasing CPM rates from both the patient and general surgeon’s perspectives (Covelli et al., 2015; Covelli et al., 2014). However, the literature is unable to provide a complete picture of the decision making environment, as the voices of reconstructive surgeons are notably absent from previous research. The present study is unique in that it is the first to examine the plastic surgeon’s perspective of the surgical consultation in women with early stage breast cancer in Ontario or elsewhere. Understanding their experience treating non-high-risk patients addresses known gaps in our knowledge of the CPM trend and provides additional critical insight into the paradoxical shift towards more aggressive surgical treatment.

2.3 Philosophical Underpinnings

An important aspect of performing any type of qualitative inquiry is to acknowledge the philosophical assumptions that underpin the investigative process (Kelly, 2010). These assumptions comprise the research paradigm, which describes a set of basic beliefs the investigator brings into the study that have implications for how the project is conducted and how knowledge is generated (Creswell, 2007). Paradigms represent the “positionality” or “worldview” of the beholder that defines their assumptions about nature of reality (ontology), the nature of knowledge or how something can be known (epistemology), as well as the ways in which knowledge can be acquired (methodology) (Guba & Lincoln, 1994). Defining the meaning of data and how data are perceived is necessary, as this in turn influences what can be seen and known (Charmaz, 2006). Paradigms function as filters for qualitative investigators, which guide and shape the entire research experience (Mills, Bonner, & Francis, 2006). Being explicit about these assumptions increases the quality of the final product, as it makes the decisions about the study and the knowledge generated from it, apparent to others (Kelly, 2010).

The present study was informed by the constructivist paradigm, which rejects positivist views inherent to more traditional research approaches that maintain there are observable, objective and absolute truths waiting to be discovered (Giacomini, 2013). Instead of accepting this notion of universal truths, constructivism emphasizes the subjective perceptions, views, beliefs and ideologies of individuals and embraces a diversity of interpretations regarding truth claims (Creswell, 2007). Research conducted through this
paradigm seeks to understand and interpret people’s experiences and acknowledges the importance of situational contexts in shaping their view of the world around them (Kivunja & Kuyini, 2017).

Being ontologically relativist, constructivism asserts that reality is not fixed; rather, multiple realities exist and are socially constructed based on context and experience (Guba & Lincoln, 1994). Meaning is constructed by individuals while they engage and interact with their surroundings and thus, knowledge or “truth” is viewed as being relative and malleable (Crotty, 1998). The constructivist paradigm adopts a subjectivist epistemology whereby both the researcher and participant are seen to be co-constructors of the data and findings are created from their shared interactions throughout the investigative process (Charmaz, 2008). As constructivism also adopts a naturalist methodology, it follows that the research is conducted in a real-world environment, rather than in an experimental or controlled laboratory setting (Kivunja & Kuyini, 2017). Similarly, this paradigm supports flexible and open-ended data collection methods to broaden the depth of understanding beyond a simple description of events (Charmaz, 2002). It also features an inductive approach to data analysis to ensure that concepts are derived directly from the meaning expressed in the words of the participants (Pope et al., 2000).

The constructivist paradigm is beneficial when investigating areas where prior research is not available to describe a particular phenomenon, process or social interaction (Creswell, 2007). Accordingly, this approach was well-suited for the present study that explored the perspectives of Ontario plastic surgeons during the breast reconstructive consultations with women who have early stage breast cancer. Attending to the meanings and experiences articulated by the participants facilitated an in-depth appreciation of the patient-physician interaction during the treatment decision making process.

2.4 Research Ethics

Permission to conduct this study was granted through the Research Ethics Boards at both Sunnybrook Health Sciences Centre and the University of Toronto. Ethical issues were considered across all phases of the research process, such as obtaining informed consent, maintaining confidentiality and the appropriate storage of data (Kvale & Brinkman, 2009). In
addition to a signed consent form, explicit verbal consent was confirmed just prior to conducting each interview. This process included a review of the purpose of the investigation, the anticipated use of the data, as well as a discussion regarding the preservation of their confidentiality by removing all identifying information from the transcripts. Moreover, measures were employed to ensure the security of the collected data, including storing the master list on a password-protected computer and keeping physical copies of the consent forms in a locked research office. Furthermore, digital audio recordings from the interviews were stored on a secure computer accessible only by the researcher.

2.5 Sampling

As the goal of qualitative research is to gain a richer understanding of lived human experiences, it requires the collection of detailed and saturated accounts from those who have experience with the topic of interest (Polkinghorne, 2005). There are various approaches or strategies that may be used to select appropriate participants, which are included under the broad categories of convenience sampling, judgement sampling and theoretical sampling (Auerbach & Silverstein, 2003; Polkinghorne, 2005). Convenience sampling involves selecting participants who are the most accessible or least resource intensive for the researcher to recruit. Judgement sampling, more commonly referred to as purposive sampling, is when the researcher intentionally selects the most advantageous participants to better understand a specific research question. Theoretical sampling is a technique typically associated with grounded theory methods in which participant selection is theory-driven and additional participants are chosen to investigate new and evolving concepts as they arise in the data (Polkinghorne, 2005).

Sampling within this study was designed to include participants who were able to provide relevant descriptions of their experiences, as well as to reflect a sufficient amount of group diversity to ensure the fullness of the topic under investigation was being conveyed (Auerbach & Silverstein, 2003). Accordingly, purposive sampling techniques were chosen whereby the researcher actively selected participants who varied in terms of practice location; institution type (i.e., academic and community hospitals); number of years in practice; participant gender; and volume of breast cancer patients consulted per month. Additionally, snowball sampling (i.e., recommendations for additional potential candidates
from current study participants) was used to recruit plastic surgeons that were otherwise inaccessible due to outdated or incomplete contact information (Polkinghorne, 2005). In particular, snowball sampling was beneficial in terms of targeting recruitment towards male participants who worked in the community setting, as the study population had become skewed in favour of female participants, as well as those who worked in academic centres. Therefore, as the study progressed, participants were asked to recommend additional male colleagues from the community setting until data saturation was achieved.

2.6 Participants

The population of interest for this study included plastic surgeons who perform breast reconstructive surgery and who work at either an academic or community hospital across the province of Ontario, Canada. Participants were excluded if they were not currently in active practice in Ontario or did not perform breast reconstruction in women who have early stage breast cancer. For the purpose of this study, early stage breast cancer was defined as either ductal carcinoma in situ or a tumour less than 5cm in size with no known lymph node, skin or muscle involvement. An Ontario cohort was selected since it provided a variety of surgeon attributes, practice settings, experiences and perspectives to allow for the collection of a rich dataset, while simultaneously being accessible and feasible in terms of the scope of the project.

2.7 Recruitment

Potential participants for this study were initially identified from the Canadian Collaboration of Breast Reconstruction Directory (http://breastreconstructioncanada.ca/), which is a publically accessible website that contains demographic information, practice details, as well as contact information for plastic surgeons across the country. Eligible Ontario surgeons were selected from this online directory and contacted via mail with a study package inviting them to participate. The package contained a hand-signed invitation letter describing the background and study objectives (appendix A), an informed consent form (appendix B), as well as a response form (appendix C). Interested surgeons were instructed to sign and return the consent form along with the completed response form in a pre-addressed business reply envelope indicating their preferred interview date and time. An email invitation with an
attachment containing an electronic version of the study package was sent to non-responders two weeks after the initial mail out, followed by a telephone call to the remaining non-responders two weeks following that.

2.8 Data Collection

As is typical with qualitative research, data collection was conducted via semi-structured one-on-one interviews where participants were all asked a set of similar open-ended questions based on an interview guide (Bernard & Ryan, 2010). Since this study involved participants from across a wide geographic region, for the sake of feasibility, all interviews were performed via telephone rather than face-to-face. Prior research has indicated there to be no significant differences in the quality of data between research interviews that are conducted over the phone compared with those performed in person (Sturges & Hanrahan, 2004). The semi-structured interview format was selected as it directed the participants, yet also provided enough flexibility for the researcher to adjust the order that the issues were covered, as well as to investigate fresh ideas or novel topics that were raised (Charmaz, 2002). Although this approach surrenders some control over how the interviews progressed, since participants were all asked similar questions, their responses could be compared and examined for patterns across the entire dataset (Bernard & Ryan, 2010).

Semi-structured interviews are beneficial in that participants are free to speak in their own terms, allowing them to provide in-depth information pertaining to the topic under investigation that results in detailed material for analysis (Charmaz, 2002). This was of particular importance for the current study, as it was exploratory in nature due to the lack of information available on CPM decision making from the perspective of plastic surgeons. In keeping with the constructivist paradigm, the interviews were interactive, resulting in a reflection of what both the researcher and participants brought to the interview, as well as the relationship they co-constructed (Charmaz, 2002).

An interview guide was developed based on content informed by relevant literature, combined with expert opinion from breast surgeons (FW, TZ) and input from an experienced qualitative researcher (LGC). The guide was designed with open-ended questions and prompts to explore the experiences of plastic surgeons during their preoperative consultation
with women who have early stage breast cancer and DCIS. Topics included their overall approach to counseling patients, the decision making process, as well as their knowledge, perspectives and opinions regarding various reconstructive options. The guide included questions such as “Please describe a typical consultation with a patient who has been diagnosed with early stage breast cancer”, “How do you and the patient typically arrive at the final treatment decision?” and “What is your approach to situations in which a patient requests a bilateral procedure, but they have a unilateral breast cancer?” (see appendix D for the full interview guide).

A draft of the interview guide was pilot-tested with 4 plastic surgeons in order to refine the wording and the flow of questions and prompts. The pilot interviews were transcribed and reviewed by the research team to ensure that the areas of interest were being adequately explored. The guide was adjusted and revised accordingly based on data from the pilot interviews. All study interviews were conducted by the same interviewer (SS) to maintain internal consistency and were audio recorded and transcribed verbatim.

Data collection concluded once saturation was reached (i.e., no new ideas or themes were introduced and there was a high level of repetition in participant responses) (Fusch & Ness, 2015). Saturation was determined through consensus by three independent members on the research team (SS, FW, and LGC). Additionally, data were collected by way of memo-ing. This refers to a technique adopted by qualitative researchers as a means to record thoughts or ideas while the study progresses and is helpful for providing context or interpretations with respect to the data (Charmaz, 2002; Tweed & Charmaz, 2012).

### 2.9 Reflexivity

Reflexivity is increasingly recognized as an essential component of generating knowledge through qualitative research (Berger, 2015). It involves a “personal interrogation” whereby the researcher makes explicit their influence over the research process both to themselves and to their readers in order to uphold the integrity and trustworthiness of the data (Finlay, 2002). Reflexivity refers to a researcher’s self-awareness and recognition of the ways in which the research process has been shaped (Charmaz, 2006; Cutcliffe, 2000).
From an epistemological standpoint, constructivists assert that meaning is context dependent and knowledge is co-constructed through the interactive and reciprocal relationship between the participant and researcher who bring their own unique assumptions and understandings to these interactions (Mills et al., 2006). Accordingly, within the constructivist paradigm, researchers must locate themselves in the research and the world in which they live in order to uncover the filters through which they see and ultimately shape the data (Mills et al., 2006). As the investigator is central to all aspects of the research from a project’s inception and design, to data collection, analysis and interpretation, it is important to maintain transparency in decision making and to continually question and uncover assumptions that have been made throughout the entire research experience (Finlay, 2002). Reflexivity is best demonstrated through the use of first-person language, as well as comprehensive and transparent descriptions regarding study-related choices and their rationale (Berger, 2015).

2.9.1 Self-Reflections

The current study was conducted as my master’s thesis while attending school at the University of Toronto. I entered this project from an “outsider perspective” as I did not have a background in either breast cancer or plastic surgery. I first became aware of the phenomenon of rising CPM rates several years ago while attending a monthly research meeting for my job as a research coordinator. During this meeting, a colleague presented preliminary results from her PhD thesis, which examined CPM decision making in both breast cancer patients and general surgeons. My master’s thesis stemmed from her research, which revealed a gap in the literature regarding the plastic surgeon’s perspective on this controversial issue.

I initially viewed this topic with a specific set of assumptions and subsequently revised my perspective on CPM and breast reconstruction upon completion of this project. I began with the belief that CPM in the setting of non-high-risk early stage breast cancer was unnecessarily harmful and I could not fully comprehend why women were selecting more aggressive surgical treatment with increasing frequency. Additionally, I assumed that plastic surgeons were simply recommending that women undergo CPM as a means to achieve
improved symmetry with bilateral breast reconstruction. However, my research committee helped me to recognize these biases and the various ways in which they impacted the initial research question, as well as the overall study proposal. They challenged me to re-frame my perspective by adopting a more neutral stance. This allowed me to approach the topic free from a priori assumptions and enabled the voices of the plastic surgeons to drive the research. The ongoing discussions with my committee and reflexive memo writing has bolstered my growth as a qualitative researcher and will likely continue to do so in future research projects.

2.10 Coding and Data Analysis

2.10.1 Overview

When conducting qualitative research, there is no single “correct” method for analysis, rather, various strategies are used and modified according to the research objectives and the collected data (Maxwell, 2013). In the present study, data were initially analyzed inductively using a thematic approach to examine the underlying assumptions shaping the content within and across the data regarding the participants’ perspectives of the clinical encounter (Braun & Clarke, 2006). In order to reach a greater depth of interpretive understanding, a more deductive approach was taken as the analysis progressed. Specifically, the developing themes were informed by the four principles comprising Beauchamp and Childress’s biomedical ethics framework and were considered both in relation to the specific research question as well as the wider literature (Beauchamp & Childress, 2007).

2.10.2 Thematic Analysis

Thematic analysis is a strategy for identifying, analyzing, organizing, describing and reporting patterns of meaning or themes derived from raw qualitative data (Braun & Clarke, 2006). It can also be used for analyses that extend beyond surface level descriptive content where the researcher considers the significance of the themes and the broader implications of the findings (Clarke & Braun, 2013). Thematic analysis is beneficial in that it provides a systematic and coherent method that yields high-quality results, yet is untethered to a specific theoretical paradigm, making it flexible enough to be compatible across a range of theoretical frameworks and research interests (Braun & Clarke, 2006).
The purpose of analysis is to transform large amounts of text from qualitative transcripts into meaningful summarized categories and also establishes connections between the study aims and findings interpreted from the data (Thomas, 2006). As described by Braun and Clarke, this is achieved through a phasic process of data familiarization, coding, searching for themes, reviewing themes, defining themes and final reporting, which is detailed below (Braun & Clarke, 2006). Thematic analysis provides an organic means of coding and theme development that also emphasizes an active role of the researcher throughout the analytic process and as such, aligns well with the constructivist research paradigm (Clarke & Braun, 2017).

The data in this study were initially approached inductively, which required handling the data in a bottom-up manner resulting in findings that were “data-driven”, rather than applying a deductive or top-down method used when confirming a priori theories (Braun & Clarke, 2006; Thomas, 2006). An inductive process involves examining the experiences of participants in their own words and identifying themes that are clearly and directly linked to the actual data (Braun & Clarke, 2006). The inductive approach is particularly useful when investigating novel or previously unexplored phenomenon, and is frequently used in health and social sciences research (Pope et al., 2000).

2.10.3 Phases of Thematic Analysis

Although the various stages of the analysis are presented in a step-wise fashion, in practice, the process is iterative and resembles methods employed by other common qualitative approaches. For instance, similar to grounded theory methods, it involves a constant comparative or recursive process of sifting back-and-forth between phases of reading the transcripts, the coded fragments of data within the transcripts and the analysis or interpretation of the data being constructed, as necessary (Braun & Clarke, 2006; Glaser, 1965).

2.10.3.1 Phase 1: Data Familiarization

The initial phase of data familiarization was an essential and foundational stage in the analytic process in which the audio-recorded interviews were transcribed verbatim by the same investigator who performed the interviews (SS). Although the researcher already had
prior knowledge of the interview content, the transcription process provided an opportunity to gain a deeper understanding of the details communicated by the study participants by paying particularly close attention to everything that was said. This was followed by further immersion in the raw data through an active process of reading and re-reading the transcribed interviews to search for similarities and recurring commonalities within the data (Braun & Clarke, 2006). Throughout this process, preliminary thoughts were documented to highlight any developing ideas or analytic observations identified within the transcripts (Sandelowski, 1995).

2.10.3.2 Phase 2: Generation of Codes

This phase signified the beginning of a more formal coding process and entailed creating initial codes to represent interesting features of the data applicable to the research topic (Braun & Clarke, 2006; Clarke & Braun, 2017). Codes are meant to capture the essence of an experience and should have clearly defined boundaries to avoid a redundancy of ideas (Nowell, Norris, White, & Moules, 2017). The goal of coding in qualitative research is to deconstruct the data and then reorganize it into categories to facilitate comparisons between repeating concepts (Maxwell, 2013). Coding is not only a method for data reduction by separating it into analogous segments, it is a purposeful process which requires the researcher to actively think about what is being conveyed in the textual content, both semantically and conceptually (Bernard & Ryan, 2010; Ryan & Bernard, 2000). Coding provides the essential link between data collection and the construction of more coherent patterns of meaning (Apramian, Cristancho, Watling, & Lingard, 2016).

Coding in this study involved a systematic and close reading of each interview. Concise codes depicting meaning and action in the data were highlighted and manually recorded in the margins of the transcript pages (Auerbach & Silverstein, 2003; Charmaz, 2006). The data were approached in an inductive manner, whereby codes were constructed directly from the raw transcripts without attempting to force them into preexisting groups (Thomas, 2006). A code guide was subsequently developed to help organize and sort the large volume of information into meaningful categories. Since the codes were data-driven, the guide was flexible to allow for new and developing ideas to be included. The guide contained the various code names, a brief description and a representative quote corresponding to each
Coding was performed by two independent researchers (SS, FW) to increase the range of perspectives brought to the data. Coding by multiple investigators also minimized the likelihood that key concepts would be missed, and enhanced the transparency of the process (Nowell et al., 2017; Pope et al., 2000).

In keeping with the inductive approach, the investigators refrained from consulting the wider literature during the initial phases of analysis to avoid “tunnel-vision” towards a particular aspect of the data or inadvertently imposing their own views over and above those expressed by the participants (Maxwell, 2013). Once all of the transcript data were coded and collated into a larger list of codes, investigator triangulation (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2014) was employed in which the two investigators conferred with a third qualitative researcher (LGC). Together they met to discuss and compare codes, as well as to resolve any areas of discrepancy. Investigator triangulation beneficial in that it allows for the confirmation of findings and also provides a deeper understanding of the data by introducing multiple perspectives regarding how each individual views the phenomenon (Carter et al., 2014).

2.10.3.3 Phase 3: Searching for Themes

The next phase was when the analysis shifted to a broader level that moved beyond basic coding and involved arranging and grouping similar codes together in order to form potential themes (Braun & Clarke, 2006). A theme refers to an implicit topic that organizes a set of repeating concepts or meaningful patterns in the data that share a core idea (Ryan & Bernard, 2000). Themes are not simply buried within the data awaiting discovery, rather, the search is a deliberate process whereby the researcher actively considers and constructs each separate theme (Clarke & Braun, 2013).

During this phase, colour-coded computerized tables were generated and used to assist with the organization of potential themes. This helped to visually structure and illustrate the relationships between the codes and between the themes, as well as to reflect over how they may fit together to produce different levels of themes (Braun & Clarke, 2006). This phase concluded once a set of plausible or “candidate” themes, and all coded data extracts in relation to those themes, had been established (Braun & Clarke, 2006).
2.10.3.4 Phase 4: Reviewing Themes

This phase was focused on determining whether or not the potential themes “worked” with respect to the coded data extracts and in relation to the entire dataset (Clarke & Braun, 2013). This meant ensuring that the data comprising each theme were meaningfully connected to each other and also that clear delineations were apparent between each individual theme (Braun & Clarke, 2006). During this stage, the researchers opted to introduce extant theory to help guide and structure the analysis and interpretation of the data. An informal literature review was conducted to discern if the categories and potential themes were reflective of any current models, frameworks or theories. The literature search was predominantly structured around communication, decision making, interpersonal health behaviours and the patient-physician dyad, as these were some of the important topics relevant to the research question and were also represented in the coded data.

The literature search resulted in several candidate models and frameworks, which were considered in relation to the developing themes. In particular the Cancer Survivorship and Agency Model developed by O’Hair et al depicts a phasic experience for cancer patients as they progress through the process of survivorship, originating in uncertainty and leading to a place of empowerment and agency (O'Hair et al., 2003). Although initially promising, the developing themes were ultimately not a good fit with the principles of this model, as too much was left unaccounted for and the potential themes appeared forced within the model’s constructs. Through input from the investigative team, in conjunction with an iterative process of constant comparison between developing concepts and findings from the literature, it became clear that the data resonated well with the principles of biomedical ethics as described by Beauchamp and Childress (Beauchamp & Childress, 2007; Teven & Grant, 2018). These principles were: non-maleficence, respect for autonomy, justice and beneficence, which are described in detail under the theoretical considerations section below.

At this stage, the analysis transitioned into more of a deductive process in which these four principles were used as the analytic lens through which the data were viewed. They also served as a conceptual framework to inform the interpretation and structure the presentation of findings during the subsequent phases of analysis. Using these ethical principles as
organizing constructs helped to refine potential themes. For instance, certain themes were merged together due to significant overlap, others were separated out to form additional, discrete themes and some were abandoned altogether from a lack of supporting data (Braun & Clarke, 2006; Javadi & Zarea, 2016). The goal at the end of this phase was for the researchers to have a stronger sense of the various themes and how they might form an overall story with the data (Braun & Clarke, 2006). At this time, validity checks were conducted with members of the investigative team for agreement of themes and to assess how well the themes fit within the framework of the bioethical principles.

2.10.3.5 **Phase 5: Defining Themes**

During this stage, further refinement occurred as the analysis progressed. The researchers characterized the scope and content of the respective themes by conducting a detailed analysis of each one and clearly identified the story it told (Braun & Clarke, 2006). Additionally, they considered how the themes aligned with the four organizing ethical principles and also how they fit together to form a cohesive account of the entire dataset as it related back to the study question (Nowell et al., 2017). By the end of this phase, all themes, including the overarching narrative theme, were clearly defined and assigned definitive names (Braun & Clarke, 2006).

2.10.3.6 **Phase 6: Producing the Report**

Once the final themes were established, the process of writing the manuscript began. The goal was to create a coherent story about what each theme revealed about the topic by combining the analytic narrative with extracts of raw data to make a compelling argument with respect to the overall research question (Braun & Clarke, 2006). As demonstrated in subsequent chapters, direct quotes from study participants were embedded within the write-up to help clarify the story of the data and to lend credence to the validity of the analysis (Nowell et al., 2017). The themes are presented in the results section. They are also discussed in detail in the final chapter and are considered within the context of the broader literature to add to the current understanding of the clinical encounter and decision making process between plastic surgeons and patients with early stage breast cancer.
2.11 Theoretical Considerations

Qualitative researchers commonly rely on theories, or coherent systems of ideas, from a broad range of disciplinary paradigms as a means to direct their research and to clarify or transform their findings into useable knowledge (Giacomini, 2013; Reeves, Albert, Kuper, & Hodges, 2008). Theories take on different forms and functions in various qualitative pursuits and may enter or exit a project during different phases of the inquiry process (Kelly, 2010; Sandelowski, 1993). For instance, theory may influence the research question or study design, guide the selection of relevant data, serve as a model from which to organize, analyze and interpret the findings, or act as a novel product of the research itself (Sandelowski, 1993).

Since there is no gold standard for understanding multifaceted social issues, theories are especially beneficial for providing “lenses” to view phenomena under investigation by directing the focus towards particular features of the data that may not have otherwise been attended to (Reeves et al., 2008). Simply put, for qualitative researchers, a theory is essentially a conceptual tool to help critically examine and make sense of data (Kelly, 2010). According to Sandelowski, a theory is considered to be a “good fit” when investigators do not distort the meaning of their data by forcing it into a preconceived theoretical structure, but instead, are able to easily draw straightforward comparisons to a theory’s primary concepts (Sandelowski, 1993).

As described above, theory was introduced into this study using the principles of Beauchamp and Childress’s biomedical ethics framework to inform the developing categories while analyzing the data. This helped to provide a richer overall understanding of the perspectives and experiences of plastic surgeons and how they account for their role in the treatment decision making process for women with early stage breast cancer.

2.12 The Four Principles Framework of Biomedical Ethics

Biomedical ethics refers to the examination and analysis of ethical issues that arise in the setting of research, healthcare, health sciences and health policy (Ashcroft, 2004). Although the foundation of medical ethics was established over 2,000 years ago, the 1960s is the era in
which bioethics truly began to mature academically and emerged as a focus of empirical research (Ashcroft, 2004). In 1979, Beauchamp and Childress introduced four principles of biomedical ethics to assist physicians who encountered moral issues while caring for sick patients (Beauchamp & Childress, 2007). These principles offer a comprehensible and culturally neutral means of thinking about contentious healthcare issues and currently serve as the ethical framework for modern surgical practice in North America (Sterodimas, Radwanski, & Pitanguy, 2011). This framework describes an approach to ethical decision making that has come to be known as *Principlism*, and is based on the core moral principles of: (i) non-maleficence, (ii) respect for autonomy, (iii) justice and (iv) beneficence (Beauchamp & Childress, 2007; Teven & Grant, 2018).

### 2.12.1 Non-Maleficence

A key tenet of non-maleficence, “primum non nocere” (first do no harm), is reflected in the Hippocratic oath and refers to an obligation of physicians to avoid inflicting harm on a patient, as well as reducing the risk of harm due to inappropriate care (Beauchamp & Childress, 2007). Although this principle acknowledges that some medical interventions may cause a certain degree of unavoidable harm, the net benefit to patients must outweigh these harms (Gillon, 1994). For plastic surgeons, non-maleficence means that they can refuse to perform surgery if they do not consider the procedure to be in the best interest of their patient (Sterodimas et al., 2011). Similarly, they may express reservations about operating on someone who holds unrealistic expectations regarding their overall aesthetic outcomes as the patient will most likely be unsatisfied and may have a diminished quality of life (Sterodimas et al., 2011). This principle is particularly salient in the context of the CPM trend and lies at the heart of the ongoing debate among the medical community over the applicability of this treatment choice for women with early breast cancer who are considered low risk for developing a contralateral breast cancer.

### 2.12.2 Respect for Autonomy

The principle of patient autonomy centres around the moral obligation to respect a patient’s right to make their own decisions regarding the medical care they receive, even if these decisions seem inconsistent with recommended care (Lawrence, 2007). It also includes a
patient’s right to accept or refuse treatment altogether. In healthcare, respect for autonomy is closely tied to the concept of informed consent. It requires that the individual possesses the capacity to make decisions free from outside control and also has a sufficient level of understanding of the risks, benefits and consequences in order to make appropriate treatment choices (Coyle, 2014; Lawrence, 2007).

Historically, the model for medical decision making was strictly physician-centric whereby decisional authority rested exclusively with the treating doctor (Sterodimas et al., 2011). Only more recently has the patient-physician relationship evolved towards a model that respects the patient as an autonomous, self-governing agent (Charles, Gafni, & Whelan, 1997). This movement away from paternalism promotes an increasingly active role for patients in terms of their own healthcare decisions so that they ultimately receive treatments best aligned with their personal values, beliefs and preferences (Charles et al., 1997). Tension may be created between competing principles in circumstances where a patient’s expectations and goals differ from that of the physician, who must then carefully balance their obligation to do no harm, while also providing patients with the care they want.

### 2.12.3 Justice

Justice is tantamount to fairness and refers to a moral obligation to provide patients with medical care that is equitable and accessible to all (Coyle, 2014). This principle means that patients who have similar health related conditions should receive similar treatment (Chung, Pushman, & Bellfi, 2009). Justice also speaks to the equal allocation of resources, including a social responsibility to ensure benefits, harms and costs are evenly and appropriately distributed across a given population (Lawrence, 2007). Although the equitable receipt of health care is considered to be a fundamental human right, in practice, this has proven to be more challenging due to various factors, such as geographic location or language barriers that may impact access to equal care (Platt et al., 2015; Sterodimas et al., 2011). The principle of justice is further complicated by the increasing incidence of CPM, particularly within Ontario’s publically funded healthcare system, as CPM may be viewed by some health care providers as a medically unnecessary procedure that is both resource-intensive and overly aggressive in the treatment of early stage breast cancer (Boughey, Attai, Chen, Cody, Dietz,

2.12.4 Beneficence

Beneficence means “doing good” by acting in the best interest of the patient (Coyle, 2014). It is a principle that refers to the ethical duty to maximize benefits while also minimizing the risks of harm (Sterodimas et al., 2011). Beneficence requires physicians to provide care that promotes well-being and involves advocating for patients to ensure that their voice is heard (Coyle, 2014). This can be especially challenging in the plastic surgery setting. For instance, performing reconstructive procedures to enhance self-esteem may be a primary goal of plastic surgeons, yet defining a patient’s best interest is contingent upon each individual’s perspective; what represents a net benefit for one may be considered detrimental by another (Gillon, 1994; Sterodimas et al., 2011). Plastic surgeons are tasked with reconciling their responsibility towards competing ethical principles when providing best care for breast cancer patients.

2.13 Applying the Bioethical Framework through Specification

Beauchamp and Childress’s four-principles framework is the most commonly taught approach to modern medical ethics in America (Chung et al., 2009). This approach to ethical decision making is not theory per se, nor does it offer an ordered set of rules or method for choosing a course of action, rather, it provides a set of principles to think about moral issues in research and clinical practice (Beauchamp & Childress, 2007; Gillon, 1994).

The founders of the framework maintain that it is impractical to prioritize the importance of their principles in a pre-established order, as every ethical dilemma contains subtleties that must be considered within the climate of the particular situation (Beauchamp & Childress, 2007; Lawrence, 2007). In order to apply the framework, context must be given through “specification,” which is a process that reduces hypothetical conceptions of the principles and transforms them into practical tools to provide guidance for ethical decision making (Beauchamp & Childress, 2007; Horner, 2007). This is achieved through an active reasoning process that reduces the broad scope of the general principles and gives them content by specifying, in a case-by-case manner, the particular acts that might occur within each
principle (Beauchamp & Childress, 2007; Horner, 2007). As context is the primary factor that influences the final decision, previously specified rules may require additional specification when encountering new moral dilemmas (Beauchamp & Childress, 2007). Accordingly, plastic surgeons and other health care professionals need to carefully balance and weigh these four ethical principles when delivering care to their patients.
Chapter 3
Results

3 Study Results

3.1 Participants and Interviews

Overall, 43 Ontario plastic surgeons were mailed an invitation package for the study. Six of them subsequently declined to participate: 5 indicated they no longer performed breast reconstructions as part of their practice and 1 specified that they were not interested due to time constraints, 19 did not respond. Of these non-responders, 14 were male (10 worked in the community setting, 4 academic) and 5 were female (1 worked in the community setting, 4 academic). The remaining 18 plastic surgeons consented to the study and participated in one-on-one telephone interviews that were conducted over a six month period from June 2017 to December 2017. The mean interview time was 33 minutes (range 21-53 minutes). Ten of the 18 participants were female and 56% (10/18) came from academic hospitals, while the remaining 44% (8/10) worked in community centres. The participants varied with respect to the number of years they had been in practice for (mean of 13, range 3.5 – 25 years) and in terms of the volume of their practice, as indicated by the number of breast cancer patients they consulted per month (mean of 13, range 1-25 patients/month). A summary of the demographic details is shown below in Table 1.

Table 1: Summary of Demographic Details (n=18)

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td><strong>Institution Type</strong></td>
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<tr>
<td>Academic</td>
<td>10</td>
</tr>
<tr>
<td>Community</td>
<td>8</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
</tr>
<tr>
<td><strong>Average number of years in practice</strong></td>
<td>13 years (range 3.5 – 25 years)</td>
</tr>
<tr>
<td><strong>Average number of patients per month</strong></td>
<td>13 patients (range 1 – 25/month)</td>
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<tr>
<td><strong>Residency Location</strong></td>
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</tr>
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<td>Canada</td>
<td>17</td>
</tr>
<tr>
<td>Outside Canada</td>
<td>1</td>
</tr>
<tr>
<td><strong>Fellowship Location</strong></td>
<td></td>
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<tr>
<td>Canada</td>
<td>9</td>
</tr>
<tr>
<td>Outside Canada</td>
<td>9</td>
</tr>
</tbody>
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3.2 The Surgical, Social and Psychological Context of CPM Decision Making

During the interviews, all of the plastic surgeons described various aspects of their reconstructive consultations which, taken together, characterized the surgical, social and psychological milieu they perceived to influence the decision making process in patients with early stage breast cancer (Table 2). In particular, they discussed the impact of improved surgical techniques, the desire for breast symmetry, media effects, as well as patient anxiety and fear. Overall, these factors are consistent with previous findings documented in the contralateral prophylactic mastectomy literature investigating why women with non-high-risk disease choose CPM with increasing frequency (Brown et al., 2017; Buchanan et al., 2016; Fu, Zhuang, Dewing, Apple, & Chang, 2015; Sabel & Dal Cin, 2016).

Within the surgical milieu, the plastic surgeons perceived the widespread availability and access to immediate reconstructive procedures, coupled with substantial advancements in surgical techniques and improvements in cosmetic outcomes, as significantly contributing to CPM being more acceptable in the non-high-risk breast cancer population. The participants expressed these beliefs by stating the following:

“As we get better and better reconstructions, people are more and more comfortable having a prophylactic mastectomy. Some of the reconstructions really are quite lovely and there are people out there who look better – their bodies are better after their cancer and reconstruction than they were before because they get other benefits like when you get fat-grafting and then you have the lipo and the breast – it’s the best of both worlds.” (ID 7)

“People are understanding that our reconstructions are getting better and better and better so they can have, a lot of times, something that actually looks pretty much like a close to normal breast.” (ID 5)

“With the increased availability of immediate reconstruction and the options there, you’re able to give them a shorter procedure and a very reasonable aesthetic result, so I think that there is a little less anxiety about what they’re going to look like...we’ve contributed to that by improving our technical skills and what we’re able to offer.” (ID 12)
Furthermore, the participants shared their views of what they understood to be of primary concern for patients with early stage breast cancer during their reconstructive consultations. They explained that although this typically varies from individual to individual, most commonly, women express apprehension regarding their cancer diagnosis, the risks and complications associated with the reconstructive procedures, and their surgical recovery time. The plastic surgeons described how a desire for breast symmetry also increased the likelihood of a patient undergoing CPM, as illustrated in the comments below.

“I think they want something that looks perfect symmetrical when they’re finished and the common line I get is: ‘if I had to get breast cancer, I want a set of boobs that are better than the ones I had.’ So I think there is a lot of aesthetic focus on it.” (ID 4)

“I think symmetry is up near the top – looking balanced - that’s near the top for sure. I mean, it’s so important, you know, looking balanced is so important to patients, it really is.” (ID 18)

Similarly, some of the plastic surgeons revealed their personal inclination towards performing bilateral breast reconstructions following CPM, as this approach is optimal for achieving the ideal aesthetic outcomes.

“From a plastic surgeons point of view, I prefer if they have a contralateral procedure done because it’s easier to get a better cosmetic result, right? A bilateral procedure will always look better than a unilateral breast procedure, even if you do a balancing reduction or a lift, because you’re doing the same thing to both sides, so I’m completely happy and fine with it.” (ID 13)

“In some ways, sometimes it’s actually preferable to me because it’s a lot easier to achieve something symmetric if you’re starting from the same starting point.” (ID 5)

“Sometimes I would recommend prophylactic mastectomies for symmetry. Sometimes they have a pretty mutilated breast to start with. I mean, I wouldn’t say mutilated, but this is our opportunity - this is the time we can take the tissue and we can give you two matching breasts and we can make them match up nicely and it might be aesthetically better in the long run. So sometimes you’ve got to look at what you’re saving too. If it’s kind of an ugly breast, I would recommend it.” (ID 7)

The social milieu was also perceived to affect the CPM rate. Plastic surgeons described how recent media coverage of high-profile celebrities who have undergone bilateral prophylactic mastectomies has shaped this procedure into an increasingly mainstream choice for women.
The participants further remarked that these public disclosures by notable figures are often inaccurately portrayed, thus creating false conceptions regarding the applicability of CPM procedures for patients without high-risk genetic mutations.

“I think the whole prophylactic thing is really the whole Angelina Jolie effect. That article that she wrote was very provocative and I think that really set people thinking about having the opposite breast off without knowing the context of her disease and without knowing why it was important for her to have a prophylactic and why it’s not important for them to have a prophylactic.” (ID 4)

“I think they get the idea from some of the more prominent women that have undergone bilateral mastectomies for gene positivity, right? They see that these people look pretty good when they’re done. I don’t know that everybody understands the gene positive thing, but I think they see - well she had breast cancer, she had both breasts off, she looks pretty good, maybe I should consider that.” (ID 12)

“I think some of the publicization of patients having prophylactic mastectomies in the media over the last 5 or 6 years has created a lot of anxiety among women who have a unilateral breast cancer that somehow, they’re going to be at very high risk of getting it in the opposite breast...The media never really portrayed it very clearly and so that was one of the problems.” (ID 18)

The majority of the plastic surgeons discussed the psychological milieu surrounding the CPM trend by communicating their awareness regarding the considerable role that fear and anxiety of developing a contralateral breast cancer plays in a woman’s decision to undergo CPM. In fact, many of the interviewees acknowledged this to be among the strongest driving forces behind this choice.

“I think it’s all fear and anxiety. I don’t think there is any other reason than fear and anxiety for people who have a contralateral prophylactic mastectomy.” (ID 16)

“Anybody who hears cancer of any form, it just stops your heart because everybody knows someone who’s died of cancer and everybody knows someone who has died of breast cancer...They’re trying to gain control of an uncontrollable situation and I think that prophylactic mastectomy gets lumped into that basket: “I’m going to do everything I can to live and get rid of this cancer.” (ID 4)

“I think they’re coming up with the request from just their own anxiety. It makes sense, right? If you’re 32 and you had right sided breast cancer, do you really want to live 50 more years with your left breast? You’re probably going to get cancer on that side if
“you’re 32 and you already got it on one side, right? It's reasonable thinking if you don’t know.” (ID 13)

Table 2: The Surgical, Social and Psychological Context of CPM Decision Making

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**Concept 4: Anxiety and Fear**

“I think it’s all fear and anxiety. I don’t think there is any other reason than fear and anxiety for people who have a contralateral prophylactic mastectomy.” (ID 16)

“Anybody who hears cancer of any form, it just stops your heart because everybody knows someone who’s died of cancer and everybody knows someone who has died of breast cancer...They’re trying to gain control of an uncontrollable situation and I think that prophylactic mastectomy gets lumped into that basket: “I’m going to do everything I can to live and get rid of this cancer.” (ID 4)

“I think they’re coming up with the request from just their own anxiety. It makes sense, right? If you’re 32 and you had right sided breast cancer, do you really want to live 50 more years with your left breast? You’re probably going to get cancer on that side if you’re 32 and you already got it on one side, right? It's reasonable thinking if you don’t know.” (ID 13)

### 3.3 Thematic Findings

#### 3.3.1 Maintaining Non-Maleficence

Non-maleficence, one of the principles of the bioethical framework used to inform the analysis in this study, refers to the moral obligation for physicians to do no harm when treating patients. According to current guidelines, CPM is considered to be an unwarranted and overly aggressive procedure in the setting of non-high-risk early stage breast cancer and is therefore in direct opposition with this core principle (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Lander casper, Lemaire, MacNeill, Song, et al., 2016; Wright et al., 2018). Consistent with the goal to prevent harm, the plastic surgeons stated that they were reluctant for patients to have CPM with bilateral breast reconstruction when it was not medically indicated or in situations where a patient requested a procedure in which they thought the likelihood of the reconstruction failing was too high. The participants described
the myriad of ways in which their consultations were reflective of the doctrine to avoid causing harm. These included subtle approaches, such as deferring decision making to the treating oncologist and emphasizing that breast reconstructions should not be done at the expense of a cancer operation, to more direct strategies by referring patients for second opinions, and actively discouraging them from undergoing CPM, as detailed below (Table 3).

3.3.1.1  Deferral to Oncologists

Nearly all of the plastic surgeons described their role in the management of breast cancer patients as being disconnected from any oncologic discussions and didn’t perceive themselves as being directly involved in the surgical decision making process for therapeutic cancer care. In particular, if the subject of removing the contralateral, unaffected breast was raised by a patient during the reconstructive consultation, the plastic surgeons stressed that they would defer to the general surgeon or treating oncologist. The participants did not feel that they had the necessary expertise to properly counsel patients regarding the impact of removing the contralateral breast on improving cancer outcomes, as illustrated in the following comments:

“It ultimately is the general surgeon’s decision and we have to respect that...the plastic surgeon doesn’t make the absolute decision of prophylactic mastectomy. That is made by the general surgeon with the patient.” (ID 18)

“I would have them go back to their oncologist or their mastectomy surgeon for that discussion. I do reconstructions pure and simple.” (ID 8)

“That’s a decision between them and the breast surgeon – I’m not the one qualified to tell them whether they’ll live longer or have a benefit from having the other breast off.” (ID 2)

“I want them to discuss that with their oncologic surgeon. I don’t help them decide if they need two sides or one side. I don’t counsel them with respect to if they’re a good candidate or not for a contralateral prophylactic mastectomy.” (ID 1)

“That’s for them to discuss with the general surgeon – that’s not a plastic surgery discussion. So the other side - if it’s a mastectomy prophylactically – is a discussion between the oncologic surgeon and the patient.” (ID 14)
3.3.1.2 Cannot Compromise Cancer Outcomes for Aesthetics

Aligned with the principle to do no harm, many of the plastic surgeons stated that they were not supportive of performing particular procedures, such as nipple-sparing or skin-sparing reconstructions under circumstances in which that decision would ultimately compromise the oncologic operation or cancer outcomes. Similarly, some of the plastic surgeons explained that they would not recommend for patients to undergo CPM in order to achieve a superior aesthetic result or a more symmetrical reconstruction. Rather, they emphasized that any treatment decision making should first and foremost be based on oncologic factors and that any reconstructive decisions should be secondary.

“I don’t use reconstruction as a way to persuade them to have uni or bilateral. I think that’s a decision that they need to make because of cancer purposes.” (ID 1)

“I’m never going to compromise a cancer operation for an aesthetic operation ever.” (ID 4)

“I tell them to do exactly what is necessary for the cancer part of the operation and whatever they leave me, I can reconstruct, but compromising on the oncology part of it to leave me something better so I can make a better breast if it’s not a proper cancer decision, that’s always the wrong decision.” (ID 5)

“If they have altered their opinion as to whether they’re getting a contralateral mastectomy based on a nicer reconstruction, then somebody’s given them poor information. They should be basing their decision on a contralateral mastectomy on their cancer risk and cancer treatment...I’m the number two guy – the surgery for cancer is the number one priority.” (ID 14)

3.3.1.3 Referrals and Second Opinions

In an effort to avoid causing undue harm, the plastic surgeons also explained that they would frequently refer their breast cancer patients to colleagues or send them for second opinions in instances where patients remained insistent upon undergoing a particular reconstructive procedure that they were not a good candidate for or that was specifically recommended against for purposes of safety.
“What concerns me is giving an operation to somebody that I don’t believe is the best option for them because then I’m responsible for potentially causing harm and that’s unacceptable for me. If they don’t think that my recommendation is what they want, and they really want to undergo a different type of reconstruction, I will refer them to another plastic surgeon.” (ID 3)

“If I’m really adamant that I don’t think it’s safe, I just say, ‘I’m not comfortable doing this. I’ll send you for another opinion.’ I don’t need the business that badly!” (ID 7)

“Whatever decision they make, I have to be comfortable with it and I have to think that it’s reasonable. If I don’t think it’s reasonable, I’ll get them to get a second opinion.” (ID 9)

“I would give them my best medical advice, but I would never provide a procedure that I don’t think is reasonable or recommended. I would explain to them about why I feel the way that I do and I would tell them that they would be welcome to go seek out another surgeon for a second opinion.” (ID 11)

### 3.3.1.4 Dissuade Patients

Some of the plastic surgeons demonstrated an adherence to the principle of non-maleficence when they described their approach to purposefully and explicitly advise patients with early stage breast cancer against undergoing CPM and breast reconstruction, unless there was a specific medical justification for it.

“I set it up in the most common sense terms that I can: here’s all the reasons why you don’t need a prophylactic, but ultimately, it’s still up to you what you choose to do, but you have to realize that every surgery comes with a consequence and every surgery comes with complications and just because it’s a healthy breast, doesn’t mean it’s not going to have a complication. You’re doubling your surgical time, you’re double the amount of things that are done to you, you’re doubling the amount of recovery.” (ID 4)

“I tell them that there is, as far as I know based on the information I have about their cancer, no oncologic reason to have this done. Yes, it can be done, but in terms of doing it to prevent cancer, you’re going to go through a whole lot where your risk of getting a cancer is relatively low.” (ID 12)

“I tell them that as long as they’re gene negative, the chance of them developing a contralateral breast cancer is the same essentially as any other female in the population.
In general, we don’t recommend it and some surgical societies actively discourage contralateral prophylactic mastectomies.” (ID 13)

“I say to them, there’s no good reason to do this, there just isn’t...you’re just like any woman who’s never had breast cancer...I try and counsel them out of it.” (ID 18)

3.3.2 Supporting Patient Autonomy

Another core principle in the biomedical ethics framework is respect for autonomy. In the context of healthcare, this describes a patient’s right to make their own decisions regarding their medical treatment, including the choice to have CPM. As described above, the plastic surgeons expressed trepidation towards non-high-risk patients undergoing CPM and breast reconstruction, since it does not provide any oncologic benefit, yet increase the likelihood of surgical risks and the potential for both short and long-term complications. Although the participants tried to maintain non-maleficence, they demonstrated respect for a patient’s right to self-governance by supporting those who self-advocated for CPM or in circumstances where patients indicated that they would not cope well with yearly mammograms or other surveillance testing, as shown below (Table 3).

3.3.2.1 Self-Advocating

Despite some of the plastic surgeons counselling women against CPM and breast reconstruction during their consultations, others acknowledged that they were comfortable with it if the patient strongly advocated for themselves. In fact, there were instances in which participants described initially discouraging patients, but would ultimately agree if they remained determined to pursue CPM after being properly informed of the associated risks and benefits.

“I request that they meet with the general surgeon or oncologist in order to realize that it is not a necessary procedure and if they still feel strongly, then we just go ahead with it.” (ID 6)

“If patients want a prophylactic mastectomy, I don’t spend a lot of time trying to talk them out of it because they have to be comfortable with the decision and most of the patients who bring it up, they’re going to have it. They’re very determined.” (ID 7)
“I think if we spend the time and they understand that it isn’t an oncologically necessary procedure, my opinion is that they should be allowed to have it done.” (ID 12)

“I know very few reconstructive surgeons who will ultimately say no to a prophylactic if the patient advocates for themselves, even in situations where there really isn’t a good medical cancer reason to take off the opposite breast...if they really want it, they’re going to get it.” (ID 4)

### 3.3.2.2 Surveillance Stress

Moreover, some of the plastic surgeons explained that they were in support of a patient’s choice for CPM and breast reconstruction as a means to mitigate the significant stress and cycle of anxiety associated with ongoing monitoring and surveillance following breast cancer surgery. These views were exemplified in the following comments:

“If they’re really anxious and they’re not going to do well with yearly monitoring and all these things, then I will tell the patient that they just need to convince the general surgeon to do the procedure and I have no problem doing the bilateral reconstruction.” (ID 15)

“I’d say for those women who say, I just don’t want to go through another mammogram recall again, and they are very reasonable about that, I would say that they would be a good candidate for contralateral prophylactic mastectomy.” (ID 3)

“If they are significantly nervous, anxious and worried about it and it’s something that’s going to prevent them from sleeping at night, then I don’t have any issue with it.” (ID 14)

“I have seen lots of women who have had prophylactic mastectomies that maybe didn’t need it but they’re just happier they did it. There’s a fair number of women who aren’t that attached to their breast and they don’t want the worry. I don’t think it’s wrong. I’m not too hard to talk into prophylactic mastectomy.” (ID 7)

### 3.3.3 Delivering (un)Equal Healthcare

In its most basic form, the ethical principle of justice in the context of healthcare refers to the provision of care that is equitable and fair to all. The plastic surgeons highlighted several concepts which illustrate the complex dilemma surrounding the notion of justice as it relates to breast reconstruction within Ontario’s publicly funded healthcare system. These included perceptions that breast cancer patients are not provided with the same information and education pertaining to their breast cancer treatment options, the fact that not all women have
equal access to appropriate reconstructive breast procedures, as well as a recognition regarding the impact of finite resources on breast reconstruction decision making, as illustrated below (Table 3).

3.3.3.1 *Informational Inequities*

The plastic surgeons pointed out that many of the patients being referred to them for a reconstructive consultation arrive at their appointment seemingly without adequate education or an understanding concerning the true oncologic risks and survivability of their disease, particularly in relation to the contralateral side. They explained that this would ultimately create friction during the consultation if the patient then requested to remove their healthy breast, since the plastic surgeon was the first person in their circle of care to advise against it. The study participants explained this informational inequity in the following way:

“I don’t know how well educated they are about the actual risk of cancer in that contralateral breast. I try to educate them as best I can - that in most cases, they aren’t at any increased risk over the population of developing a second cancer in the other breast, but I sometimes feel like I’m the only person who’s telling them that. I don’t think that we’re all presenting the same information to the patients, so I don’t know what they base their decision on. If they’re telling me that someone at the cancer centre told them it was a good idea and then I’m telling them it’s not a good idea – it’s not really a united front...I find it’s often a little confrontational because I’m the first person bringing up that maybe this isn’t a great plan.” (ID 10)

“I would say almost every patient will bring up the discussion with me about my thoughts on the contralateral side. I don’t think the contralateral side is being addressed in depth enough by the general surgeons that are then referring the patients over to me.” (ID 13)

“I would say that probably 60% or 70% of the patients I see have some reasonable education on breast reconstruction and 30% or 40% have almost nothing.” (ID 15)

“We asked our general surgery group to be more emphatic in explaining that to the patients because otherwise they’re at our clinic and they’re anxious and want to talk about the other breast and we’re trying to suggest they shouldn’t do it, unless there are specific reasons...We want the general surgeons to be more emphatic in reassuring patients there’s no good reason to go and have a prophylactic mastectomy on the other side.” (ID 18)
3.3.3.2 Reconstruction Inaccessibility

Another concept introduced by the study participants relating to the principle of distributive justice was their perception that breast cancer patients across Ontario are not afforded equal access to the full range of breast reconstructive procedures currently available. The participants explained that although it appears to be less of a concern in recent years, certain women who are diagnosed with breast cancer are not being referred for consultations with plastic surgeons. Similarly, they noted that more rural patients are frequently restricted to selecting options offered at their nearest institution, instead of being referred to other centres that may provide additional reconstructive choices more in line with their individual needs and preferences.

“The other obvious problem that’s an issue is there’s a lot of women in the province that aren’t being offered reconstruction at the optimum time in the course of their treatment planning and that’s just because of accessibility. I think in the more highly populated areas of southern Ontario it is offered, but once you get outside of southern Ontario, I’m not so sure.” (ID 12)

“It’s more important that women are seen in a centre where all options are offered because if you don’t offer them all the different options then you’re not going to capture what’s best for them.” (ID 2)

“I have a bit of a biased view because we are kind of a minority of centres where you can have any breast reconstruction that is physically possible...That is very different from what I see around me where people usually know one trick or maybe two tricks and advise that to every patient that comes through the door where not all of them are suited for it.” (ID 16)

“I think patients have to be offered – told what is available, even if your centre doesn’t offer it. That’s something that I think is gradually being corrected.” (ID 18)

3.3.3.3 Limited Healthcare Resources

The plastic surgeons in this study also described what they perceived to be corollaries of limited healthcare resources on breast cancer decision making across the province. For instance, they identified increased wait times for breast cancer treatments to be a consequence of the growing demand for CPM operations. Similarly, they discussed how restricted hospital resources, such as operating room availability, can impact the choice for...
immediate implant reconstructions versus autogenous reconstructions, as these latter operations can take from 8-12 hours. They also pointed out some philosophical questions raised by healthcare spending and resource allocation towards CPM in the setting of non-high-risk early stage breast cancer.

“Almost everybody was asking for contralateral prophylactic mastectomy and it was overwhelming the OR. It was taking up too many OR resources and the patients that had breast cancer had to wait longer for their breast cancer to be treated because the time to do contralateral prophylactic mastectomy obviously increases OR times, so the number of patients getting their surgery was decreasing and their wait times were increasing.” (ID 3)

“The reality for most hospitals is that they just don’t have that time available and the consequence of that is, no question, that more and more, certainly most patients having…implant reconstructions and fewer have autogenous and that’s one of the main reasons because to schedule an all-day procedure, an operating room at short notice, is pretty darn difficult in most hospitals.” (ID 18)

“The healthcare system is busting at the seams and we’re doing what people would see as unnecessary surgery - how does the general population feel about that? Like what would they think if they knew we were taking off perfectly good breasts for patients? Would they be okay with that because it’s cancer or would they say we’re wasting their healthcare dollars?” (ID 4)

3.3.4 Providing Care to Enhance Well-Being
The fourth principle of the biomedical ethics framework is beneficence, which refers to “doing good” by delivering care that enhances well-being and includes advocating for the patient’s voice in healthcare decisions. Although a minority of plastic surgeons stressed that they were unequivocally opposed to women with early stage breast cancer undergoing CPM in the absence of medical reasons such as a genetic mutation or strong family history, many others expressed conflicted opinions in that regard. These participants described the challenge between wanting patients to avoid unnecessary risks and the desire to actively contribute to their emotional welfare by supporting requests for CPM and breast reconstruction. This latter position is reflective of the principle of beneficence. There were several concepts raised by the plastic surgeons which exemplified their alignment with this perspective, including a belief that the evidence could evolve, an awareness that the plastic
surgeon’s role is to provide patients with improved quality of life and an acknowledgement of the empathy they feel towards the plight of cancer patients, as discussed below (Table 3).

3.3.4.1 The Evidence Could Evolve

The plastic surgeons explained that despite current guidelines recommending against CPM in non-high-risk patient populations (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Landercasper, Lemaine, MacNeill, Song, et al., 2016; Wright et al., 2018), the evidence will not necessarily remain static. They stated that they would be remorseful under circumstances in which they specifically counselled a woman out of a CPM operation and she either developed a cancer in her contralateral breast or was found to be at higher risk for developing one.

“All these women that we’re saying you have no increased risk or you’re gene negative so you don’t need to do anything to the other side, I wouldn’t be surprised if in five years, we knew that there is actually increased risk and we should have done the other side. I never tell patients that, but that’s certainly something that I think is a trend that we’re seeing and so I really leave it to the general surgeons to use available data, but I can’t in good conscience dissuade a patient because the reality is we don’t know everything.” (ID 15)

“If their genetic testing is negative, they often still want to proceed and to be honest, I think it’s reasonable given a younger aged patient that’s already had a breast cancer, even if genetic testing is not yielding anything, ‘cause I’m not sure that we know everything at this point. There have been several prophylactic mastectomies that weren’t indicated that we’ve done here and we found a cancer on that breast, so it’s hard to imagine denying someone that when it’s impacting their life on a daily basis. I mean, they’ve usually been counselled that it’s not required and it’s still bothering them enough to put themselves through such a big surgery.” (ID 6)

“I think as practitioners, we’re kind of on a rocky slope – we know all the science and we know all the statistics, but if you’re that unlucky one who happens to get a breast cancer in the opposite breast ten years later and you talked a women out of a prophylactic mastectomy for exactly those reasons, I think people would have a very hard time dealing with that...you wouldn’t forgive yourself if you really were aggressive about telling a woman not to have a prophylactic and then she got something down the road.” (ID 4)
3.3.4.2  **Patient Quality of Life**

The plastic surgeons articulated that their primary role throughout the treatment journey is to help improve the self-image and self-esteem of their patients. Accordingly, they explained that their goal is to provide reconstructions best aligned with the patient’s preferences to achieve optimal quality of life outcomes, regardless of the fact that the desired procedure may not be recommended based on current guidelines.

“I provide a quality of life operation and if that’s what it takes to give them a quality of life, who am I to say that that’s not the right choice for them, even if it might not be the right choice for the system, or the right choice for recurrence of their cancer?” (ID 4)

“I’m there to make really nice breasts to improve their image, to improve their self-esteem.” (ID 9)

“If they really understand and they still have that anxiety, I think for their peace-of-mind that they should be allowed to undergo that prophylactic mastectomy.” (ID 12)

“It’s a quality of life surgery and I’m not saving anybody’s life by reconstructing their breast, but I just want to make them really, really happy for the rest of their life. They will survive and are young, so I just really want them to get over this and live a happy life after.” (ID 16)

3.3.4.3  **Empathy for the Patient**

Many of the plastic surgeons also described empathizing with the overwhelming anxiety experienced by women who have early stage breast cancer and indicated that they too would want to undergo the most aggressive treatment available if faced with a similar diagnosis. Some of the participants indicated that they simply felt badly for cancer patients, thus motivating them to provide care that may compromise their recommended surgical plan for one that would deliver the greatest peace of mind and long-term patient satisfaction.

“I can tell you that I have a feeling that if it was me, if I had that diagnosis, I would definitely want bilateral mastectomies. I would not want to go through mammograms and monitoring, or the risk of having another breast cancer. I would want to be radical.” (ID 2)
“I think about this a lot, just because it comes up all the time and I have this conversation all the time with patients. I think I understand where they’re coming from and every now and then, I wonder if I was a patient, would I want the prophylactic mastectomy?” (ID 10)

“You can quote to them the figures and all that, but it doesn’t mean much to them. They say, I’m 28 and I want to live to see my children grow up and I want a contralateral mastectomy. I totally understand that. I’m very empathic towards that patient...Who would argue with somebody making that argument? I mean, it’s totally understandable.” (ID 18)

“We feel badly for these patients - they have cancer; we want to help them. We want to get them a good result. We want them to get on with their lives and sometimes I think we would often comprise our number one or two choice for a number three choice that may not be the best choice, but we really want to get them where they want to go.” (ID 4)

3.3.5 **Overarching Theme: Striving to do no harm and yet respect patient autonomy**

The overarching theme that resonated across the interviews with Ontario plastic surgeons was the ongoing push-pull between maintaining non-maleficence and also respecting autonomy, a patient’s right to self-governance. This was most apparent within the context of providing care to patients who request CPM, since this was perceived to directly contradict the doctrine to avoid causing harm. Indeed, the plastic surgeons articulated the challenge of balancing their equal responsibility towards upholding this principle with the additional risks that are inherent to prophylactic surgery and breast reconstruction among non-high-risk populations (Table 3). They described the push-pull between these competing ethical principles in the following way:

“I think we often struggle with the whole idea that we’re taking off perfectly healthy tissue, we’re adding another operation with another level of complexity and another potential risk for a patient and you can have a really awful outcome on the non-cancer side and so for all of that, I think we struggle.” (ID 4)

“I’m of the opinion that resecting a normal breast is not the way to treat the anxiety and I know it’s easier said than done. It’s hard to not share their anxiety and share their concerns but it’s also more surgery to take off another breast and have another reconstruction.” (ID 2)
“There’s been the odd occasion where I might support that decision or advocate for it, but for the most part, I think its extra risk that isn’t worth taking on. I think some of the most complicated reconstructions that I’ve seen in my practice where things maybe didn’t go well and patients needed lots of revisions, or the result was really sub-par, have been contralateral prophylactic mastectomies and what keeps ringing in my mind is the fact that that side didn’t even need to be done and now that’s the one that’s causing all the problems.” (ID 10)

“We say the incidence, the risk is almost negligible – it’s the same as women who’ve never had breast cancer, but they’ve got young children to look after and they just cannot go forward with that anxiety at a young age with young families regarding the contralateral breast. I’ve done mastectomies, prophylactic mastectomies, in very young women over the years for that reason. So I guess I’ve broken my own rules to some extent in some very young women. I understand why – I get it.” (ID 18)
### Table 3: Main Themes, Overarching Theme and Representative Quotes

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-Themes</th>
<th>Representative Quotes</th>
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| Theme 1                         | Maintaining Non-Maleficence    | *Deferral to Oncologists*  
It ultimately is the general surgeon’s decision and we have to respect that…the plastic surgeon doesn’t make the absolute decision of prophylactic mastectomy. That is made by the general surgeon with the patient. (ID 18)  
I would have them go back to their oncologist or their mastectomy surgeon for that discussion. I do reconstructions pure and simple. (ID 8)  
That’s a decision between them and the breast surgeon — I’m not the one qualified to tell them whether they’ll live longer or have a benefit from having the other breast off. (ID 2)  
I want them to discuss that with their oncologic surgeon. I don’t help them decide if they need two sides or one side. I don’t counsel them with respect to if they’re a good candidate or not for a contralateral prophylactic mastectomy. (ID 1)  
That’s for them to discuss with the general surgeon — that’s not a plastic surgery discussion. So the other side - if it’s a mastectomy prophylactically — is a discussion between the oncologic surgeon and the patient. (ID 14) |
|                                 | Cannot Compromise Cancer       | Outcomes for Aesthetics  
I don’t use reconstruction as a way to persuade them to have uni or bilateral. I think that’s a decision that they need to make because of cancer purposes. (ID 1)  
I’m never going to compromise a cancer operation for an aesthetic operation ever. (ID 4)  
I tell them to do exactly what is necessary for the cancer part of the operation and whatever they leave me, I can reconstruct, but compromising on the oncology part of it to leave me something better so I can make a better breast if it’s not a proper cancer decision, that’s always the wrong decision. (ID 5)  
If they have altered their opinion as to whether they’re getting a contralateral mastectomy based on a nicer reconstruction, then somebody’s given them poor information. They should be basing their decision on a contralateral mastectomy on their cancer risk and cancer treatment…I’m the number two guy – the surgery for cancer is the number one priority. (ID 14) |
|                                 | Referrals & Second Opinions    | What concerns me is giving an operation to somebody that I don’t believe is the best option for them because then I’m responsible for potentially causing harm and that’s unacceptable for me. If they don’t think that my recommendation is what they want, and they really want to undergo a different type of reconstruction, I will refer them to another plastic surgeon. (ID 3)  
If I’m really adamant that I don’t think it’s safe, I just say, ‘I’m not comfortable doing this. I’ll send you for another opinion.’ I don’t need the business that badly! (ID 7) |
<table>
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<th>Theme 2</th>
<th>Supporting Patient Autonomy</th>
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| **Dissuade Patients** | Whatever decision they make, I have to be comfortable with it and I have to think that it’s reasonable. If I don’t think it’s reasonable, I’ll get them to get a second opinion. (ID 9)  
I would give them my best medical advice, but I would never provide a procedure that I don’t think is reasonable or recommended. I would explain to them about why I feel the way that I do and I would tell them that they would be welcome to go seek out another surgeon for a second opinion. (ID 11) |
| **Self-Advocating** | I set it up in the most common sense terms that I can: here’s all the reasons why you don’t need a prophylactic, but ultimately, it’s still up to you what you choose to do, but you have to realize that every surgery comes with a consequence and every surgery comes with complications and just because it’s a healthy breast, doesn’t mean it’s not going to have a complication. You’re doubling your surgical time, you’re double the amount of things that are done to you, you’re doubling the amount of recovery. (ID 4)  
I tell them that there is, as far as I know based on the information I have about their cancer, no oncologic reason to have this done. Yes, it can be done, but in terms of doing it to prevent cancer, you’re going to go through a whole lot where your risk of getting a cancer is relatively low. (ID 12)  
I tell them that as long as they’re gene negative, the chance of them developing a contralateral breast cancer is the same essentially as any other female in the population. In general, we don’t recommend it and some surgical societies actively discourage contralateral prophylactic mastectomies. (ID 13)  
I say to them, there’s no good reason to do this, there just isn’t...you’re just like any woman who’s never had breast cancer...I try and counsel them out of it. (ID 18) |
| **Theme 2** | I request that they meet with the general surgeon or oncologist in order to realize that it is not a necessary procedure and if they still feel strongly, then we just go ahead with it. (ID 6)  
If patients want a prophylactic mastectomy, I don’t spend a lot of time trying to talk them out of it because they have to be comfortable with the decision and most of the patients who bring it up, they’re going to have it. They’re very determined. (ID 7)  
I think if we spend the time and they understand that it isn’t an oncologically necessary procedure, my opinion is that they should be allowed to have it done. (ID 12)  
I know very few reconstructive surgeons who will ultimately say no to a prophylactic if the patient advocates for themselves, even in situations where there really isn’t a good medical cancer reason to take off the opposite breast...if they really want it, they’re going to get it. (ID 4) |
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<th>Theme 3</th>
<th>Delivering (un)Equal Healthcare</th>
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<tr>
<td><strong>Surveillance Stress</strong></td>
<td>If they’re really anxious and they’re not going to do well with yearly monitoring and all these things, then I will tell the patient that they just need to convince the general surgeon to do the procedure and I have no problem doing the bilateral reconstruction. (ID 15)</td>
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<td>I’d say for those women who say, I just don’t want to go through another mammogram recall again, and they are very reasonable about that, I would say that they would be a good candidate for contralateral prophylactic mastectomy. (ID 3)</td>
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<td>If they are significantly nervous, anxious and worried about it and it’s something that’s going to prevent them from sleeping at night, then I don’t have any issue with it. (ID 14)</td>
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<td></td>
<td>I have seen lots of women who have had prophylactic mastectomies that maybe didn’t need it but they’re just happier they did it. There’s a fair number of women who aren’t that attached to their breast and they don’t want the worry. I don’t think it’s wrong. I’m not too hard to talk into prophylactic mastectomy. (ID 7)</td>
</tr>
<tr>
<td><strong>Informational Inequities</strong></td>
<td>I don’t know how well educated they are about the actual risk of cancer in that contralateral breast. I try to educate them as best I can - that in most cases, they aren’t at any increased risk over the population of developing a second cancer in the other breast, but I sometimes feel like I’m the only person who’s telling them that. I don’t think that we’re all presenting the same information to the patients, so I don’t know what they base their decision on. If they’re telling me that someone at the cancer centre told them it was a good idea and then I’m telling them it’s not a good idea – it’s not really a united front...I find it’s often a little confrontational because I’m the first person bringing up that maybe this isn’t a great plan. (ID 10)</td>
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<td>I would say almost every patient will bring up the discussion with me about my thoughts on the contralateral side. I don’t think the contralateral side is being addressed in depth enough by the general surgeons that are then referring the patients over to me. (ID 13)</td>
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<td>I would say that probably 60% or 70% of the patients I see have some reasonable education on breast reconstruction and 30% or 40% have almost nothing. (ID 15)</td>
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<td>We asked our general surgery group to be more emphatic in explaining that to the patients because otherwise they’re at our clinic and they’re anxious and want to talk about the other breast and we’re trying to suggest they shouldn’t do it, unless there are specific reasons...We want the general surgeons to be more emphatic in reassuring patients there’s no good reason to go and have a prophylactic mastectomy on the other side. (ID 18)</td>
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<tr>
<td>Theme 4 Providing Care to Enhance Well-Being</td>
<td>The Evidence Could Evolve</td>
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<td>Reconstruction Inaccessibility</td>
<td>The other obvious problem that’s an issue is there’s a lot of women in the province that aren’t being offered reconstruction at the optimum time in the course of their treatment planning and that’s just because of accessibility. I think in the more highly populated areas of southern Ontario it is offered, but once you get outside of southern Ontario, I’m not so sure. (ID 12)</td>
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<td>It’s more important that women are seen in a centre where all options are offered because if you don’t offer them all the different options then you’re not going to capture what’s best for them. (ID 2)</td>
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<td>I have a bit of a biased view because we are kind of a minority of centres where you can have any breast reconstruction that is physically possible...That is very different from what I see around me where people usually know one trick or maybe two tricks and advise that to every patient that comes through the door where not all of them are suited for it. (ID 16)</td>
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<td>I think patients have to be offered – told what is available, even if you’re centre doesn’t offer it. That’s something that I think is gradually being corrected. (ID 18)</td>
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<tr>
<td>Limited Healthcare Resources</td>
<td>Almost everybody was asking for contralateral prophylactic mastectomy and it was overwhelming the OR. It was taking up too many OR resources and the patients that had breast cancer had to wait longer for their breast cancer to be treated because the time to do contralateral prophylactic mastectomy obviously increases OR times, so the number of patients getting their surgery was decreasing and their wait times were increasing. (ID 3)</td>
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<td>The reality for most hospitals is that they just don’t have that time available and the consequence of that is, no question, that more and more, certainly most patients having...implant reconstructions and fewer have autogenous and that’s one of the main reasons because to schedule an all-day procedure, an operating room at short notice, is pretty darn difficult in most hospitals. (ID 18)</td>
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<td>The healthcare system is busting at the seams and we’re doing what people would see as unnecessary surgery - how does the general population feel about that? Like what would they think if they knew we were taking off perfectly good breasts for patients? Would they be okay with that because it’s cancer or would they say we’re wasting their healthcare dollars? (ID 4)</td>
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<td>All these women that we’re saying you have no increased risk or you’re gene negative so you don’t need to do anything to the other side, I wouldn’t be surprised if in five years, we knew that there is actually increased risk and we should have done the other side. I never tell patients that, but that’s certainly something that I think is a trend that we’re seeing and so I really leave it to the general surgeons to use available data, but I can’t in good conscience dissuade a patient because the reality is we don’t know everything. (ID 15)</td>
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|                                            | If their genetic testing is negative, they often still want to proceed and to be honest, I think it’s reasonable given a younger aged patient that’s already had a breast cancer, even if genetic testing is not yielding anything, ’cause I’m not sure that we know everything at this point. There have been several prophylactic mastectomies that weren’t indicated that we’ve done here and we found a cancer on that breast, so it’s hard to imagine denying someone
<table>
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<tr>
<th>Empathy For the Patient</th>
<th>Patient Quality of Life</th>
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<td>I can tell you that I have a feeling that if it was me, if I had that diagnosis, I would definitely want bilateral mastectomies. I would not want to go through mammograms and monitoring, or the risk of having another breast cancer. I would want to be radical. (ID 2)</td>
<td>I provide a quality of life operation and if that’s what it takes to give them a quality of life, who am I to say that that’s not the right choice for them, even if it might not be the right choice for the system, or the right choice for recurrence of their cancer? (ID 4)</td>
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<td>I think about this a lot, just because it comes up all the time and I have this conversation all the time with patients. I think I understand where they’re coming from and every now and then, I wonder if I was a patient, would I want the prophylactic mastectomy? (ID 10)</td>
<td>I’m there to make really nice breasts to improve their image, to improve their self-esteem. (ID 9)</td>
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<td>You can quote to them the figures and all that, but it doesn’t mean much to them. They say, I’m 28 and I want to live to see my children grow up and I want a contralateral mastectomy. I totally understand that. I’m very empathic towards that patient...Who would argue with somebody making that argument? I mean, it’s totally understandable. (ID 18)</td>
<td>If they really understand and they still have that anxiety, I think for their peace-of-mind that they should be allowed to undergo that prophylactic mastectomy. (ID 12)</td>
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<td>We feel badly for these patients - they have cancer; we want to help them. We want to get them a good result. We want them to get on with their lives and sometimes I think we would often comprise our number one or two choice for a number three choice that may not be the best choice, but we really want to get them where they want to go. (ID 4)</td>
<td>It’s a quality of life surgery and I’m not saving anybody’s life by reconstructing their breast, but I just want to make them really, really happy for the rest of their life. They will survive and are young, so I just really want them to get over this and live a happy life after. (ID 16)</td>
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- that when it’s impacting their life on a daily basis. I mean, they’ve usually been counselled that it’s not required and it’s still bothering them enough to put themselves through such a big surgery. (ID 6)

- I think as practitioners, we’re kind of on a rocky slope – we know all the science and we know all the statistics, but if you’re that unlucky one who happens to get a breast cancer in the opposite breast ten years later and you talked a women out of a prophylactic mastectomy for exactly those reasons, I think people would have a very hard time dealing with that...you wouldn’t forgive yourself if you really were aggressive about telling a woman not to have a prophylactic and then she got something down the road. (ID 4)
<table>
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<th>Overarching Theme</th>
<th>Striving to Do No Harm and yet Respect Patient Autonomy</th>
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I think we often struggle with the whole idea that we’re taking off perfectly healthy tissue, we’re adding another operation with another level of complexity and another potential risk for a patient and you can have a really awful outcome on the non-cancer side and so for all of that, I think we struggle. (ID 4)

I’m of the opinion that resecting a normal breast is not the way to treat the anxiety and I know it’s easier said than done. It’s hard to not share their anxiety and share their concerns but it’s also more surgery to take off another breast and have another reconstruction. (ID 2)

There’s been the odd occasion where I might support that decision or advocate for it, but for the most part, I think its extra risk that isn’t worth taking on. I think some of the most complicated reconstructions that I’ve seen in my practice where things maybe didn’t go well and patients needed lots of revisions, or the result was really sub-par, have been contralateral prophylactic mastectomies and what keeps ringing in my mind is the fact that that side didn’t even need to be done and now that’s the one that’s causing all the problems. (ID 10)

We say the incidence, the risk is almost negligible – it’s the same as women who’ve never had breast cancer, but they’ve got young children to look after and they just cannot go forward with that anxiety at a young age with young families regarding the contralateral breast. I’ve done mastectomies, prophylactic mastectomies, in very young women over the years for that reason. So I guess I’ve broken my own rules to some extent in some very young women. I understand why – I get it. (ID 18)
Chapter 4  
Discussion

4 Discussion

This chapter presents a brief summary of the findings, a discussion of the overarching theme, as well as the main themes and how they relate to the broader literature. It also examines some of the limitations of the current project, describes potential directions for future investigations and presents the overall summary and conclusions of the research.

4.1 Summary of Findings

The purpose of this qualitative study was to understand how plastic surgeons describe their roles in the surgical decision making process through their consultations with women who have early stage breast cancer. Their general observations of the clinical encounter highlight the surgical, social and psychological milieu underlying the decision making process for their patients. Consistent with existing literature on the increasing CPM trend, a combination of improved reconstructive techniques, a desire to achieve optimal breast symmetry, the perceived influence of the media on the patient, as well as a patient’s anxiety and fear all play important roles in shaping and motivating the pursuit of more aggressive surgical management (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Landercasper, Lemaire, MacNeill, Song, et al., 2016; Brown et al., 2017; Buchanan et al., 2016; Fu et al., 2015; Sabel & Dal Cin, 2016).

Using the conceptual lens of biomedical ethics, four main themes from the plastic surgeon interviews were developed: (1) maintaining non-maleficence, (2) supporting patient autonomy, (3) delivering (un)equal healthcare, and (4) providing care to enhance well-being. The ongoing push-pull between competing ethical principles was the overarching theme that resonated across the entire dataset; specifically, striving to balance parallel responsibilities to maintain non-maleficence (i.e., do no harm) while also respecting autonomy, a patient’s right to make their own healthcare decisions. Each of these themes will be discussed below in relation to the wider literature.
4.2 Results in Context

4.2.1 Overarching Theme: Striving to do no harm and yet respect patient autonomy

Currently, an ethical debate exists among the medical community regarding CPM in women with unilateral breast cancer who are at average risk of developing CBC. The dramatic rise in CPM among this cohort over the last decade has raised concerns that patients are being over-treated (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Lander, Lema, Lame, Lac, Sng, et al., 2016; Lostumbe et al., 2010; Wright et al., 2018). The rising CPM trend has occurred alongside the movement away from paternalism in which physicians dominated the clinical encounter by making treatment decisions for patients without regard for their individual needs, rather than with patients (Martinez, Kurian, Hawley, & Jagsi, 2015). Increasingly, the medical culture has embraced patient autonomy, a situation in which patients’ preferences, values and goals are now paramount to the final treatment choice (Charles et al., 1997). However, some argue that the decision making model has shifted too far in the direction of the patient and that they are making decisions which may be potentially harmful (Yang, Pike, Rose, & Botnick, 2016).

The results of the present study are reflective of the ongoing CPM controversy. We found that the plastic surgeons strive to balance their equal commitment towards maintaining non-maleficence and yet support patient autonomy during treatment decision making. In particular, they are challenged by having to reconcile that CPM with bilateral breast reconstruction involves removing healthy tissue and introduces surgical complexity that may cause long-term morbidity, in an effort to alleviate patient anxiety, create breast symmetry and potentially improve self-esteem. This concern is supported by previous research that surveyed members of the American Society of Breast Surgeons regarding their perspectives on CPM. Findings from this recent survey revealed that nearly 60% of the surgeons experienced discomfort performing CPM in non-high-risk patients at some point throughout their practice, while nearly 100% reported that they would be comfortable if the patient was a BRCA gene carrier (Bellavance et al., 2016). This suggests that plastic surgeons are not alone in their desire to minimize harm while also supporting patient autonomy throughout the decision making process with women who have early stage breast cancer.
4.2.1.1 Conceptual Framework

The four principles of Beauchamp and Childress’s bioethical framework were used to make sense of the reconstructive consultations as described by the plastic surgeons in this study. Although useful as a conceptual tool, the framework does have certain limitations that must be addressed. For instance, as is true for qualitative approaches that apply a model or theory during thematic analysis, inevitably data remains that does not “fit” within the boundaries of the chosen framework. In the current study, this was presented separately in section 3.2 and described the surgical, social and psychological milieu surrounding CPM decision making.

Additionally, despite the popularity and broad acceptance of the bioethical framework across a variety of healthcare disciplines (Chung et al., 2009), its practical utility for ethical decision making has been criticized in the literature. In particular, ethicists and other healthcare decision makers have argued that these principles are problematic in that they are unable to provide a method for choosing a particular course of action when individuals are faced with moral dilemmas (Horner, 2007). As illustrated in the present study, the lack of hierarchical structure behind the framework did make it difficult for the plastic surgeons to determine which principle should be granted primacy over another while providing counsel to patients about their reconstructive options.

Previous research has investigated whether or not ethical principles could be measured and used to predict decision making in the medical setting. One study found a strong preference towards non-maleficence when compared to other principles such as justice, autonomy, beneficence, truth-telling and confidentiality (Page, 2012). Therefore, when healthcare providers encounter moral dilemmas, a desire to cause no harm emerges as the preeminent principle driving their recommendations. However, the investigators also indicated that the predictive capabilities of the ethical principles are limited to the context of each specific scenario, and so it may not be possible to gauge how individuals will act when encountering novel situations (Page, 2012). Other researchers have asserted that in the current climate of patient-centred care, the principle of autonomy may implicitly take precedence over the others (Gillon, 2003). This belief is in line with the findings from the present study in which some of the plastic surgeons described initially counselling women against CPM and breast
reconstruction, but ultimately accepted their choice if patients strongly advocated for this treatment approach.

Although it is important to respect patient autonomy during the decision making process, it is essential to acknowledge that autonomy is not realized by granting every request (Angelos et al., 2015). Instead, it is best supported via a process of shared decision making where physicians and patients actively communicate in a two-way exchange of information and preferences, resulting in a treatment that is agreeable by both parties (Charles et al., 1997; Martinez et al., 2015). Shared decision making is an optimal approach when making complex treatment decisions. It is especially suitable in the breast cancer setting, as patients encounter treatments with clinical equipoise and must carefully consider the inherent benefits and risks of each option (Bellavance & Kesmodel, 2016). More recently, the American Society of Breast Surgeons have recommended that physicians facilitate shared decision making by incorporating discussions of CPM into their consultations, engaging patients throughout the clinical encounter and ensuring the final treatment plan aligns with their preferences and goals (Boughey, Attai, Chen, Cody, Dietz, Feldman, Greenberg, Kass, Landercasper, Lemaine, MacNeill, Margenthaler, et al., 2016).

Another example that supports shared decision making is through the use of multidisciplinary breast cancer clinics (MDBCC), whereby a team approach involving all relevant medical and allied health disciplines is applied to the provision of care for patients in a “one-stop shop” consultation environment (Gabel, Hilton, & Nathanson, 1997). Although challenging to implement due to the required coordination of busy clinician schedules, MDBCC have been shown to both increase patient satisfaction regarding their treatment decisions, as well as significantly decrease the time between diagnosis and the initiation of treatment (Gabel et al., 1997). Overall, shared decision making beneficial in that it will allow for the negotiation of a treatment plan that is mutually agreed upon by patients and other members of the healthcare team.

4.2.2 Maintaining Non-Maleficence

The interviews with Ontario plastic surgeons revealed that they are generally opposed to women undergoing CPM and bilateral breast reconstruction if they have non-high-risk early
stage disease, as this approach is seen as causing unwarranted harm and provides no survival benefit. Although the majority of patients raise the topic of CPM during their reconstructive appointments, plastic surgeons distance themselves from discussions concerning therapeutic cancer treatments, including the oncologic impact of removing the unaffected breast, by deferring to the expertise of the treating breast surgeon. Aligned with the principle of non-maleficence, some participants purposefully and actively advise patients against pursuing CPM unless it is otherwise medically indicated.

In situations where patients insist upon undergoing an operation that they are not a good candidate for or is potentially harmful due to comorbidities, a widespread strategy adopted by plastic surgeons is to recommend that patients seek a second opinion. Second medical opinions are common in cancer care and have been shown to play an important role in terms of providing reassurance for patients (Philip, Gold, Schwarz, & Komesaroff, 2010). On the other hand, it has also been suggested that surgeons who are less willing to accommodate specific treatment requests may face losing patients to other surgeons (Katz et al., 2018). However, this is likely more of a concern in the privatized healthcare setting, as all of the participants in this study indicated that referring patients for second opinions is regularly practiced among their Ontario peers. In fact, for many patients, second opinions can serve to solidify their commitment to continue with the recommended plan and return to the initial referring physician to receive their actual treatment (Philip et al., 2010). Evidence suggests that physician attitudes, communication and direct treatment recommendations all have significant implications for a patient’s final surgical decision and overall satisfaction (Chen et al., 2008; Jagsi et al., 2017; Katz et al., 2018). Therefore, it follows that plastic surgeons should attempt to motivate patients to contemplate the benefits and risks of CPM, as well as to consider alternative, less aggressive treatment options (Yang et al., 2016).

4.2.3 Supporting Patient Autonomy

Despite highly valuing the principle of non-maleficence, plastic surgeons equally tried to respect patients’ rights to autonomous decision making. They supported women who advocated for themselves and their choice to undergo CPM with breast reconstruction, provided that patients were informed they would not gain any oncologic benefits and were aware of the additional risks associated with these procedures. This perspective aligns with
the recently released consensus statement on indications for CPM in unilateral breast cancer. In this statement, an expert panel of Canadian physicians concluded that CPM may be performed, even when not recommended from a medical perspective, so long as both patients and surgeons deem it to be suitable following a detailed discussion of the rationale, costs and benefits (Wright et al., 2018).

The study participants also recognized that patients frequently experience heightened anxiety and ongoing cycles of worry caused by monitoring and imaging surveillance following breast cancer surgery. Under these circumstances, plastic surgeons viewed CPM to be a reasonable and appropriate treatment option for patients with early stage breast cancer, as it may be able to deliver peace of mind. This belief aligns with the patient-centric perspective adopted by members of the medical community who maintain that although CPM does not provide survival advantages, women are justified in selecting this approach due to the potential psychological benefits and other implications beyond oncologic outcomes (Buchanan et al., 2016).

Despite a wish to be patient-centered, a persistent concern among surgeons is that peace of mind may be desired by women who request CPM, yet their knowledge about the various treatment options and understanding of the respective risks and benefits are generally low (Angelos et al., 2015). Furthermore, many women with early breast cancers frequently make fear-based decisions due to overestimation of the likelihood of a recurrence or of developing cancer in the contralateral breast, which motivates them to pursue aggressive treatment (Covelli et al., 2015; Martinez et al., 2015; Yao et al., 2016). Since CPM is irreversible, coupled with the fact that no techniques exist to predict whether patients will truly gain peace of mind, the Society of Surgical Oncology Breast Disease Working Group caution that these treatment decisions still need to be made on an individual case-by-case basis after meaningful consideration and education from the healthcare team to ensure women are making informed choices (Hunt et al., 2017).

4.2.4 Delivering (un)Equal Healthcare

The study participants highlighted some of the challenges surrounding the principle of justice as it relates to CPM and breast reconstruction within Ontario’s publicly funded healthcare
system. Although justice dictates that everyone has the same right to receive equal medical care, the plastic surgeons described a different reality for many of the women they encounter in their practice. For instance, they identified a form of information inequity whereby patients do not seem to receive consistent education from their breast surgeons in terms of treatment options, oncologic risks and disease survivability, particularly regarding the contralateral breast. This is problematic in that tensions arise during the clinic appointment if patients request CPM with bilateral breast reconstruction and the plastic surgeon is the first person to counsel them against it. In order for patients to receive consistent and accurate communication from the entire healthcare team, the plastic surgeons would like the referring general surgeons to discuss CPM in their initial consultations and be more emphatic in reassuring patients that CPM does not improve their chance of survival.

However, from the general surgeon’s perspective, it can be challenging to cover all aspects of breast cancer care in equal measure, as patients possess different informational needs at different times and also have individual preferences for how involved they want to be during the consultation and decision making process (Degner et al., 1997). As surgeons are increasingly pressured to improve workflow efficiencies and reduce clinic wait times (Hamel et al., 2014), discussions surrounding the contralateral breast may not occur among this non-high-risk cohort, particularly if patients do not broach the topic themselves (Yao, 2018). Consequently, women may leave their surgical consultations lacking the necessary understanding to make informed choices about their breast cancer treatment and return home seeking advice and guidance from others. In fact, several studies have shown that the opinions of loved ones and involvement with friends or family who previously faced breast cancer, are among the most influential sources of information for patients during the decision making process and are also strongly linked to increased rates of CPM (Buchanan et al., 2016; Klitzman & Chung, 2010; Venetis et al., 2018). These data further emphasize the importance of surgeons educating and informing all early stage breast cancer patients about their individual risk of developing CBC and incorporating a discussion of the pros and cons of this treatment approach into their surgical consultations.

In the realm of healthcare, justice also speaks to the idea of equity in terms of access to medical treatments. The plastic surgeons indicated that this right is frequently violated, since
not all women across Ontario are offered the full range of possible reconstructive procedures that are currently available. Instead, they are limited to the one or two options provided by their nearest cancer centre, which may or may not capture what is best for them. Relatedly, the participants noted that some women are not referred for a consultation with a plastic surgeon altogether. These observations compliment prior research on accessibility, which found several factors, including advanced age, socioeconomic status, geographic location and language to be among the main barriers towards receipt of breast reconstruction following mastectomy in Canada (Nelson, Nelson, Tchou, Serletti, & Wu, 2012; Platt, Baxter, & Zhong, 2011; Zhong et al., 2014). Similarly, an Ontario study concluded that rates of reconstruction remain low in certain regions across the province, as a sizeable proportion of women do not have access to plastic surgeons who regularly perform breast reconstruction (Platt et al., 2015).

Accessibility inequities are widespread and are experienced outside of Canada’s healthcare setting. For instance, research from the United States found that areas featuring a higher density of plastic surgeons were strongly correlated with rates of breast reconstruction and that non-white, publicly insured patients were the least likely to receive breast reconstruction overall (Bauder et al., 2017). Since evidence shows that women highly value breast symmetry when making decisions about their cancer treatment (Hoskin et al., 2016; Rosenberg et al., 2013), it is important they are given opportunities to discuss reconstructive options so they can make appropriate and informed choices that are aligned with their preferences and goals. Therefore, health policy efforts and interventions should focus on jurisdictions that lack sufficient access to plastic surgeons to improve overall equity of care (Platt et al., 2015).

The study participants also discussed some of the consequences of limited healthcare resources on breast cancer care in their practice. They observed that the upsurge in demand for CPM with breast reconstruction increasingly overwhelmed operating rooms and other hospital resources, which then translated into longer surgical wait times for breast cancer surgery. This compliments research from the United States, which examined the impact of breast reconstruction on the time to definitive surgical treatment and found there to be a 33%
increase in the period between diagnosis and surgery for women undergoing immediate breast reconstruction (IBR) compared with those not undergoing IBR (Jabo et al., 2018).

Longer wait times to receive surgical cancer treatment are problematic in that they not only contribute to psychological distress (Paul et al., 2012) and reduced patient satisfaction (Bleustein et al., 2014), there are also concerns that delays may be associated with diminished survival outcomes. For instance, a recent study conducted in the United States demonstrated that incremental delays in time to surgery negatively impacted overall survival, as well as breast cancer-specific survival (Bleicher, 2018; Bleicher et al., 2016). In particular, Bleicher concluded that time from diagnosis to surgery of greater than 90 days reduced overall survival by 3.1 - 4.6% in the setting of non-neoadjuvant breast cancer (Bleicher, 2018). Notably, a study examining wait times at a single academic centre in Ontario found that women with breast cancer seeking IBR waited an average of 98 days from referral to receipt of surgery, although the authors indicated that these numbers have likely improved since the study period (Boyd, Temple, & Ross, 2010).

The plastic surgeons described how restricted resources can influence breast cancer treatment decision making. For instance, they observed that operating room and surgeon availability contributes to more women choosing to undergo immediate implant-based reconstruction over autogenous breast reconstruction, as the latter operation is significantly more complex, time consuming and challenging to coordinate, thus causing further delays. This finding is important in that studies exploring surgical trends in women with unilateral breast cancer indicate that patients undergoing IBR are significantly more likely to choose CPM compared with those not undergoing immediate reconstruction (Ashfaq et al., 2014; Hoskin et al., 2016).

The study participants also raised philosophical issues about resource allocation for CPM and breast reconstruction in women with non-high-risk early cancers. They acknowledged the ethical quandary behind spending limited healthcare dollars on what some view to be an unnecessary operation from an oncologic standpoint. Consistent with these concerns, several studies have investigated the financial impact associated with CPM in women with unilateral breast cancer. For instance, a single-institution study conducted in the United States found
that CPM resulted in a significant increase of nearly 17% in mean total healthcare costs compared to women who did not undergo CPM (Deshmukh et al., 2014). Conversely, CPM was shown to be a cost-effective treatment approach for average-risk patients younger than 70 years of age relative to routine surveillance in a decision-model simulation study (Zendejas et al., 2011). A recent nationwide database project from the United States evaluated the medical cost of CPM and reconstruction and determined that CPM was significantly more expensive than unilateral mastectomy, with the cost of the initial procedures (i.e., mastectomy and reconstruction) and secondary revision of the reconstructive procedures being the greatest contributors to the cost differential between groups (Billig et al., 2018). Notably, the authors maintain that the intangible value CPM provides in terms of improved peace of mind and quality of life for patients may justify or offset this additional financial burden (Billig et al., 2018).

4.2.5 Providing Care to Enhance Well-Being

Counselling patients with respect to their surgical options for breast cancer is difficult due to the personal nature of the decision and the numerous factors that may influence the final treatment choice. The plastic surgeons in this study were conflicted between their competing desire for patients to avoid the additional risks of CPM and also wanting to “do good” by improving patients’ emotional welfare and advocating for their voice throughout the decision making process. Some of the participants explained that they could not, in good conscience, deny someone their preferred treatment approach, as the evidence for whom CPM is medically indicated may change. They wanted to avoid the potential guilt associated with discouraging a woman from pursuing CPM, as she may ultimately develop CBC, or it may subsequently be discovered that she was at higher risk for CBC. This position is reasonable, given the significant progress that has been made over the previous decade with respect to our scientific knowledge of breast cancer biology and the efficacy of various treatment approaches (Hunt et al., 2017). Despite these advances, many gaps remain in our current conceptions of the relationship between genetic and environmental variants and the risks of cancer (Yang et al., 2016). Therefore, it stands to reason that the criteria for CPM eligibility will likely continue to evolve alongside further innovations in our understanding of this disease.
Many of the plastic surgeons in this study also believed that their primary role throughout the treatment journey was to enhance self-esteem and well-being in their patients. Consequently, they aimed to provide reconstructive procedures that were consistent with the patient’s wishes in order to maximize quality of life outcomes both physically and emotionally. However, this can be challenging, since determining the costs and benefits of surgical outcomes and quality of life is inherently subjective (Gillon, 1994; Sterodimas et al., 2011). The process is additionally challenged when the emotional and psychological state of the patient is compromised by having to make time sensitive treatment decisions following a breast cancer diagnosis.

Evidence demonstrates that patients and physicians do not necessarily value treatment outcomes in a similar manner. Indeed, a review article investigating the congruency between patient preferences and physicians’ judgements in treatment decision making reported that for many health conditions, physicians frequently overemphasize the importance of clinical factors and underrate the significance that patients place on quality of life (Muhlbacher & Juhnke, 2013). It is important for physicians to recognize these differences and acknowledge that what may provide the greatest benefit from a medical standpoint may not necessarily be best from the perspective of the patient (Angelos et al., 2015). Accordingly, the priorities, beliefs, goals and preferences of each individual must be factored into the final treatment decision.

Plastic surgeons empathized with the immense anxiety experienced by their patients. In fact, some of the participants revealed that if they received a diagnosis of early stage breast cancer, they would want to be aggressive by choosing CPM, even though they would not recommend the same for their patients. This view is supported by the literature, which shows variation in recommendations between physicians selecting treatments for themselves versus their patients. For instance, a survey study involving primary care physicians randomized participants to make treatment decisions for hypothetical clinical scenarios imagining they were the patient or they were recommending treatment to a patient and found that 37.8% of the respondents selected a particular course of treatment for themselves, while only 24.5% recommended that same approach to the imaginary patient (Ubel, Angott, & Zikmund-Fisher, 2011). Similarly, another study involving orthopaedic, trauma and plastic surgeons asked
them to make hypothetical treatment decisions for upper extremity conditions and found that these physicians were 6% more likely to recommend surgery for a patient than they were to choose that surgery for themselves (Janssen, Teunis, Guitton, & Ring, 2015). These findings further demonstrate that physicians may weigh and value factors differently than patients when making healthcare choices, thus highlighting the importance of eliciting patient’s preferences and respecting patient autonomy during treatment decision making.

4.3 Limitations and Future Directions

This study is novel in providing new insight into the CPM phenomenon by examining plastic surgeons’ perspectives of the clinical encounter with women who have early stage breast cancer. However, the research has limitations that must be considered. For instance, the nature of qualitative investigations means there is a tradeoff in terms of the depth and richness of the data versus the generalizability of the results beyond the present study. Although participants varied with respect to the volume of their practice and experience level, sampling was limited to academic and community cancer centres in the Ontario setting. Therefore, it is possible that the opinions expressed by the plastic surgeons may not be reflective of those in other hospitals in Canada and beyond, as cultural attitudes towards the use of CPM and breast reconstruction are likely to vary across geographic regions.

Anecdotally, some of the study participants felt that breast reconstruction may play a larger role in CPM decision making in the United States, as legislation requires a discussion of reconstructive options during the initial surgical consultation for all breast cancer patients, whereas the same is not true in Canada. This opinion is supported by previous research, which demonstrated that the CPM trend has not been observed to the same degree in other countries. For instance, a single-institution study from an academic cancer centre in Europe did not find a significant increase in CPM over time in their patient population and concluded that differences in public perceptions toward plastic surgery and breast cancer may account for these variations in CPM rates (Guth et al., 2012). Accordingly, future research would benefit from exploring the perspectives and experiences of a broader range of reconstructive surgeons, general surgeons and breast cancer patients in different decision making environments throughout Canada, the United States and Europe.
A common criticism of qualitative research is that the interpretation of the data may be easily influenced by the researcher’s personal biases. This limitation was addressed in several ways in the current study. For instance, the interviewer did not have a background in either breast cancer or plastic surgery, which meant that the data could be approached with a certain naivety and minimized potential upfront biases. Additionally, coding of the raw data was performed by two independent researchers to increase the range of perspectives brought to the data. Furthermore, during the initial phase of analysis, the researchers refrained from consulting the literature to avoid fixating on specific aspects of the data. Moreover, an expert qualitative researcher was consulted during coding and analysis to ensure that the developing themes were data-driven, rather than being forced into potentially preconceived categories and investigator triangulation was employed to further minimize potential biases. Finally, actively attending to the researcher’s biases through a process of reflexivity and memo writing enhanced the transparency how the data were interpreted.

Given that the interviews were semi-structured and involved open-ended questions, some of the participants introduced novel topics of interest where data saturation was not achieved, which may warrant further investigation. In particular, a phenomenon was observed during the clinical encounter whereby a subset of patients presented “surgical ultimatums” by refusing surgery to treat their breast cancer unless they were permitted to undergo their preferred type of reconstruction. Although the patient was not considered to be a good candidate, the plastic surgeons would ultimately agree to perform the reconstruction, as that was the only way to get the patient’s cancer treated. Further research into this issue may improve our understanding of the treatment decision making process for early stage breast cancer, as well as the clinical interaction between plastic surgeons and patients seeking breast reconstruction.

4.4 Summary

Previous research established that treatment decision making for early stage breast cancer is complex and that the decision to pursue CPM is patient-driven. The rising CPM trend among non-high-risk patients is motivated by many interconnected factors including a desire to reduce cancer-related anxiety and improve quality of life. Additionally, prior research demonstrated that general surgeons do not recommend CPM in the setting of early stage
breast cancer, as this treatment approach is viewed to increase patient morbidity and provides no oncologic advantage compared to other less aggressive breast cancer surgeries. This study adds to the current literature by providing a previously unknown factor in the decision making process – namely, the perspective of the plastic surgeon. Overall, the Ontario plastic surgeons were conflicted and felt the push-pull between competing ethical principles when providing care to breast cancer patients. As the ongoing controversy surrounding CPM is about avoiding harm, perhaps it is time that we reexamine how harm is defined (i.e., surgical harm versus psychological harm) and consider who’s point of view matters.

4.5 Conclusions

This is the first study to provide qualitative insight into the plastic surgeon’s perspective of the reconstructive consultation with women who have early stage breast cancer in Ontario or elsewhere. Examining their experiences of the clinical encounter through the lens of the four principles of biomedical ethics has enabled a deeper understanding of the link between breast reconstruction and decision making for CPM. Although these principles provided a useful conceptual tool from which to interpret the data, the practical application of this framework for healthcare decision making is limited by its lack of hierarchical structure and inability to extend beyond the context of each unique scenario.

The paradigm of the patient-physician relationship has transformed over the years towards increasing acceptance of the patient’s voice and respecting their autonomy in treatment decision making, which has created unique challenges in terms of providing evidence-based care. Plastic surgeons must carefully balance their ethical responsibilities to do no harm, while also supporting the patient’s right to make autonomous decisions concerning their breast cancer management. In this evolving decision making climate, it is important for physicians to recognize and accept that patients may value other outcomes, such as peace of mind or quality of life above other clinical factors and are willing to incur additional risks in order to achieve them.

Equally, as CPM is a permanent decision that may lead to negative emotional and physical sequelae, it is critical that patients acquire a full understanding of the potential associated costs and benefits in order to properly evaluate these against their desired outcomes. In the
context of rising rates of CPM, physicians have an ethical responsibility to effectively communicate comprehensive medical information and counsel patients in a manner that allows them to make informed choices, reduces their anxiety and also respects their preferences and personal values. Decision making for early stage breast cancer is complex and is frequently underpinned by fear, thus reinforcing the need for greater interaction between the patient-physician dyad during the clinical consultation. A shared decision making environment will help to reveal the rationale underlying each individual’s treatment choice, which, in turn, will allow physicians to appropriately weigh patient requests with the best available medical evidence when counselling women on surgical decision making for breast cancer care.


Fisher, B., Bauer, M., Margolese, R., Poisson, R., Pilch, Y., Redmond, C., . . . et al. (1985). Five-year results of a randomized clinical trial comparing total mastectomy and


Appendices

Appendix A: Invitation letter for Ontario plastic surgeons to participate in the study

Dear Dr. __________.,

This letter is an invitation to participate in a 30 minute qualitative interview study entitled: “Ontario plastic surgeons’ accounts of the surgical consultation for breast reconstruction in non-high-risk women diagnosed with early stage breast cancer.”

We are planning to interview 15-20 surgeons across Ontario and you have been specifically identified because of your expertise in breast reconstructive surgery.

Brief Study Overview
Since 2003, patterns of breast cancer surgery have been changing. There has been a notable increase in the number of women electing to undergo contralateral prophylactic mastectomy (CPM) for the treatment of non-high-risk, early-stage breast cancer and ductal carcinoma in situ. Evidence shows that breast reconstruction is significantly associated with CPM, however, the interaction and decision making process between reconstructive surgeons and patients has not been well described in the literature, particularly from the plastic surgeon’s perspective.

As a breast reconstructive surgeon who has first-hand experience consulting with women during the surgical decision making process in this patient population, your perspective may provide key information and insight into this phenomenon. Accordingly, we would like to invite you to participate in a telephone interview in order to explore this topic further.

Your Involvement
As a part-time MSc student in the Department of Health Policy, Management and Evaluation at the University of Toronto, Ms. Selina Schmocker is currently conducting research under the supervision of Dr. Frances Wright and Dr. Toni Zhong exploring the clinical encounter between breast reconstructive surgeons across Ontario and patients who have early-stage breast cancer.

Selina will follow up with you by phone to review the goals and method of the study and would be happy to address any question or concerns you may have. She will arrange a telephone interview at a time convenient to your schedule, which will last approximately 30 minutes. To ensure the accuracy of your input, your permission is asked to audio-record the interview.

Participation in the interview is entirely voluntary and there are no known or anticipated risks to participating in this study. If you choose to be interviewed, you may decline to answer any of the questions you do not wish to answer. Further, you may decide to withdraw from this study at any time. All information you provide will be confidential, and the data collected...
will be kept in a secure location and disposed of in accordance with research ethics board standards (i.e., ten years following study completion).

**Contact Information**
If you have any questions regarding this study, or would like additional information about participating, please contact Selina Schmocker MSc(c) at 416-xxx-xxxx.

This study has been reviewed and approved by the Sunnybrook Health Sciences Centre and University of Toronto Research Ethics Boards. However, the final decision to participate is yours. If you have any comments or concerns resulting from your participation in this study, please contact Dr. Wright at 416-xxx-xxxx. Thank you in advance for your interest and assistance with this research.

Please review the Informed Consent Form and if you are interested in participating, sign and return the signature page (last page), along with the Response Form indicating your availability for an interview and mail these back in the envelope provided. If we do not hear from you, Selina will contact your office in approximately two weeks to follow-up.

Sincerely,

______________________________
Appendix B: Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Ontario plastic surgeons’ accounts of the surgical consultation for breast reconstruction in non-high-risk women diagnosed with early stage breast cancer

PRINCIPAL INVESTIGATOR: Dr. Frances Wright MD, MEd, FRCSC
Sunnybrook Health Sciences Centre

FUNDER: This study is being internally funded and is an MSc dissertation conducted by Selina Schmocker under the supervision of Dr. Frances Wright (staff physician) at Sunnybrook Health Sciences Centre.

INFORMED CONSENT:
You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study procedures, possible risks and benefits, and the rights of participants.

Please read this form carefully and ask any questions you may have. You may have this form and all information concerning the study explained to you. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Please ask the study staff or the investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

INTRODUCTION:
You are being asked to consider participating in this study because you have expertise in breast reconstructive surgery and you perform reconstructive breast procedures in women undergoing treatment for breast cancer.

BACKGROUND:
Since 2003, patterns of breast cancer surgery have been changing. There has been a notable increase in the number of women electing to undergo contralateral prophylactic mastectomy (CPM) for the treatment of non-high-risk, early-stage breast cancer and ductal carcinoma in situ (DCIS).

The decision-making process in this population is challenging and recent research suggests that the CPM trend is predominantly patient-driven, reflecting the increasingly active role patients adopt when it comes to surgical decision making. The growing awareness,
availability and advancements in reconstructive breast procedures may have added to the complexity of this choice. Interestingly, evidence shows that breast reconstruction is significantly associated with the decision to undergo CPM, however, the interaction and decision making process between reconstructive surgeons and patients has not been well described in the literature, particularly from the plastic surgeon’s stance.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to use qualitative methods to perform an in-depth exploration of the perspectives and experiences of reconstructive surgeons across Ontario to better understand how they account for their roles in the treatment decision-making processes in women who have early stage breast cancer and DCIS.

As a breast reconstructive surgeon who has first-hand experience consulting with women during surgical decision making in this patient cohort, your knowledge and perspective may provide key information and insight into this phenomenon.

WHAT WILL HAPPEN DURING THIS STUDY?
Your participation in this study would involve participating in a 30 minute semi-structured interview with the researcher. The interviews will take place over the telephone at a time which is convenient for you. During the interview, you will be asked several open-ended questions that ask you to reflect on your experience with patients during their surgical decision-making process. There are no right or wrong answers to the questions, as you will be asked for your opinions only. The conversation will be audio-recorded but your responses will remain completely confidential and any identifying information will be removed from the transcript.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
It is anticipated that about 15-20 breast reconstructive surgeons will participate in this study from both academic and community centres across Ontario. The entire study is expected to take about a year to complete and the results should be known in a 1.5 years.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?
There are no medical risks to you from participating in this study, but taking part in this study may make you feel uncomfortable. You may refuse to answer questions or stop the interview at any time if you experience any discomfort. Additionally, if personal identifying information were to be inappropriately released, then the potential for loss of anonymity exists. You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
You will not benefit directly from participating in this study. Your perspective and experience communicating with and treating patients may help to address known gaps in the literature, which may or may not help make it possible to improve the overall quality of care for future patients diagnosed with early-stage breast cancer.

CAN PARTICIPATION IN THIS STUDY END EARLY?
The investigator may decide to remove you from this study without your consent for any of the following reasons.
• You are unable or unwilling to follow the study procedures.

If you are removed from this study, the investigator will discuss the reasons with you. You can also choose to end your participation at any time without having to provide a reason. If you withdraw voluntarily from the study you are encouraged to contact Selina Schmocker, MSc candidate, University of Toronto at 416-xxx-xxxx.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?
Participation in this study will not involve any additional costs to you.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?
You will not be paid to participate in this study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?
You have the right to have any information about you that is collected, used or disclosed for this study to be handled in a confidential manner. If you decide to participate in this study, the investigator(s) and study staff will look at your personal information and collect only the information they need for this study.

The following people may come to the hospital to look at your personal information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

• Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook

Access to your personal information will take place under the supervision of the Principal Investigator. "Study data" is information about you that is collected for the study, but that does not directly identify you. Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you. Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigator, study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The Principal Investigator will keep any personal information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy. When the results of this study are published, your identity will not be disclosed.

You have the right to be informed of the results of this study once the entire study is complete.

ARE THERE ANY CONFLICTS OF INTEREST/RELATIONSHIPS?
There are no conflicts of interest to declare related to this study.
WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?
You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) Dr. Frances Wright, Department of Surgery 416-xxx-xxxx or Selina Schmocker, MSc candidate, University of Toronto at 416-xxx-xxxx.

The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Chair of the Sunnybrook Research Ethics Board at (416) xxx-xxxx.

DOCUMENTATION OF INFORMED CONSENT

You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Full Study Title: Ontario plastic surgeons’ accounts of the surgical consultation for breast reconstruction in non-high-risk women diagnosed with early stage breast cancer

Name of Participant: ________________________________________

Participant

By signing this form, I confirm that:
• This research study has been fully explained to me and all of my questions answered to my satisfaction
• I understand the requirements of participating in this research study
• I have been informed of the risks and benefits, if any, of participating in this research study
• I have been informed of any alternatives to participating in this research study
• I have been informed of the rights of research participants
• I have read each page of this form
• I authorize access to my personal information, and research study data as explained in this form
• I have agreed, or agree to allow the person I am responsible for, to participate in this research study

_______________________        __________________________        ________________
Name of participant (print)              Signature                           Date

Person obtaining consent

By signing this form, I confirm that:
• This study and its purpose has been explained to the participant named above
• All questions asked by the participant have been answered
• I will give a copy of this signed and dated document to the participant

_________________________        _____________________________        ___________________
Name of person obtaining                       Signature                                                      Date
consent (print)
Study Response Form

**Study Title:** Ontario plastic surgeons’ accounts of the surgical consultation for breast reconstruction in non-high-risk women diagnosed with early stage breast cancer

☐ I am interested in participating in this study. I consent to being contacted by the researcher to provide me with additional information and/or to schedule an interview.

I prefer to be contacted during the:

☐ Day, please specify a convenient time: _______________________

☐ Evening, please specify a convenient time: _________________

☐ Anytime

Other, please specify: ________________________________

I prefer to be contacted at the following number or email address: _________________________

☐ I am not interested in participating in this study. Please do not contact me.
Appendix D: Study Interview Guide

Thank you for agreeing to participate in this study. The interview will take approximately 30 minutes to complete. I will be asking questions regarding the plastic surgery consultation with women who have early-stage breast cancer, including your perspectives and experience with patients undergoing contralateral prophylactic mastectomy. Additionally, I will be asking you some demographic questions about your practice. I will be recording the interview, but I want to ensure you that your responses will remain completely confidential and all identifiers will be removed from the transcripts to protect your privacy. You can also choose to stop the interview at any time or ask for certain parts of our discussion to be removed from analysis.

For this study we have defined early stage breast cancer as women who have either DCIS or a breast cancer < 5cm in size and no known lymph node involvement, and no skin or muscle involvement.

Before we begin, do you have any questions?

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<th>Concept</th>
<th>Questions (and prompts)</th>
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<td><strong>Surgeon Demographics</strong></td>
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<td>Size/volume of practice (how many new consults and reconstructions per month):</td>
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<td>Training location for residency (USA vs. Canada vs other):</td>
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<td>Type of fellowship completed:</td>
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<td><strong>Surgical Trends</strong></td>
<td>• What is your experience on recent trends in reconstruction after a breast cancer diagnosis in terms of patient preferences?</td>
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<td>o How have these changed over the last 5-10 years?</td>
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<td>o What types of questions do patients ask today that they didn’t ask before?</td>
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<td>• Have you noticed a change in the types of reconstruction you have performed over the previous 5 years?</td>
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<td>o Implant vs tissue reconstruction?</td>
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<td>o Bilateral vs unilateral procedures?</td>
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<td>• What do you think are factors influencing these changes?</td>
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<tr>
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<td>o Patient awareness?</td>
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<td></td>
<td>o Cancer Care Ontario support of procedures?</td>
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<td>o Research?</td>
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<td>General Approach</td>
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<tr>
<td>• Please describe a typical consultation with a patient who has been diagnosed</td>
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<tr>
<td>with early-stage breast cancer</td>
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<tr>
<td>• Can you describe how reconstructive options are presented to patients?</td>
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<tr>
<td>o Please describe the discussion regarding tissue reconstruction</td>
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<tr>
<td>o Please describe the discussion regarding implant reconstruction</td>
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<tr>
<td>o Please describe the discussion regarding breast symmetry</td>
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<td>o Do you show pictures of outcomes?</td>
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<tr>
<td>• Do you discuss oncologic outcomes with your patients?</td>
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<tr>
<th>Decision-Making</th>
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<td>• How do you and the patient typically arrive at the final treatment decision?</td>
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<td>o Do women generally arrive at their clinic appointment already having made a</td>
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<td>treatment decision?</td>
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<tr>
<td>• What is your impression of what patients consider important when deciding</td>
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<tr>
<td>between treatment options?</td>
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<td>• What is your approach to patients who express a preferred treatment?</td>
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<td>o Do you have a different approach for replying to this request?</td>
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<td>• Can you describe a scenario in which a patient would change their treatment</td>
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<td>decision after their plastic surgery consultation? (e.g. from bilateral to</td>
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<td>unilateral or unilateral to bilateral mastectomy)</td>
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<tr>
<td>o Do you give a recommendation to patients about their best reconstruction</td>
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<td>options?</td>
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<td>• What is your approach to situations in which a patient requests a bilateral</td>
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<td>procedure, but they have a unilateral breast cancer?</td>
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<td>o What do you discuss with women who explicitly request CPM?</td>
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<td>• Are there ever instances where a patient requests a surgical option that you</td>
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<td>wouldn’t recommend; if so, can you describe what transpires?</td>
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<td>• Are you ever concerned that if you advise against a patient undergoing a</td>
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<td>particular reconstructive procedure that they might seek out another plastic</td>
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<td>surgeon?</td>
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<th>Risk Perceptions</th>
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<tr>
<td>• Please describe what information you share with patients around the risks/</td>
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<td>benefits of the reconstructive options</td>
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<td><strong>Patient Factors</strong></td>
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| What is your impression of the patients’ understanding of the risks?  
  - How do you assess if the patient has a good understanding of these factors?  
| Would you describe the discussion you have with patients around body image and sexual functioning?  
  - Who typically initiates this conversation?  
  - What do you tell patients about the short/long term complications of breast reconstruction?  
| Do you have a preferred or optimal approach to breast reconstruction for the average-risk woman with early-stage breast cancer?  
| What is your opinion of contralateral prophylactic mastectomy?  
  - Describe circumstances in which you would recommend CPM  
  - Describe circumstance when you would not recommend CPM  
| From a plastic surgery perspective, is there a scenario where you would recommend to a woman that they undergo a prophylactic mastectomy? |
| **Surgeon Communication** | **Wrap-up** |
| How do you typically communicate with the general surgeon about a patient? (e.g. joint clinics, emails, phone calls, or referral, coordinate OR times)  
  - How many general surgeons refer to you?  
| Do you always agree with their surgical plan?  
  - Have you ever disagreed with the surgical plan?  
| How important is your relationship with the general surgeon to the final decision about reconstruction?  
| Is there anything else you’d like to add that we have not discussed? |

*Thank you very much for your input and for taking the time to meet with me*