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*The Experience of the Health Care Team Members involved in Facial Transplant Surgery
and Patient Care*

A Dissertation Presented

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Dedication

To my husband, Bob. You show me every day that love really is patient and kind. I am grateful for your love; which always protects, always trusts, always hopes, always endures.

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Abstract

The attitudes and experiences of the health care team members involved in facial transplant surgery and patient care were explored in this study, which utilized a qualitative descriptive method. The Specific Aims of the study and the interview questions were guided by “Moore’s Ethical Criteria for Surgical Innovation.” Overall, the participants believed that the risk-benefit ratio of facial transplantation favored proceeding with the procedure in the clinical scenarios with which they had been exposed. The participant’s experience was challenging and rewarding, and they expressed personal fulfillment from the opportunity to be involved in the transformation of another human being’s life. Moreover, the entire effort exhibited highly effective team work which displayed esprit de corps, was guided by superior leadership, and illuminated the importance of the clinical, intellectual, and historical environment of the institution where the procedures took place. These components represent a “surgical innovation cluster,” a proposed framework for guiding surgical innovative efforts which represent major paradigmatic shifts in both scientific effort and social philosophy.

Chapter 1

State of the Science

Introduction

In the past seven years a total of 17 facial transplantation surgeries have been performed worldwide (Siemionow & Ozturk, 2012). Facial transplantation is a surgical option when soft tissue and bone loss is accompanied by severe cosmetic, sensory, and functional deficiencies due to disease (Hui-Chou et al., 2010), trauma (Devauchelle et al., 2006; Ravindra, Wu, McKinney, Xu, & Ildstad, 2009; Pomahac et al., 2011; Siemionow et al., 2009), or congenital malformations (Barker et al., 2007). The procedure is an option only considered when all conventional reconstructive methods have failed (Barker et al., 2007; Morris et al., 2007).

The introduction of facial tissue transplantation surgery engendered complex clinical, technological, and ethical patient care issues (Barker et al., 2007; Chenggang et al., 2008; Devauchelle et al., 2006; Morris et al., 2004; Morris et al., 2007). The complex issues included: determining patient selection criteria (Butler, Clarke, & Hettiaratchy, 2005; Pushpakumar et al., 2010), refining donor tissue procurement techniques (Meninguad, Paraskevas, Ingallina, Bouhana, & Lantieri, 2008; Pushpakumar et al., 2010), predicting expected functional outcomes (Landin, Cavadas, Gonzalez, Rodriguez, & Caballero, 2008; Pushpakumar et al., 2010), appreciating the limitations of obtaining a fully informed consent for an innovative procedures (Hurlburt, 2007; King, 2003; Reitsma & Moreno, 2006; Renshaw, Clarke, Diver, Ashcroft, & Butler, 2006), and deliberating the immunological response and post-operative immunosuppressant requirements of the recipient (Petit, Paraskevas, Minnus, Lee, & Lantieri, 2004; Pomahac, Aflaki, Chandraker, & Pribaz, 2008; Swearingen et al. 2008; Wu, Xu, Ravindra, & Ildstad, 2009). Additionally, psychological implications for the patient (Clarke & Butler, 2009; Morris et al., 2007; Swindell, 2006), societal

consequences (Furr et al., 2006; Kalliainen, 2010), and ethical concerns (Hurlburt, 2007; O'Neill & Godden, 2009; Renshaw, Clarke, Diver, Ashcroft, & Butler, 2006) have been described.

The U.S. Department of Defense (DoD) has acknowledged the emerging field of facial tissue transplantation as a research priority (Kowalczyk, 2009). United States military troops are equipped with better body armor today than during prior times of war (Johns Hopkins University Applied Physics Laboratory, 2009) and field triage and transportation mechanisms are also dramatically improved (Jenkins, 2011). Consequently, military men and woman are returning home with devastating, life-altering injuries that would have killed them in previous war times (Johns Hopkins University Applied Physics Laboratory, 2009). Among them are soldiers who have suffered partial or full facial deformities (Brigham and Women's, 2011; Torriero, 2008). The DoD has awarded \$3.4 million to Brigham and Women's Hospital in Boston, Massachusetts, to advance face transplantation technology and patient care (Brigham and Women's Hospital, 2011). Brigham and Women's staff performed the nation's second face transplant in April, 2009, and have performed three additional facial transplantation procedures since that time. As we move forward to provide and understand this complex surgical procedure for patients, there are no data on the impact of this procedure on the interdisciplinary health care team members involved in the care of these patients.

The professional caregiver's perception of involvement in solid organ procurement and transplantation procedures has been found to be morally complex and deeply important (Hibbert, 1995; Regehr, Kjerulf, Popova, & Baker, 2004; Wang & Lin, 2009). The perception and experience of the health care team involved in facial transplantation procedures and patient care are unknown. Situations which highlight our mortality, present ethically-laden questions, and are innovative in nature, may have a long term personal and professional impact on caregivers (Jameton, 1993; Reitsma & Moreno, 2006). Consequently, the caregiver's perception and experiences may directly or indirectly effect patient care (Jameton, 1984). There is no evidence to support the impact that caring

for patients involved in facial transplantation has on multidisciplinary healthcare team members. No studies have empirically described the experience of healthcare team members who have cared for this patient population.

Understanding the healthcare team member's experience of involvement in facial transplantation will identify patient-related topics in need of further exploration, expand a narrow evidence-base, and suggest interventions to assure optimal patient outcomes. Describing their experiences will also help explain if personal or professional ethical challenges are a consequence of involvement in this innovative procedure.

Therefore, the purpose of this exploratory, qualitative descriptive study was to describe the experience of the healthcare team members caring for patients receiving or donating a facial graft. This study was framed by Moore's "Ethical Criteria for Surgical Innovation" (Moore, 1970, 1988, 1989).

The specific aims were:

1. To describe the skill-set, attitudes, and experiences of the multidisciplinary healthcare team members who have been involved in facial transplant surgery and patient care.
2. To describe the ethical impact on the multidisciplinary healthcare team members of involvement in facial transplant surgery and patient care.

The purpose of this chapter is to review the empirical literature on the emerging science of facial transplantation; to define what is known on the topic, and to identify knowledge gaps which support this study.

Historical Summary of Transplantation

Solid Organ Transplant. Legendary accounts of organ transplantation date back to 348_{AD} when brothers Cosmos and Damian are said to have transplanted the leg of a recently deceased black Ethiopian man to a white man whose cancerous leg they had amputated (Barker et

al., 2007; Gander et al., 2006). In modern times, it wasn't until the mid 1950s that the first reported successful kidney transplant was performed (Vasilic et al., 2008; Tilney, 2003). The field of transplant medicine advanced dramatically during the subsequent fifty years prevailing over clinical and technical challenges for caregivers, as well as moral and ethical issues for donors, recipients, and society as a whole (Tilney, 2003). Advances in knowledge about immune function and surgical techniques gave way to successful transplantation of other organs including livers, hearts, lungs, pancreases, abdominal organs, cornea, skin, and bone (Vasilic et al. 2008, Tilney, 2003). These organ and tissue transplants are now generally considered routine, life-sustaining, surgical procedures (Vasilic et al. 2008). A persistent challenge to the expansion of transplantation efforts is the shortage of available organs for transplantation (US Dept. Health and Human Services, 2010). The gap between those needing organs and the availability of willing donors continues to widen (Roberts, 2003).

Composite Tissue Allotransplantation (CTA). The term “organ transplant” generally presumes the implantation of a kidney, heart, or other solid internal organ. Composite transplantation consists of the implantation of a combination tissue graft which may include bone, skin, muscle, tendon, and nerve (MD Anderson Cancer Center, 2011; Wu, Xu, Ravindra, & Ildstad, 2009). Such transplant procedures have been undertaken to replace body parts lost to disease (Hui-Chou, Nam, & Rodriguez, 2010), trauma (Devauchelle et al., 2006; Ravindra et al., 2009; Pomahac et al., 2011; Siemionow et al., 2010), or congenital malformations (Barker et al., 2007). Composite tissue transplantation procedures to date have included hand, abdominal wall, tongue, larynx, face (Morris et al., 2007; Swearingen et al., 2008; Wu et al., 2009), esophagus, and a vascularized knee (Wu et al., 2009). CTA is an option when multiple reconstructive surgical attempts have failed to resolve severe functional and aesthetic deficits (Barker et al. 2007; Morris et al., 2007). An estimated

7 million people per year in the United States could benefit from CTA (Barker et al. 2007; Gander et al., 2006; Wu et al. 2009).

Notably, the legendary account of the earliest organ transplant was the transplantation of a limb (Barker et al., 2007; Gander et al., 2006). Other early composite tissue transplantation efforts are described: the transplantation of a nose by Gaspare Tagliacozzi in the late 16th century, and in the early 20th century, the successful transplant of a hind leg of a dog by Alexis Carrel and the heterotopic allotransplantation of the heads of dogs by Guthrie (Barker et al. 2007). However, the immunological barriers to successful organ transplantation were as yet unconquered (Barker et al. 2007).

Other milestones and outcomes in the development of CTA are reported (Appendix A). In summary, a total of approximately 62 hand transplantation procedures in 46 patients have been performed throughout the world (Jewish Hospital & St. Mary's Healthcare, Kleinert Institute, Kleinert Kutz Hand Care Center, and University Of Louisville School Of Medicine, 2011). The success of hand transplantation surgery supported the advent of facial transplantation efforts as many technical, clinical, and ethical challenges are shared (Barker et al., 2007). A total of 17 facial transplantation procedures (Appendix B) have been performed worldwide since 2005 (Siemionow & Ozturk, 2012).

Emerging Science of Facial Transplantation

The complexity of the human face's functional and aesthetic properties, and the prospect of reassigning such complexities from one human being to another, has "captured the interest and imagination of the media, scientists, physicians, and the lay public" (Barker et. al., 2007, p. 233). The role of the face in the expression of emotion, and as the gateway to an individual's social interactions (Barker et al. 2007), gives the prospect of this type of transplant a very different gestalt than the solid organ transplantation of a heart, lung, or kidney (Prior & Klein, 2011).

Early deliberations regarding the appropriateness and feasibility of facial transplantation surgery generated significant discussion (Barker et al., 2007; Morris et al., 2004; Powell, 2006). A multiplicity of factors regarding facial transplantation surgery and its subsequent treatment were illuminated by these discussions (Alexander, Alam, Gullane, Lengele', & Adamson, 2010; Morris et al., 2004; O'Neill & Godden, 2009; Powell, 2006; Wiggins et al., 2004). Factors included those inherent to innovative surgical procedures: the surgeon's autonomy and capacity for therapeutic decision making, the lack of capacity to obtain a fully informed consent, and the uncertain nature of a risk-benefit ratio analysis (Kalliainen, 2010; King, 2003; Paradis et al., 2010; Reitsma & Moreno, 2006). Additionally, factors common to the broader science of transplantation were included: the development of donation protocols and the prioritization for organ distribution (Blogowski, 2009; Kalliainen, 2010), and subjecting recipients to life-long immunosuppressive therapies post-transplant (Bermudez, 2006; Blogowski, 2009; Kalliainen, 2010; Petit et al., 2004). Importantly, factors unique to facial transplantation surgery were also discussed: the potential for significant psychological consequences for the recipient (Clarke & Butler, 2009; Morris et al., 2007; Swindell, 2006), including questions regarding personal identity and subjectivity (Clarke and Butler, 2009; Fitchett, 2008; Morris et al. 2007, Swindell, 2006), societal consequences (Furr et al., 2006; Kalliainen, 2010), and ethical concerns (Hurlburt, 2007; O'Neill & Godden, 2009; Renshaw et al., 2006)

To follow is a synthesis of the literature as background for the emerging science of facial transplantation. The review is divided into three sections: clinical considerations, psycho-social consequences, and ethical issues.

Clinical Considerations. Seventeen facial transplantation procedures have been performed worldwide since 2005 (Siemionow & Ozturk, 2012). Two of the seventeen patients have died. The patient who underwent the second-ever face transplant procedure in China in April 2006, died twenty-seven months after transplant (Hui-Chou et al., 2010). The patient who received the first

simultaneous face-bilateral hand transplant in France in April 2009, died two months after transplant of septic shock (Siemionow, Zor, & Gordon, 2010). Despite these deaths, the procedure has been lauded as a practical and feasible option for those with devastating disfigurements (Devauchelle et al., 2006; Pomahac, 2011; Siemionow, Zor, & Gordon., 2010). Several of the transplant patients have regained function, as well as sensory and motor capabilities, while reportedly adjusting well psychologically to their new “organ” (Devauchelle et al., 2006; Pomahac et al., 2011; Siemionow, Papay, Djohan, Bernard, Gordon, Alam...Fung, 2010).

Immunology. Immunological response is inevitable following the transplantation of tissue (Tilney, 2003). In 1954, Dr. Joseph Murray led a team of surgeons in the first successful solid organ transplant, a kidney (Barker et al., 2007; Morris et al., 2007; Tilney, 2003). The donor and recipient patients were identical twins mitigating the risk of a devastating immunological response (Barker et al., 2007; Morris et al., 2007). This hallmark surgical procedure is regarded as one of the greatest breakthroughs of modern medicine (Barker et al. 2007). However, the advancement of organ transplantation science has only been realized due to advances in immunosuppressive therapy and tissue typing processes (Gander et al., 2006; Pomahac et al., 2008; Morris et al., 2007; Barker et al., 2007). Kidney, liver, heart, pancreas, intestine, lung and heart-lung organ transplantation procedures are now considered routine (Department of Health and Human Services, 2010).

The tragedies of war time have often coincided with revolutions in medical science and the field of immunology is no exception (Gander et al., 2006). Following the Battle of Britain during World War II, significant progress was made understanding the immune response when severely disfigured fighter pilots received skin grafts (Gander et al. 2006). Discoveries made during this time period provide the framework for the field of transplant immunology (Gander et al. 2006). Skin is recognized for its immunogenic properties, and because it is a major component in facial

transplantation, many early discussions reported trepidation about anticipated issues of acute and chronic rejection (Barker et al., 2007; Morris et al., 2007; Swearingen et al., 2008; Wu et al., 2009).

The patient receiving a facial transplantation will require a life-long immunosuppressive medication regimen (Morris et al., 2004; Morris et al., 2007; Swearingen et al., 2008; Wu et al., 2009). Side effects and the propensity to create conditions that may shorten the life span are well-established consequences of this class of medications (Morris et al., 2004; Morris et al., 2007; O'Neill & Godden, 2009; Powell, 2006; Swearingen et al., 2008; Wu et al., 2009). In life-saving situations, the risk-benefit ratio is considered acceptable, however subjecting patients to these risks following reconstructive surgical procedures has been controversial (Morris et al., 2004).

Additionally, patient selection criteria must include a comprehensive evaluation of the potential for the patient to remain adherent to the required life-long therapies (Chenggang et al., 2008; Pomahac, et al., 2008; Pushpakumar et al., 2010). Postoperatively, facial transplant recipients have experienced varying levels of rejection (Devauchelle et al., 2006; Morris et al., 2007; Pomahac et al., 2011; Siemionow et al., 2009). However, all are reported to have successfully responded to increased or altered immunosuppressive therapies (Devauchelle et al., 2006; Morris et al., 2007; Pomahac, 2011; Siemionow et al., 2009). No episode of rejection had resulted in graft loss, though the cause of death of the second face transplant patient has been reported to follow an episode of acute rejection after the patient ceased immunosuppressive therapy and initiated herbal therapy at the suggestion of witch doctors in his remote village (Chenggang et al., 2008). The speculation that controlling rejection following facial transplantation would require high-intensity immunosuppressive therapy has been unsubstantiated, and recipients have been maintained on dosages similar to patients post renal transplant (Gander et al., 2006; Swearingen et al., 2008).

Extensive work continues in the area of immunology and specifically, the potential for inducing donor-specific tolerance (Swearingen et al., 2008).

Technical Processes. The technical procedures and sophisticated micro-vascular techniques used during facial transplantation procedures are similar to those used in other complex reconstructive surgical procedures (Pushpakumar et al., 2010). Facial transplantation procedures are undertaken after conventional methods of reconstruction have been attempted and failed (Barker et al., 2007; Gander, 2006; Morris, 2007; Swearington, 2008). All currently transplanted patients had previously undergone multiple surgical procedures and revisions prior to face transplant, which was considered an extreme and unusual intervention (Devauchelle et al., 2006; Siemionow et al., 2009, Pomahac, 2011). Some case reports describe surgical results, including both aesthetic and functional outcomes which are superior to conventional reconstructive treatments (Pomahac, 2011).

Psychosocial Consequences. The psychosocial consequences of facial transplantation surgery are multifactorial (Barker et al., 2008; Clarke & Butler, 2009; Fitchett, 2008; Furr et al., 2007; Hui-Chou et al., 2010; Kalliainen, 2010; Morris et al., 2007; Swindell, 2006). Among these factors are: understanding the “role of face” in social interactions (Morris et al. 2007), interpreting how facial expression affects an individual’s personal identity and societal roles (Fitchett, 2008; Furr et al. 2007), quantifying the impact of an individual’s facial disfigurement on their self-esteem (Morris et al. 2007), evaluating a patient’s expectations regarding the outcome of facial transplant surgery (Barker et al. 2008), and assessing the availability of appropriate social supports for the transplant recipient post-operatively (Hui-Chou et al. 2010; Morris et al. 2007). The potential for facial transplantation surgery to alleviate long-term psychosocial difficulties for disfigured individuals remains unknown due to the novel nature of the procedure (Furr et al. 2007). Case reports of early transplants have reported positive results regarding renewed social interaction

without psychological disturbance (Pomahac, 2011; Siemionow, Papay, Djohan, Bernard, Gordon, Alam...Fung, 2010).

Clark and Butler (2009) describe the following criteria for consideration to ensure appropriate patient selection for the procedure: "...issues of altered appearance and identity, adjustment to change, the management of suboptimal adherence to immunosuppression,...and how we present and understand risk, particularly related to immunosuppression and rejection" (p. 1087).

The donor family must also be considered as the psychosocial ramifications of donating a loved one's face may be complex (Fitchett, 2008). Issues of identity, and the thought that a loved one "lives on" may foster complications for the grieving family during, and subsequent to, the decision to participate in facial tissue donation (Fitchett, 2008). The results of the transplant however do not represent a physical replication of the donor as the transplanted tissue takes on the facial structural support of the recipient. Nor does the recipient again look like his/her original self (Fitchett, 2008).

The final category of potential psychosocial consequences is the impact of facial transplant surgery on multi-disciplinary healthcare team members. There are few empirical studies published on this topic. However, the existing studies involve the attitudes and opinion of professional caregivers during the conceptual phase of facial transplantation efforts (Clarke et al., 2007; Mathes, Kumar, & Ploplys, 2009; Vasilic et al., 2008) and will be reviewed in the section of this chapter "Healthcare Team Members and Facial Transplantation." The psychosocial consequences of caregivers who have been involved in facial transplantation procedures and patient care has not been explored.

Ethical Impact of Facial Transplantation. The novel and innovative nature of facial transplantation surgery has captured the attention and imagination of health care providers, patients,

and society as a whole (Belanger, Harris, Nikolis, and Danino, 2009). The ethical questions regarding the procedure and subsequent treatment were widely discussed and central to early debates on the feasibility of this innovative surgery (Barker et al., 2007). Ethical arguments as to the appropriateness of the procedure are abundant; both in favor (Alexander et al., 2010; Kalliainen, 2010; Morris et al. 2007) and against (Kalliainen, 2010; Morris et al., 2004; Strong, 2010).

The most frequently discussed ethical question is that of subjecting individuals to required life-long immunosuppressive therapy following transplantation (O’Neil, 2009; Powell, 2006; Renshaw et al., 2006; Wu et al., 2009). An increased risk of developing diabetes, infection, cancers, and renal toxicity exist with this therapy (O’Neil, 2009; Powell, 2006; Renshaw et al., 2006). Critics argue facial transplant surgery is not “life-saving” in the same manner as heart, lung or kidney transplants, and therefore the risks of immunosuppressive therapy may outweigh the benefits of the procedure (Morris et al., 2004; Strong, 2010). Proponents argue that restoring functional capabilities is life-restoring and dramatically improves the patient’s quality of life (Alexander et al., 2010; Clarke & Butler, 2009; Pomahac et al., 2011). Should the patient develop a resistant infection or becomes non-adherent to immunosuppressive therapy which results in graft rejection, graft loss may result (Strong, 2010; Wu et al., 2009). Few options remain for the patient should this occur (Strong, 2010).

Additionally, the ability to obtain a fully informed consent assuring patient autonomy is difficult with innovative procedures (Reitsma & Moreno, 2006). However, Institutional Review Board approval has been obtained prior to undertaking the procedure (Siemionow & Gordon, 2010b). As this procedure is still considered experimental, the financial burden for such procedures is absorbed by the health care system (Kalliainen, 2010). If the patient fails to comply with necessary treatment to preserve their transplant, the health care system must support them through subsequent surgical interventions and treatment, presumably at great financial cost (Kalliainen, 2010).

Publications speculate on future trends and ask what implications the facial transplantation has for future cosmetic procedures (Belanger et al., 2009; O'Neill and Godden, 2009; Powell, 2006). Though it seems unlikely that the procedure would ever become routine as a means of changing one's identity, media representations and film productions have suggested this may be the case. The argument about the level of disfigurement that may be acceptable in the future as indication for the surgery is also prevalent (Chenggang et al., 2008; O'Neill and Godden, 2009).

The decision to subject a patient to lifelong immunosuppressive therapy as well as to a variety of other medical complications that this type of surgical procedure may generate, may potentially create ethical questions for the healthcare team members (Clarke et al., 2007). Equally concerning is the experience of the healthcare team members caring for the donor patient. Studies addressing the attitudes and opinions of healthcare team members toward facial transplant surgery and these ethical questions have been conducted (Clarke, Simmons, White, Withey, & Butler, 2006; Clarke et al., 2007; Mathes et al., 2009; Prior & Klein, 2011; Vasilic et al., 2008). However, all were done during the conceptual phase of facial transplantation surgery and therefore based on speculation, rather than experience. No published research studies have yet explored the personal experiences or ethical considerations of caregivers who have actually cared for this patient population.

Conclusion. The complex clinical, technical, and immunological patient care issues in this emerging science appear to mirror those of other reconstructive and organ transplantation procedures (Devauchelle et al., 2006; Siemionow et al., 2009). The short-term results have been positive however the long-term physical, emotional, and psychological effects on the recipient patient, as well as long-term consequences to the donor's family are yet to be validated (Siemionow & Gordon, 2010a). Ethical arguments as to the appropriateness of the procedure were abundant during the conceptual phase of the procedure. The ethical impact on the healthcare team members involved in this innovative procedure is unexplored.

Healthcare Team Members and Organ Transplantation

Team Members and Skill Sets. The desire to treat end-stage renal disease with kidney transplantation became a reality in the 1950's (Moore, 1995; Tilney, 2003). Francis Moore lauded the team approach to early efforts describing the necessity of a Department of Surgery willing to undertake the innovative procedure, supported by a Department of Medicine with expertise in kidney disease, and strengthened by a clinically powerful Pathology department interested in the microscopic appearances of transplanted organs (1995). Importantly, the progression of kidney transplantation in the 1950s evolving into acceptance of solid organ transplantation as routine, life-sustaining surgery (Vasilic et al., 2008) was a direct result of continued advances in immunology (Butler, Roderick, Mullee, Mason, & Peveler, 2004; Linden, 2008; Tilney, 2003) and the management of infectious diseases (Linden, 2008).

The early reports of multidisciplinary transplantation efforts describe various specialty trained physicians as critical team members (Linden, 2008; Murray, 2001; Moore, 1995). However, the transplant teams described today, in addition to the surgeons, nephrologist, pathologists, and immunologist, include anesthesiologists, nurses, transplant coordinators, social workers, psychologist and psychiatrists, dietitians, financial coordinators, chaplains and occupational and physical therapists (American Association of Kidney Patients, 2011). Additionally, pharmacists, organ procurement specialists, donor advocates, and multiple ancillary staff members are important components of the multidisciplinary transplantation teams. As the need to assemble multidisciplinary teams for face transplantation patient care is new, defining team composition and describing the necessary skill-sets required will provide guidance for future efforts.

Team Members' Attitudes and Experiences. Although extensive empiric data are available regarding the technical and immunological aspects of tissue transplantation, the family member's decision to donate (Manuel, Solberg, & Macdonald, 2010; Moraes et al., 2009; Van Leiden, Jansen, & Haase-Kromwijk, 2010), and the experiences of recipient patients and their quality of life

measurement related to transplantation (Devine, Reed-Knight, Simons, Mee, & Blount, 2010; Parikh, Ladner, Abecassis, and Butt, 2010; Rodrigue et al., 2010), little is known about the direct experiences of multidisciplinary team members. Among the health-care providers issues that have been explored are: the attitude of the health care team members regarding organ donation (Rodriguez-Villar et al., 2009), the role their attitudes play in promoting transplantation efforts (Fonouni et al., 2010; Siminoff, Arnold, & Caplan, 1995), and the experience of nurses working with potential organ donor patients in intensive care units (Hibbert, 1995; Kim et al., 2006) and during the organ procurement process (Page, 1996; Regehr et al., 2004; Saviozzi, 2010; Wang and Lin, 2009; Smith, Leslie, & Wynaden, 2010).

Attitudes. Members of the healthcare team are on the front line of providing information and education on health-related topics to patients, families and the general public. This is also the case with organ transplantation. The significant issue of the shortage of available organs for transplantation continues to challenge the medical community. More than 105,000 individuals are awaiting organ transplantation (US Dept. Health and Human Services, 2010) and the gap between those needing organs and the availability of willing donors continues to widen (Roberts, 2003). Therefore, the attitudes and experiences of the team toward organ donation are critical and may impact requests for donation and overall availability of organs for transplantation (Rodriguez-Villar et al., 2009). Thus far, little is known about those team members who have had direct contact with patients that have received face transplants.

Siminoff, Arnold, & Caplan (1995) studied health care providers (N= 568) attitudes about organ donation and reported a positive attitude about organ donation was found to correlate with being more likely to request donation ($r=.62$; $p=.000$). Fonouni et al., (2010) found that instituting an interdisciplinary transplant team with a common goal of increasing living kidney donation resulted in a 48% increase in donation.

Experiences. The experiences of nurses working with potential organ donor patients in intensive care units (Hibbert, 1995) and caring for the patient during the organ procurement process (Page, 1996; Regehr, Kjerulf, Popova, & Baker, 2004; Saviozzi, 2010; Wang and Lin, 2009; Smith, Leslie, & Wynaden, 2010) have been described. The actual experiences of other health care providers are less well explored.

Hibbert (1995) conducted a retrospective, exploratory, descriptive study of nurses (N= 17) working in a neurological intensive care unit. The study was guided by Lazarus and Folkman's Stress and Coping Theory (Hibbert, 1995). Individual interviews were conducted to explore the nurses' appraisal of stressors experienced while caring for organ donors and their families (Hibbert, 1995). Stressors identified by the participants included: the threat of losing a patient, inconsistency of some physicians in intervening in the process, some family's difficulties understanding brain death, and the need for more time and knowledge to address family needs (Hibbert, 1995). Requests for education on the issue of grief, crisis interventions, stress, coping theories were elicited from the participants (Hibbert, 1995). Additionally, the study participants desired an opportunity to discuss their feelings and experiences during debriefing sessions following caring for this patient population (Hibbert, 1995).

The experiences of perioperative nurses participating in organ procurement procedures have been reported (Carter-Gentry & McCurren, 2004; Page, 1996; Regehr et al., 2004; Wang and Lin, 2009). Nurses participating in these procedures found the process highly stressful. Page reported that perioperative nurses described the process of organ procurement surgery as "an emotive procedure, fraught with ethical and moral dilemmas" (p. 9).

Carter-Gentry & McCurren's (2004) qualitative study consisted of semi-structured interviews with perioperative nurses (N=8) and sought to explore challenges faced when participating in the procurement process. The challenges identified were: acknowledging the abrupt cessation of life, sympathy for the family members, personalization of events, post-mortem care, and a shift in

thinking from usually saving a life with a surgical intervention, to ending one (Carter-Gentry & McCurren, 2004).

Regehr et al. (2004) conducted in-depth qualitative interviews with operating room nurses who participated in organ procurement procedures (N=14) working in a large urban trauma center. The study concluded that the procedure resulted in distress among the nurses. The stressors identified include: difficult relationships among the surgical teams, concern for the dignity of the patient, the well-being of the family, and exposure to death and trauma (Regehr, 2004).

The experiences, feelings, and self-care strategies of Taiwanese perioperative nurses (N=6) during the organ procurement process was qualitatively studied by Wang & Lin (2009). Results of the face-to-face interviews concluded that witnessing death make the nurses “uncomfortable and even induced trauma” (p. 278). Self-care measures undertaken by the participants included time for reflection engaging in leisure activities, embracing religious beliefs, separating work and leisure time, exercise and sharing (Wang & Lin, 2009).

Summary. Studies have demonstrated the impact of the attitudes of the multidisciplinary health care team members on the availability of organs for transplantation. Additionally, the experience of nurses in intensive care units and operating rooms during the organ donation process has been found to be exceedingly difficult. Therefore, it is important to understand the impact of the health care team’s experience with facial transplant patient care. Not only might the experiences impact patient outcomes, but may affect the individual care giver’s personal and professional well-being as well.

Healthcare Team Members and Facial Transplantation

The advent of facial transplantation surgery has challenged the healthcare team to provide physical care to a patient population using knowledge gained from caring for others who have undergone other similarly complex reconstructive and transplantation surgical procedures. The availability of technically advanced, often experimental and innovative procedures present options to

patients not previously thought possible. Acute patient care issues as well as long-term patient outcomes to newly introduced techniques and procedures are often speculative, and the impact of involvement on the healthcare team members unknown. Such is the case with facial transplantation surgery.

Team Members and Skill Set. Post-procedure case details by individual surgical teams who have performed facial transplantation procedures have been reported (Devauchelle et al., 2006; Hui-Chou et al., 2010; Pomahac et al., 2011; Siemionow et al., 2010) and recommendations for others planning to undertake the procedure in the future have been outlined (Siemionow & Gordon, 2010a). The recommendations include strategies to promote Institutional Review Board acceptance of the procedure as a research-based initiative (Pomahac et al., 2008; Siemionow & Gordon, 2010b), simulated surgical procedures to refine the surgical plan (Pomahac et al., 2008; Siemionow & Gordon, 2010a), and determination of patient selection criteria (Pomahac et al. 2008; Siemionow & Gordon, 2010a). Additionally, members of the multidisciplinary team involved in the screening and management of patients planning to undergo facial transplantation surgery have been categorically outlined by one transplant center (Siemionow & Gordon, 2010a), and captures the vastness of this patient care effort.

There are multiple unique and well-developed skill-sets required to care for this complex patient population and this is directly addressed by Specific Aim #1 of this study. It is recommended that this procedure be undertaken only at university-based institutions due to the availability of diverse resources (Siemionow & Gordon, 2010a). Multidisciplinary team members identified by one institution performing the procedure include: a Plastic Surgery team leader supported by physicians with specialization in cranio-maxillo-facial surgery, micro-surgery, transplant surgery, ear, nose and throat/head and neck surgery, ophthalmology, anesthesiology, infectious diseases, psychiatry, and dentistry (Siemionow & Gordon, 2010a). Additionally, a psychologist, social worker, face transplant coordinator, physical and speech therapists, bioethics

representative, and media spokesperson are key team members (Siemionow & Gordon, 2010a).

Other health care team members involved in facial transplantation patient care include nurses across the continuum of care, nursing assistants, security officers, organ procurement organization professionals, occupational therapist, chaplaincy staff, Family & Patient Relations staff members and multiple ancillary personnel. There are no published studies which describe the personal, professional, and ethical experiences of the healthcare team members who have participated in facial transplant procedures. Considering the tremendous diversity of professionals and associated personnel, a comprehensive description of their experiences is warranted.

Team Members' Attitudes and Experiences. Thus far, only a few empirical studies have been published on the topic of facial transplantation. However, four studies examined the attitudes and opinion of professional caregivers and/or the general public with regards to the innovative procedure (Clarke et al., 2007; Mathes et al., 2009; Prior & Klein, 2011; Vasilic et al., 2008). Notably, each study was carried out prior to the first facial transplantation procedure. Therefore, the data were not based on direct experiences of the participants caring for facial transplantation patients. However, this small body of literature can provide some insight into team members attitudes and experiences.

Attitudes. The earliest study (Vasilic et al., 2008) explored the amount of risk that would be tolerated by individuals when considering whether to proceed with facial transplant surgery using a quantitative, survey-based design. Vasilic sampled five groups of individuals ($N=305$): facially disfigured ($n=33$), reconstructive surgeons ($n=45$), recipients of other organ transplants ($n=42$), professionals who manage immunosuppressive therapy for transplant recipients ($n=37$), and a healthy control group ($n=148$) using the Louisville Instrument for Transplantation survey tool (Cronbach's $\alpha = .748$ for facial tissue transplant). The instrument was developed to objectively measure transplantation risk acceptance (Vasilic et al., 2008). Risk was operationally defined in terms of time trade-off, benefits versus risks of long-term immunosuppressant therapy, and through a

standard gamble estimate of success versus failure rates (Vasilic et al., 2008). The study found that the five groups significantly differed from each other in the amount of risk they would accept ($F_{4, 299} = 6.52, p < 0.0001$) to receive either a kidney or a face transplant (Vasilic et al., 2008). Additionally, it was found that all groups would accept greater risk to receive a face transplant than a kidney transplant ($F_{1, 299} = 4.47, p = .035$) (Vasilic et al., 2008). The study concluded that the healthy volunteer control group would accept the most risk, while the reconstructive surgeons would accept the least (Vasilic et al., 2008). The differences found in this study may suggest that individuals with different experiential bases evaluate the risks of facial transplantation differently (Prior & Klein, 2011).

Clarke et al., (2007) conducted a mixed methods study to evaluate transplant professionals' attitudes toward facial transplantation in the United Kingdom. A questionnaire generated from a focus group of transplant coordinators was utilized (Clarke et al., 2007). Three main themes were generated by the focus group and were reflected in the questionnaire: organ retrieval issues, issues affecting the team, and issues related to the donor family (Clarke et al., 2007). The sample ($N=170$) consisted of 80% nurses including operating room staff, and 18% transplant coordinators (Clarke et al., 2007). The sample was not further defined. The questionnaire was administered following a lecture given by a surgeon leading the development of a facial transplant program in the United Kingdom (Clarke et al., 2007). The study found that 76% of participants supported facial transplantation procedures, while 23% felt more research was needed prior to its initiation (Clarke et al., 2007). Importantly, no participants disagreed in principle with the procedure (Clarke et al., 2007). There was a significant association ($\chi^2_2 = 8.28, p = .016$) between knowing someone with a disfiguring condition and being in favor of facial transplantation (Clarke et al., 2007). In addition, participants recommended that more attention be paid to the "needs of the donor family, support for the team, and the development of clear management pathways" (Clarke et al., 2007, p. 232). The

recommendation of “support for the team” (Clarke et al., 2007, p. 232) is noteworthy in support of the current study.

Mathes, Kumar, and Ploplys (2008) utilized a web-based survey to assess presumed risk to benefit ratio and the evaluation of clinical indications for facial transplant in three patient scenarios. As such, the participants utilized personal, professional and ethical judgment. The sample (N=164) consisted of burn and plastic surgeons. The strongest support for the procedure was found with the scenarios detailing multiple failed reconstructions and when the patient had sustained total facial burns. Respondents also supported the advancement of immunosuppressive protocols (Mathes et al., 2008).

A qualitative study (Prior & Klein, 2011) assessed the attitudes of a small sample of the general public ($n=8$) and medical professionals ($n=8$) toward face transplantation. The medical professionals group consisted of 4 males and 4 females; 4 (2 male, 2 female) who were nurses and 4 (2 male, 2 female) who were physicians. In-depth, semi-structured interviews were carried out to assess the level of support for the proposed procedure (Prior & Klein, 2011). Five themes emerged: agreement in principle, caveats and conditions, medical and technical difficulties, function and appearance, and the significance of the human face (Prior & Klein, 2011). The technical feasibility of the procedure, the quality of life for the recipient and the ability to cope with the changed appearance were concerns for both the general public and the medical professional groups (Prior & Klein, 2011).

Prior & Klein (2011) identified a difference in attitudes and beliefs between the general public and medical professional groups in the following areas: the quality of the recipient’s appearance, the possibility and likelihood of ethical abuse, and the medical and technical difficulties of the procedure. Specific variances between groups were not reported except for one (Prior & Klein, 2011). The medical professional group had greater concern for possible consequences of long-term immunosuppressant therapy, and for the possibility of graft failure. A limitation of the study, as

identified by the authors was that the participants had no first-hand knowledge of facial transplantation (Prior & Klein, 2011). Additionally, a recommendation was made to repeat the study with a more homogenous sample (Prior & Klein, 2011). This limitation and recommendation will be addressed by the current study.

Experiences. Neither the personal or professional experiences, nor the ethical impact on the health care team involved in facial transplant patient care, have been explored. Describing the experiences of the health care team and exploring the ethical impact will be addressed in this study through Specific Aim #2.

Summary. The studies by Vasilic et. al. (2008), Clarke et al. (2007), Mathes et al. (2008) quantitatively examined the attitudes and opinions of multidisciplinary professionals during the conceptual phase of facial transplantation. Prior & Klein (2011) qualitatively examined the attitudes of medical professionals and the general public toward facial transplantation. Significantly, none of the existing empirical literature examines the multidisciplinary health care team member's attitude, experience, or the ethical impact after caring for a patient undergoing facial transplantation. This study qualitatively examined the experience of professionals who have been directly involved in facial transplantation patient care.

State of the Science Summary

The majority of published evidence is from publications prior to the successful undertaking of facial transplantation procedures, and is therefore speculative in nature. Since that time, it has been reported that the immunological, clinical, and technical barriers to facial transplantation do not appear insurmountable (Devauchelle et al., 2006; Pomahac et al., 2011, Siemionow et al., 2009).

Moral and ethical issues in circumstances of severe and debilitating disfigurement with accompanying functional deficits, are reported (O'Neill and Godden, 2009; Siemionow et al., 2009).

The long-range implications of this novel procedure, its impact on the donor family and recipient,

are unknown. The experience of the healthcare team and its impact on the future of facial transplant efforts is also unknown.

Innovative patient care options such as facial tissue transplantation have received significant focus and imaginative critique in the media. Little is known about the professional and personal impact on the health care team members that involvement in these life-altering, innovative procedures might have. Providers of health care services who confront this type of innovative procedure in their work may interpret it as laden with ethical complexities as the procedure itself, and subsequent treatment, so profoundly relate to issues of quality of life, utilization of resources, and issues of personal identity. The uncertainty regarding patient outcomes following technologically advanced interventions has been associated with an intensification of ethical and moral dilemmas for caregivers in acute care settings (Schluter, Winch, Holzhauser & Henderson, 2008). Therefore, it is imperative that the impact of involvement in facial transplant surgery has on healthcare team members be explored.

Chapter 2

Conceptual Framework

Introduction

Ethical questions are intrinsic to therapeutic innovation (Moore, 1965, 1970, 1988, 2000). This concept is extensively supported in the literature (Chong, 2007; Dean, 2001; King, 2003; Palma & Rosenbaum, 2009; Reitsma & Moreno, 2006). Consequently, the degree of acceptability of a therapeutic innovation may result in both scientific discourse and in ethical discourse (Moore, 1965, 1970, 1988, 2000).

Moore's "Ethical Criteria for Surgical Innovation" (1970, 1988, 1989, 2000) provides a contextual framework to contemplate when determining the acceptability of a new procedure or technique. Moore's framework for ethical acceptability of an innovation encourages scientific integrity through the mandate of compulsory laboratory work and the evaluation of the statistical likelihood of a positive outcome (Moore, 1970, 1988, 1989, 2000). This conviction will be further discussed in a subsequent section of this chapter. Additionally, it provides a conceptual framework to explore ethical perspectives of medical innovation with the providers involved in the procedure. Thus, it was used to undergird the present qualitative descriptive study, and to guide the initial interview questions. It was appropriate to use an 'innovation and ethics framework' given the discovery nature of the present study. Moreover, a framework developed by the physician who was an instrumental leader at the institution that performed the first successful kidney transplant, an institution that has now performed four facial transplant procedures, provided historical significance.

Dr. Francis Moore became surgeon in chief at the Peter Bent Brigham Hospital and the distinguished Moseley Professor of Surgery at Harvard Medical School at the age of thirty-four (Moore, 1995; Time, 1963). He is well known for defining the metabolic care of the surgical patient, pioneering tumor and abscess localization using radioactive isotopes, the inaugural work with heart

valve replacement surgery, and the advent of organ transplantation surgery (Chong, 2007; Moore, 1995; Tilney, 2003). During his tenure as Surgeon-in-Chief at Brigham and Women's Hospital, the staff at the institution performed the first successful kidney transplant between identical twins (Tilney, 2003). Importantly, this success followed twenty-five failed attempts; most patients dying within weeks and the longest living 5 months (Gawande, 2003). It is unclear whether these failed attempts altered Dr. Moore's beliefs about the ethics of therapeutic innovation (Francis D. Moore Jr., personal communication, July 15, 2010) though it has been reported so (Gawande, 2003).

Subsequently, Dr. Moore wrote extensively about the ethical problems unique to surgery (Moore, 2000), the "ethical revolutions" brought about by the science of transplantation (Moore, 1988), and the ethical boundaries of therapeutic innovation (Moore, 1970). It is the latter two areas of his work which provide support for this study. Moreover, it is his suggested criteria for evaluation of the ethical boundaries of a therapeutic innovation, which provide the framework.

Ethical Revolutions and the Science of Transplantation

Dr. Moore outlined three basic ethical assumptions challenged by the science of transplantation: "primum non nocere, the ethics of therapeutic innovation and desperate remedies, and the limits of voluntarism" (Moore, 1988). Specifically, Moore scrutinized ethical difficulties within the science of transplantation, including the drug-induced immunological suppression required to assure transplantation success; reminding us that this is based in an unnatural physiological response (Moore, 1970). Furthermore, the use of organs from another brings ethical questions concerning harming one human to help another in the case of living donation, and questions related to the declaration and definition of death in the case of cadaveric donation (Moore, 1988). Importantly, these arguments were not meant to forego transplantation efforts, but rather as an illumination of the difficult ethical concerns produced with the development of transplantation (Moore, 1970, 1988).

Ethical Boundaries and Therapeutic Innovation

In order to promote ethical boundaries for innovative surgical procedures and techniques, Moore believed that "good science [was] ethical science" (Moore, 1965, P. 359). Furthermore, Moore contended that structured guidelines were required to assure that patients received scientifically-based, ethical care. He first described these guidelines in 1965. The guidelines were meant to assure that patients and families would be provided with scientifically validated information, allowing them to participate in making informed decisions about their clinical care. Additionally, credible information would assure that the patient's care would be delivered from highly skilled doctors, nurses, and other well-trained personnel. The guidelines encouraged extensive laboratory work and required that such work, along with the patient's progress and experience, be documented and available for scientific and public critique (Moore, 1965). These guidelines were further refined and outlined in several of Dr. Moore's subsequent publications. Moore refers to them as "Ethical Criteria for Surgical Innovation" (1970, 1988, 1989, 2000).

Ethical and scientific discussions were abundant during the conceptual phase of facial transplant surgery; both in support (Alexander et al., 2010; Kalliainen, 2010; Morris et al. 2007) and against (Kalliainen, 2010; Morris et al., 2004; Strong, 2010). The discussions included debate on issues of patient autonomy, ability to obtain informed consent, and the technical skills of the teams undertaking the procedure. Therefore, utilizing Moore's framework to consider the ethical acceptability of facial transplant surgery, as understood by health care team members involved in the patient's care, is appropriate.

The Major Components of Moore's "Ethical Criteria for Surgical Innovation"

Dr. Moore defined criteria to evaluate the ethical acceptability of an innovative procedure or technique (1965, 1970, 1988, 1989, 2000). The criteria for evaluation he described are portrayed in Figure 1:

- the scientific background of the innovation,

- the skill and experience of the team (“field strength”),
- the ethical climate of the institution,
- open display and public and professional discussion and evaluation” (Moore; Wiggins et al., 2004, p. 7)

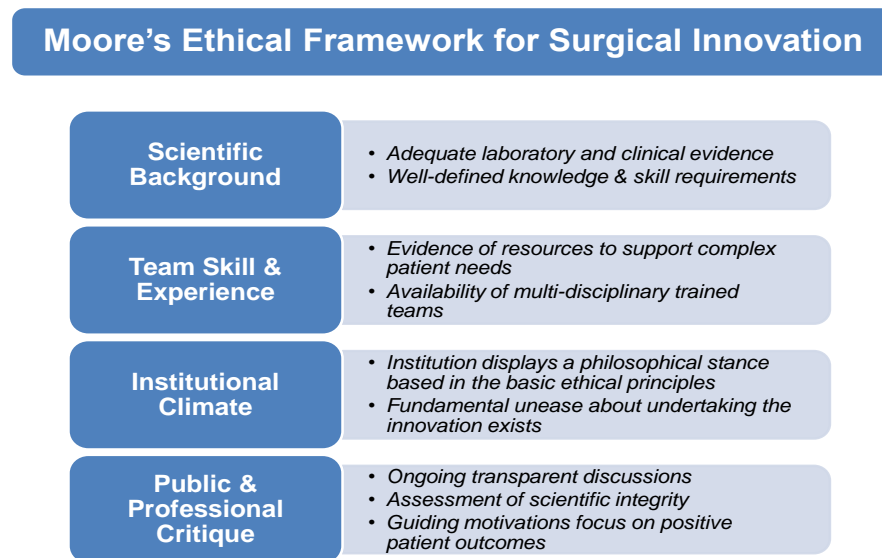


Figure 1. Moore's Ethical Framework for Surgical Innovation (1965, 1970, 1988, 1989, 2000).

Scientific Background of an Innovation. Substantive scientific laboratory work undertaken in the development of an innovative procedure is a critical component to consider when evaluating the potential success of a therapeutic innovation (Moore, 1965, 1970). Credible scientific evidence provides a means to quantify the statistical likelihood of a positive outcome and outlines the knowledge and skill necessary to assess the feasibility of the endeavor (Moore, 1965, 1970). This evidence is generally a result of extensive laboratory work or results of clinical trials (Moore, 1965, 1970). Importantly, as in the case of facial transplantation, where the sciences of transplantation, reconstructive surgery, and immunology have guided development of the innovation (Pushpakumar et al., 2010), the patient's care must be grounded in previously successful, well-developed, medical and surgical processes (Moore 1965, 1970).

Skill and Experience of the Team: “Field Strength.” The “Field Strength” necessary to assure ethical acceptability of an innovation is evidence of the knowledge, training, and experience of those undertaking the innovation. Easily validated from within the medical arena, “field strength” may not be immediately visible to the lay public (Moore, 1970). Specifically, complex innovations must be undertaken with the support of diversely trained multi-disciplinary teams in clinical centers which support complex patient needs, as in the case of facial transplantation (Siemionow & Gordon, 2010a). Moore contended that “field strength” can exist even if the specific procedure has not been previously attempted; when the skill-set and expertise of the team has been demonstrated and documented during procedures utilizing transparent transferable skills and in laboratory settings (Moore, 1970).

Ethical Climate of an Institution. According to Moore, the criteria of greatest importance is the "ethical climate of an institution" (1970). Dr. Moore believed that the reputation of the institution for sound clinical practice and ethical care was paramount (1970, 1988, 1989, 2000). In instances of a desperately ill patient, when the excuse is made that the patient was so desperately ill that the medical team had to try "something" warned Moore, a high suspicion for questionable ethical behavior is warranted (1985, 1989). Additionally Moore advised, "when the epiphenomena of medical care such as capital gain, investor profit, institutional reputation, fame, surgeon ego, municipal pride, and chauvinism become the true object of the procedure, then the ethical climate of the institution is no longer acceptable for therapeutic innovation" (Moore, 1988, p. 1064).

Open Display and Public and Professional Discussion and Evaluation. The final criteria for consideration when determining the ethical acceptability of a surgical innovation is the extent to which the procedure has been scrutinized by both the professional community as well as the general public (Moore, 2000). Open forum discussions regarding the perceptions of the scientific integrity and background of the innovation, the necessary skill set of the team, and

the institutional motivation for the undertaking, assures the patient's best interest remains the primary goal (Moore, 2000). Moore noted that although absolute consensus may not be garnered, opportunities to address scientific and ethical questions and allow for healthy debate on these issues is of utmost importance (Moore, 2000).

Innovation in Medicine Utilizing Moore's Criteria

The "Ethical Criteria for Surgical Innovation" outlined by Frances Moore has been effectively applied during for the development of innovative surgical programs (Magnus, 2010; Wiggins, 2004). Specifically, the University of Louisville applied the criteria during the conceptual phase of their facial transplantation program (Wiggins, 2004).

In addition to Moore's criteria however, the University of Louisville considered the following four additional criteria in determining the ethical acceptability of a facial transplantation program.

- Are any remaining uncertainties about the procedure resolvable through transferability of knowledge from other surgical procedures?
- Is there a cohort of well-informed patients willing to undergo the innovative procedure?
- Will the procedure have the potential to help other patients in the future?
- Has institutional review board review and approval been obtained (Wiggins, 2004)?

To date, the University of Louisville has not yet performed facial transplantation procedures.

Another application of Moore's criteria was at Stanford University, where the criteria were applied in ensuring that stem cell clinical trials proceeded in an ethical fashion (Magnus, 2010). Moore's criteria were applied in unison with the International Society for Stem Cell Research guidelines and the California Department of Public Health Human Stem Cell Research Advisory Committee to ensure a "balance of protection and innovation" (Magnus, p. 276). Moore's criteria have not been used as a framework for other empirically-based research activity.

Application of Moore's Criteria for the Proposed Study

The "Ethical Criteria for Surgical Innovation" (Moore, 1988) provided the framework for this study. Understanding the healthcare team member's experience of involvement in facial transplantation helped to identify patient-related topics in need of further exploration, expand a narrow evidence-base, and suggest interventions to assure optimal patient outcomes. Describing their experiences also helped describe whether personal or professional ethical challenges are a consequence of involvement in this innovative procedure. Therefore, a framework which provides criteria for the evaluation of the ethical acceptability of facial transplant surgery was justified and provided direction for further staff education, team building, and research foci.

Importantly, Moore's criteria for the ethical acceptability of a surgical innovation provided the language and focus of the study's Specific Aims. Specific Aim 1 addressed the skill set and field strength of the healthcare team. Specific Aim 2 addressed the ethical experience of the healthcare team caring for patients involved in facial transplant surgery. Additionally, the concepts from the framework formed the basis for the content of the interview guide and questions used during the data collection phase discussed in Chapter 3.

Chapter 3

Methods

Introduction

This study used a qualitative descriptive design to explore the experiences of members of the health care team who have participated in facial transplantation procedures and patient care. Multidisciplinary team members, including professional, ancillary, and support staff, were invited to participate in individual interview sessions to elicit their personal and professional or occupation-related experiences. Dr. Francis Moore's "Ethical Criteria for Surgical Innovation" (1970, 1988, 1989, 2000) guided this study. Moore's framework deliberates: the scientific background of the innovation, the skill-set and field-strength of the team, the ethical climate of the institution, and extent to which the innovation has been subject to professional and public scrutiny (1970, 1988, 1989, 2000).

The purpose of this chapter is to describe the research methods used in this study. The setting, sample selection, and procedures for data collection, management, and analysis are described. Additionally, procedures to assure trustworthiness and reflexivity are outlined. Finally, human subjects considerations addressed are discussed.

Qualitative Descriptive Design

An exploratory, qualitative descriptive study was undertaken. Qualitative description is a research approach within the naturalistic paradigm of inquiry (Sandelowski, 2000, 2010). This type of qualitative approach is useful when a comprehensive summary of an experience is desired; promoting rich description of real-life events without extensive theoretical or interpretive deduction (Sandelowski, 2000). The philosophical orientation of a naturalistic paradigm holds that there are multiple realities, that they are contextual, and that "constructed realities can only be studied holistically" (Lincoln & Guba, as cited by Thorne, Reimer Kirkham & O'Flynn-Magee, 2004, p. 5).

Importantly, as previous studies describing the experience of health care team members involved with facial transplantation were not available, the qualitative descriptive design allowed for an iterative process of modification of the interview questions as themes emerged during data collection and analysis.

Setting

The study took place at Brigham and Women's Hospital (BWH). BWH is a 793- bed affiliate of Harvard Medical School in Boston, Massachusetts. BWH is well-known for having performed the first successful kidney transplant in 1954. BWH has performed 4 of the 17 face transplants performed world-wide to date.

Sample

Qualitative description utilizes purposeful sampling (Sandelowski, 2000). Purposive sampling assures that the phenomenon of interest will be present in those participating in the study (Creswell, 2007). Maximum variation sampling was considered and was particularly useful as it supported data collection from those experiencing the phenomenon of interest on a wide variety of levels (Creswell, 2007). Sample size was determined by the extent to which new data collected became redundant, as recommended by Gallo & Dumas, (1996).

A purposive sample of health care team members was recruited. Review of donor and recipient patients' medical record identified the healthcare team members for the potential sample. A "snowball sampling" technique (Polit & Beck, 2004, p. 306) was also utilized. This sampling method was operationalized by asking participants to recommend other health care team members they felt had been instrumental in the care of a patient who had undergone a facial transplant procedure, or in the development of the facial transplant program. Additionally, familiarity of the researcher with many of the individuals who had been involved in facial transplant patient care supported recruitment. Efforts were made to assure that the participants were multidisciplinary and included professional, ancillary, and support staff. Sampling continued until common themes and

response redundancy was reached. It was anticipated that there would be 20-30 participants included, based on multidisciplinary healthcare team members identified in published case reports (Pomahc et al., 2011; Siemionow & Gordon, 2010a), and this estimate was found to be accurate.

Inclusion Criteria. The sample included:

- BWH health care teams members directly or indirectly involved in a facial transplantation procedure or those having cared for a patient involved in a facial transplantation procedure including: professional, ancillary, and support staff
- Health care teams members instrumental in caring for donor and recipient patients before, during, and after a facial transplant procedure not directly employed by BWH (e.g. employees of New England Organ Bank), or who no longer work at the facility but were employed at the time of a facial transplant procedure
- BWH employees who did not have direct patient contact but were instrumental in processes related to a facial transplant procedure

Exclusion Criteria. The sample did not include:

- Health care team members who had no direct patient contact or who did not participate in procedures or processes related to a facial transplant procedure

Recruitment. Potential participants were contacted in person, by phone or through email. A letter of explanation regarding the purpose of the study, its voluntary nature, and assuring confidentiality was distributed during the recruitment process. Every effort was made to include a representative of each role category of health care team member involved in facial transplantation patient care.

Data Collection

Institutional Review Board approval was secured prior to commencing data collection. A verbal informed consent agreement was obtained from each participant. A demographic data sheet (Appendix C) was distributed to and completed by each participant. No record of the names of individuals who were invited to participate but declined was kept.

Individual, private, semi-structured interviews were conducted with twenty-four participants in a private location at a time convenient to the participant and researcher. Two additional participant interviews were conducted via telephone; one due to the participant's relocation from the study's geographic area, and one due to complex scheduling issues. All face-to-face interviews, with the exception of one due to the participant's request, were audio-taped. The participant who requested not to be interviewed offered no explanation why they were hesitant to do so, even after being reassured that the interview would be confidential and anonymous. The length of each interview ranged from 22 minutes to 77 minutes, with a mean of 42 minutes. Transcribed interview dialogue yielded 779 double-spaced pages of data.

Interviews were digitally recorded using two recorders to assure recording quality. The interviews were transcribed verbatim by a professional transcriptionist, who signed a confidentiality agreement prior to commencing transcription services. In addition to the core interview questions, probes were used to stimulate dialogue and promote understanding of the questions as needed, and additional interview questions and probes were added in an iterative process. Given the exploratory nature of this study, sampling continued until response redundancy was achieved. Field notes were recorded during and after each interview by the researcher. Member checks (Lincoln & Guba, 1985) were utilized during the interview process to assure understanding of the data being presented and assure descriptive validity (Sandelowski, 2000).

The interview questions were derived from the specific aims of the study, which reflected the concepts of Moore's "Ethical Criteria for Surgical Innovation" (1965, 1970, 1988, 1989, 2000) and consisted of:

Specific Aim #1: To describe the skill-set, attitudes and experiences of the multi-disciplinary health care team members who have been involved in facial transplantation surgery and patient care.

Conceptual Area	Main Question	Probes
Introduction	Can you tell me about your experience caring for a patient involved in a facial transplantation procedure?	<ol style="list-style-type: none"> 1. How many patients have you cared for? 2. Was the patient a donor or recipient? 3. How often did you care for the patient? 4. How did it feel being involved in such a procedure? 5. What emotions were you feeling? 6. Do you agree in principle with the procedure?
Scientific Background	Were you aware of any preparatory work that led to the actual start of the facial transplant program?	<ol style="list-style-type: none"> 1. What information or training did you receive prior to caring for the patient? 2. Are there areas of education that need to be improved upon? 3. What do you see as the greatest risks to the procedure? 4. What should the patient criteria be? 5. Do you view facial transplantation the same way as you view other organ transplantation? 6. Would you consider donating your face or that of a loved one? 7. What technical concerns did you have?
Skill-set/Field Strength	Tell me about specialized training and team members that you felt were	<ol style="list-style-type: none"> 1. What skills did you bring to the team?

	critical to the care of this patient population. Tell me about the functioning of the health care team for this patient population and what efforts may promote team cohesiveness and collaboration.	<ol style="list-style-type: none"> 1. Did you feel prepared to care for the patient? 2. What other skills were integral to the patient's care? 3. Did you feel a different ownership about caring for the patient than some other more routine procedure?
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Specific Aim #2: To describe the ethical impact on the multidisciplinary healthcare team members of involvement in facial transplantation surgery and patient care.

Conceptual Area	Main Question	Probes
Ethical climate of the institution	Tell me about any personal or professional ethical issues you may have considered before, during or after caring for the patient.	<ol style="list-style-type: none"> 1. Were you aware of any of the ethical concerns published in the literature? how did they impact you? 2. Were people discussion facial transplantation? 3. Are you aware of any ethical concerns others may have had? 4. What concerns did you have? 5. Are your feelings now different than those prior to caring for the patient? 6. Are you concerned that the procedure may be abused?
Open display and Public discussion	<p>Was facial transplantation openly discussed and fairly portrayed by the institution?</p> <p>What do you see as next steps?</p>	<ol style="list-style-type: none"> 1. What did you hear? 2. Where did you hear it? 3. Were you aware of anyone who disagreed with the procedure? 4. Do you feel the patients were treated fairly? 5. Did you view the facial transplant program as a public relations conduit for BWH?

Table 1. Interview Questions and Probes

Data Management

Immediately following each interview, the audio-recording was listened to in its entirety and additional field notes taken to supplement those completed during the original interview. In-depth notes were recorded during the interviews conducted by telephone, as well as during the one face-to-face interview that was not recorded per the participant's request. The audio recording of each interview was then downloaded to a password protected computer, and a copy created for the transcriptionist. Audio recordings were listened to a second time and cross-referenced with the transcriptionist's rendering. Transcribed interviews were then uploaded to NVivo software for coding and analysis. The notes from the two interviews conducted by telephone and the interview that was not recorded were also uploaded to NVivo, and when coded, contained a notation that the comment was paraphrased by the researcher.

Data Security

Tape recordings, field notes, and all data materials will be maintained on an encrypted, password protected laptop computer. All data sources will be destroyed in five years.

Data Analysis

Qualitative description data analysis takes place through inductive processes, establishing patterns and themes (Creswell, 2007). Deep interpretation of data by the researcher is not done with this approach as the value of the data collected is the rich description of the experience in the participant's own words (Sandelowski, 2000, Sullivan-Bolyai et al., 2005). Conventional qualitative content analysis (Hsieh & Shannon, 2005) and constant comparison (Sandelowski, 2000) was carried out throughout the interview and data analysis phases. Conventional content analysis is appropriate when there is little know about the phenomenon of interest (Hsieh & Shannon, 2005), as was the case in this study. Analysis occurred at the individual participant level, as well as at the inter-disciplinary and intra-disciplinary levels. Hence, the analysis identified themes within the individual

experience and between participants to contextually describe the whole of the phenomenon (Ayers, Kavanaugh, & Knafl, 2003).

Miles and Huberman (1994) outlined a series of steps to be undertaken during qualitative content analysis. These steps are: (1) coding of the data from field notes and observation, (2) recording insights and reflections on the data, (3) identifying similar phrase, patterns, and themes, (4) looking for commonalities in the data, (5) making generalizations, and (6) examining these generalizations in relation to what is already known about the phenomenon. The analysis was supported and summarized using descriptive statistics to further clarify specific phenomena of interest (Sullivan-Bolyai et al., 2005), including the number of participants who agreed in principle with the procedure or would consider donating their own or a loved one's face.

The analysis processes described by Miles and Huberman (1994) is supported by the NVivo software. Additionally, the NVivo software aided in the conceptual organization of the data, allowing queries to be made of the data, and graphically model the emerging ideas, concepts, and relationships (Bazeley, 2010). The data was re-presented in a variety of ways to promote clarity in analysis of the findings.

At the outset, a series of broad coding categories were created which aligned with the major concepts of the study's framework: Moore's "Ethical Criteria for Surgical Innovation" (1970, 1988, 1989, 2000). These codes included: scientific background, field strength, ethical climate of the institution, and open display and discussion of the surgical innovation. Similarly, other coding categories were initially created which reflected themes extracted from prior empiric work on the topic. Importantly, these empiric works were completed during the conceptual phase of facial transplant surgery, as no prior study has explored the experience of the health care team who has cared for this patient population.

Though a series of broad coding categories were created a priori, the majority of codes emerged, were constructed, and continued to be defined throughout the data collection process.

Effort was made to code each interview within a tight timeframe to when it had occurred, allowing for emerging themes and subthemes to be incorporated into subsequent interviews. The process of code creation and analysis was an iterative process using inductive and deductive reasoning skills, thereby promoting refinement of the study questions prior to subsequent interviews. Additionally, this process assured a flexible design supporting the identification of emerging themes. Themes and subthemes were reviewed multiple times for accuracy, and expanded or consolidated as necessary to promote clarity, reliability, and validity of the coding categories. Themes constructed during data analysis sought to underscore the data using descriptive terminology, as is the focus of the study's qualitative descriptive design.

Trustworthiness

The trustworthiness (Lincoln & Guba, 1985) of qualitative research is a major consideration when evaluating the value of research findings. In qualitative description, as in other approaches to qualitative research, the investigator serves as the "research instrument" and has a personal and professional responsibility to assure that the research process is ethically sound. The data collected must be a true representation of the participant's intent. Four dimensions to consider when evaluating the trustworthiness of qualitative research are: "credibility, dependability, confirmability, and transferability" (Lincoln & Guba, p. 328). In this study, efforts were made to assure trustworthiness as defined by Lincoln & Guba (1985).

With the qualitative description approach, a rich description of a phenomenon in the participant's own words is sought; hence the dimension of credibility is particularly important. Credibility is the measure of confidence that the findings reflect "truth" as understood and expressed by the participant. Activities to support credibility in a qualitative descriptive study are peer-debriefings; having another researcher evaluate the data for agreement of findings, and member checks; affirming with the participants what the researcher "heard" as the data was collected (Lincoln & Guba, 1985). A colleague with a Doctoral degree in Nursing and an extensive program

of research served as a peer debriefer for this study. Member checks (Lincoln & Guba, 1985) were utilized during the interview process for clarification, and subsequent to the interviews ($n=6$), for verification of data. There was also an independent review and coding of 8% ($n=2$) of the transcripts by the dissertation committee Chair, Dr. Susan Sullivan-Bolayi.

If the criteria to determine “credibility” are satisfied when evaluating a study, an assumption might be made that the results of the study could also then be termed “dependable” (Lincoln and Guba, 1985). Dependability denotes that the findings would be replicated by another researcher if the study’s design and participants remained the same (Lincoln & Guba, 1985). Lincoln and Guba suggest this may be the case, but also urge further activities to substantiate the determination of dependability. A suggested activity for use with the qualitative description approach is a dependability audit (Lincoln & Guba, 1985). The auditor, who ideally is a content expert in the subject matter, critically and objectively evaluates the methods, data, and conclusions for concurrence with the study’s findings, believability, and consistency. Dr. Bohdan Pomahac, lead surgeon for the BWH facial transplant program served on the researcher’s dissertation committee and as such, evaluated the dependability of the findings. In qualitative descriptive research, the dependability audit also fulfills the tenets of confirmability (Lincoln & Guba).

The transferability of findings, the last component of trustworthiness as defined by Lincoln and Guba (1985), is not an inherent goal of qualitative descriptive research. Data collected through qualitative description are a rich description of an experience rather than deep, thick interpretive details of a participant’s experience and need not be directly transferable to other situations.

Human Subjects Considerations

IRB application process. An application was submitted to the BWH IRB and approval to undertake the study was obtained. A copy of the application and an Institutional Authorization Agreement was drafted between the BWH IRB and the University of Massachusetts Medical School IRB.

Protection of human subjects. An initial sample was identified through review of the facial transplant patients' medical records and each potential participant received a letter of explanation about the study during the recruitment phase. A verbal informed consent was obtained prior to commencing the individual interviews. Additional participants who were instrumental in the care of a facial transplant patient, and nominated by those enrolled in the study after the investigator's review of the facial transplant patients' medical record, were also asked to participate. Contact information was obtained from the hospital's staff directory. All potential participants received reassurance that they were free to decide whether or not they wanted to be included, and that regardless of their decision, that they would remain anonymous. Demographic data is reported in aggregate to protect the anonymity of the participants. In addition, any potential personal identifying descriptors were omitted during the discussion of the findings in order to protect the participants. Prior to the start of each interview, the investigator reassured participants that their participation was voluntary, confidential, and that they could choose to end the interview questioning at any time.

There were no anticipated physical or emotional risks to the participants. In the event that a participant became emotionally upset during the interview process, a referral would have been made to the BWH Employee Assistance Program (EAP). Contact information for EAP services was provided in writing to each participant at the end of their data collection session. Additionally, the peer debriefer and the investigator's dissertation chair would have been made aware of any troublesome emotional reactions of the participants.

A token of appreciation was given to each participant by the investigator at the completion of their interview. The token was a \$15.00 gift card to a local restaurant located on the hospital campus.

Reflexivity. Reflexivity is the conscience disclosure of biases, values, and experiences of the researcher that may influence the study's results (Creswell, 2007). The investigator has more than 30 years experience as a perioperative nurse and has participated in multiple organ procurement and transplantation procedures. Additionally, the investigator was involved in the intraoperative care of

the donor patient of the first facial transplant procedure performed at BWH, however is no longer a member of the operating room staff. Therefore, it was critical to be transparent and open to any potential biases that might occur during the interviews and data analysis. The investigator in this study assured reflexivity through personal reflexive journaling throughout the study. Included in this journal are extensive details about the schedule, logistics, and methodology used during data collection (Lincoln & Guba, 1985) and personal thoughts and experiences that could potentially influence the findings. The reflexive journal was discussed regularly with the peer debriefer and the Chair of the investigator's dissertation committee.

Chapter Summary

This study utilized a qualitative descriptive method to explore the experiences of the health care team members who had cared for patients involved in facial transplantation surgery. Data collection occurred through individual, multidisciplinary interviews. The sample was identified through review of a medical record of patients involved in facial transplant surgery and through a snowball technique. Qualitative content analysis occurred throughout data collection by the investigator utilizing the process outlined by Miles and Huberman (1994) and with the support of NVivo software. Efforts were undertaken to assure trustworthiness and human subjects protection.

Chapter 4

Results

Introduction

A qualitative descriptive approach was used to explore the experience of the health care team involved in facial transplantation surgery and related patient care. The purpose of this chapter is to report the study findings. Two main themes, “individual sense of purpose” and “esprit de corps,” emerged from the data. “Individual sense of purpose” describes the meaning of the experience that involvement in facial transplantation had for the participants and is comprised of three subthemes: “getting it right” (a vigilance to be attentive and thorough in providing care to assure a positive outcome), “transforming a life” (an empathic realization of the profound life-changing possibilities of the procedure) and “spirituality” (a heightened awareness of marvel and awe as a consequence of participation). The theme “Esprit de corps” conveys the morale of the health care team members involved in facial transplantation and was expressed through three subthemes: “leadership” (trust in the altruistic motivations of the lead physician), “teamwork” (a respectful acknowledgment of the critical contributions of each member of the health care team) and “environment” (the social, intellectual, and historical architecture which supported innovation at the institution). The themes and subthemes are depicted in Figure 2.

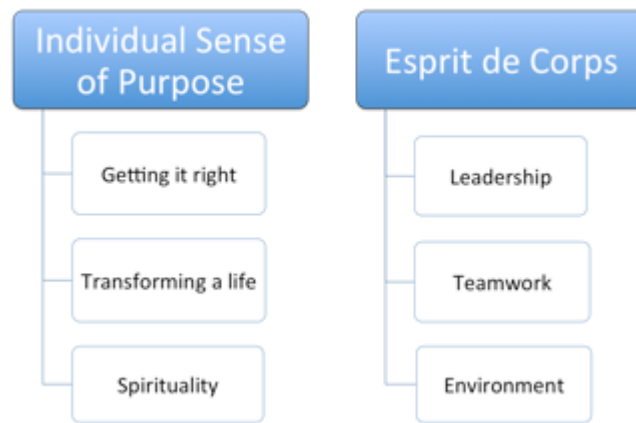


Figure 2. Themes and Subthemes

Sample

A total of fifty-two participants were contacted and invited to participate. Twenty-six individuals (50%) responded, consented to participate, and were interviewed. Of those who were invited but chose not to participate, most ($n = 25$) simply ignored the invitation. One participant responded that she felt others may be more appropriate to participate but did not elaborate. Data collection occurred between October, 2011 and December, 2011.

Demographic data including age, gender, race, health care team role, number of years working in the discipline, and highest academic degree held were collected and reported in detail in Appendix D. The mean age of the participants was 47.4 years ($SD = 9.2$; range = 26 to 63). Seventy three percent ($n=19$) were female, 27% ($n=7$) were male. Ninety-six percent ($n= 25$) were white, 4% ($n=1$) was Asian. The health care team members classified by role group included: 34.6 % ($n=9$) nursing, 19.2% ($n=5$) medicine, 27% ($n=7$) clinical support services (occupational therapy, speech therapy, physical therapy, nutrition, social work, and representatives of the New England Organ Bank) and 19.2% ($n=5$) patient care support services (administrative support, surgical technology, patient care assistant, security department representative, and a member of the public affairs staff). The participants had an average of 18.3 years of experience in their current discipline. ($SD = 10.6$; range = 4-37). The highest level of education attained by the participants was: 7.7% ($n= 2$) high school diploma, 3.9% ($n= 1$) associate's degree, 23% ($n= 6$) bachelor's degree, 38.4% ($n=10$) master's degree, and 27% ($n=7$) doctoral degrees. The majority of the participants (53.9%, $n= 14$) had cared for four facial transplant patients, 11.5% ($n=3$) had cared for three patients, 19.2% ($n= 5$) had cared for two patients, and 15.4% ($n=4$) had cared for one patient. Other demographic data collected, including religious background and self-identification of being or not being a spiritual person, will be discussed in a subsequent section of this chapter.

The Experience of the Health Care Team Members Involved in Facial Transplantation Surgery and Related Patient Care

The healthcare team members involved in facial transplantation surgery readily shared their attitudes and experiences. Almost all of the 26 participants ($n = 23$) had spent considerable time prior to and following the procedures reflecting on their professional role in caring for this patient population with their discipline-specific peers. Additionally, participants shared thoughtful individual and personal reflections with emotion, passion, and sincerity. There appeared to be little hesitation on the part of the participants to answer questions honestly and with candor. Some admitted to reflecting more intently about involvement in the procedure and its implications during the time between their invitation to participate and their actual research interview. Several ($n = 8$) articulated appreciation for the opportunity to present their feelings in a "cathartic" way.

All participants had been exposed to other organ transplantation procedures as well as other innovative procedures during their professional careers. Most ($n = 21$) maintained that facial transplantation had a very different gestalt than the other organ transplant patient care with which they had been involved. More importantly, they contended that the experience of this innovative procedure, compared to other innovation they had been part of, "reached another level." As participants sought to describe this "other level" of experience, several ($n=8$) used the word "awe," while others ($n=4$) described it as "surreal." One participant said, "people can say what they want- it's just another part of your body, like for people to give a loved one a kidney. But it's way beyond that. Way beyond that." This sentiment was reiterated many times and in many forms. Some participants described facial transplantation as being of greater magnitude than vital organ transplantation as "this operation transform(s) the patient's life and really change(s) the experience of being a human being." One participant said that though he did not view facial transplantation different from a science or mechanical view point, from the non-scientific standpoint it was "uncharted waters."

The most frequently used words to describe the experience were: “amazing, awe-inspiring, challenging, exciting, exhilarating, fascinating, hopeful, inspiring, interesting, and rewarding.” Some participants also used the words “nerve-wracking” and “frustration” when describing the experience, specifically in situations where they felt unable to adequately anticipate some aspect of the patient’s care given the innovative nature of the procedure. Phrases used by the participants to describe the experience were: “A breathtaking experience,” “pushing the envelope,” “being on the cutting edge,” “kind of the blast,” “an incredible opportunity,” and “totally surreal.” One participant described the experience in this way: “really awe inspiring. I mean, it's unbelievable to be in the room. You can hear, especially with the first one, the gasps when it happens.” Another said: “I think it was just surreal, just kind of surreal. And people said it was the best thing they've ever been involved in.” Interestingly, despite describing the experience as “awe-inspiring” and “surreal,” only a few ($n = 3$) admitted to having early skepticism about whether the procedure would actually ever take place, and no participant expressed opposition to the procedure in principle.

Individual Sense of Purpose

An “individual sense of purpose” was generated for the participants as a result of being involved in facial transplantation patient care and is representative of the multidimensional meanings that the individual health care team members described regarding the experience. The individual participants described a seriousness of effort (subtheme: “getting it right”), conveyed a commitment to assuring successful outcomes for patients (subtheme: “transforming a life”) and, for many of the participants, resulted in extensive personal reflection and a heightened sense of awe (subtheme: “spirituality.”)

Overall, the participants expressed extreme pride (13 instances) and intense honor (16 instances) at the opportunity to be involved in a facial transplantation surgical procedure or participate in the related patient care. Several cried during their interviews. Most participants

were passionate about having had the chance to do “important work” which one person described as “so out front of what is being done in medicine right now.”

Getting it Right. A subtheme that emerged from the theme *Individual Sense of Purpose* was *Getting it Right*. Clinical participants ($n= 23$) expressed confidence, despite the challenges inherent to the innovative nature of the procedure, that their prior experience caring for other complex patients- including patients who had undergone solid organ transplants, free-flap reconstructive procedures, or had suffered severe burn injuries- readied them to care for patients receiving a facial allograft. Most clinical participants ($n= 22$) were regarded as senior level practitioners in their disciplines and responsible for, as one practitioner explained, “the higher level acuity patients.” Each therefore believed that they had been likely selections for involvement in the innovation. Not only did they exhibit the knowledge and skill set required to provide care to this unique patient population, they also exhibited qualities of being forward-thinking (“we’re educated risk-takers”), passionate about their work (“this speaks to the notion of us constantly wanting to try to figure out better ways to take care of unsolved problems”), and likely “best in class” in their discipline (“these cases are the most difficult, most time consuming, with lots of brilliant people involved.”)

Several of the participants described the planning process and the implementation of care for this patient population as requiring a comprehensive skill-set; one that encompassed all technical and scientific knowledge specific to their discipline. They described this patient population as needing collectively intense physical, emotional, psychological, and spiritual care in contrast to other patient populations where one realm of care is often dominant. One nurse said: “it really brought me back to the basic foundation of nursing in -- in an incredibly meaningful way.”

Concurrently, all clinical participants expressed an overwhelming feeling of responsibility to “get it right.” One health care team member described the “heaviness” of her responsibility as:

I went to the literature and tried to see, you know, what should be in our profession's guide to practice. And so, I had to really do a lot of exploration of just what I should be

doing. And I felt like -- I felt a little bit of a weight on my shoulders that if I didn't really look into this and get it right-- I didn't want our discipline's role to not be explored.

A number of participants who provided care during the postoperative phase expressed great “weight and worry” that they may miss a physical warning sign and be responsible for the graft failing. One participant said; “this was really quite weighty. And it made me think a lot about the responsibilities, and the licensure, and the preparation of people.” Participants reported this “weight and worry” as an exaggerated emotion when compared to caring for patients undergoing other innovative procedures. Some believed that this was likely due to the intricacies of the human face’s physical and emotional qualities. Others attributed the emotion to feeling a profound level of commitment to the donor’s family. One participant described her reaction as “it's such a gift that the donor family is giving somebody that you want to make sure that you do what you can, as much as you can to make sure that that gift goes through.”

Participants described thinking about the procedure and worrying about the patients even when they weren't at work. Most believed that this was due to the innovative nature of the procedure and, moreover, due to not having well established care protocols in place to guide their practice. Additionally, they believed this reflected their realization of the great emotional impact of the procedure on the patient, and hence on members of the health care team’s desire for a positive outcome. Most who reported early fear and worry recounted that these feelings subsided with subsequent patients and reported a “de-escalation of emotion” due to evolving skill.

Though the clinical practitioners expressed a high level of confidence in their ability to care for the multiple physical needs of the patients, many expressed individual hesitation and uncertainty about “getting it right” when addressing the issue of the “new” face with the patients. In approaching one patient about their reaction to their new face, one nurse said: “...you tread on that ...you know, do you -- should I, or shouldn't I ask this question?” Many practitioners did not feel ready for this conversation. One nurse explained “things that would

come up in conversation were just kind of odd to talk about.” Additionally, few clinical practitioners felt prepared to handle the issues of identity with the patients should they arise. One nurse rationalized this concern saying “I would hope by the time that they get to us that they have received psychological counseling.”

Transforming a Life. The second subtheme linked to the theme *Individual Sense of Purpose* was *Transforming a Life*. As a whole, the participants believed that successful facial transplantation surgery had the potential to positively “transform the life” of the recipient. A participant recounted witnessing one patient’s transformation in this way:

The first time I met him I thought, "Oh, my God. You cannot have a normal life. The way that you look, there's no way that you can have a normal life, because nobody can ever -- when you walk down the street, nobody's ever going to react to you in any normal way." And I felt awful for him. And to be able to see him have the face transplant, and then talk to him more than a year later when he came back for something else. And that was a wonderful experience; he actually extended his hand for the first time to me. Before, he didn't want to talk to anybody. He would just look away. And he extended his hand. And he didn't know who I was. He didn't remember ever seeing me before. And he was happy to meet me. We had a wonderful conversation. He laughed. And he interacted with me the way most normal patients would. So, it was good for me to see that, because I saw how he had changed over a couple of years, with the face transplant in between.

All participants perceived the patient’s pre-transplant lives to be “unbearable” and several of the participants involved in the patient’s clinical care expressed desperation to transform the lives of those who have severe facial disfigurement accompanied by mechanical and functional deficits. Importantly, the participants acknowledged life-altering cosmetic post-operative outcomes for the recipients and were optimistic about successful functional and mechanical outcomes as well. Additionally, the participant’s spoke about the transformation that must have

occurred within the donor's family when making such a "precious and incredible gift," and some participants expressed a transformation of their own thinking as a result of involvement.

Perceptions of Patient Transformation. Three categories within the subtheme "transforming a life" arose in regards to the transplant recipient patients: the perception of the patient's pre and post-operative life experiences, the perception of their personality traits and potential impact on surgical outcomes, and perceptions on the process of patient selection. Patient selection received extensive attention by the participants, seemingly indicative of the recognition of the vast transformational potential of the procedure.

Perception of the patient's life experience. The participants expressed great empathy toward those in need of a face transplant. They were able to discern that these patients had significantly disfiguring injuries which resulted in a very real need for surgical intervention to improve mechanical and functional outcomes. Additionally, the cosmetic benefits of the procedure were viewed as essential for the patient in order to live any semblance of a "normal" existence. One participant summarized it as:

The people who say a heart transplant is lifesaving, but a face transplant is not, have never suffered a burn injury. They've never suffered a disfiguring injury, because anyone who has wouldn't say that. And to walk around with such a visual injury 24 hours a day, your entire life, is horrific. I'd much rather have a heart condition...

Some participants sought to describe a link between emotional identity and the appearance of a person's face. In many instances this was a difficult undertaking, in part because of the high level of emotional reaction which it elicited. One participant summarized it as, "the face, in particular, is such an emotionally charged organ that when it is disfigured, it is -- it is very -- it's a profound experience for the patient who experiences it. But it's also kind of a profound social experience for anybody who meets that patient."

Many participants spoke of the overall success of the transplants to date and that to their knowledge, each patient seemed satisfied with the outcomes. Some worried that all outcomes may not be as positive and cautioned that the long-term outcomes are unknown. Others discussed the logistical issues such a transformation brings; such as past photos, blended hair color, media attention, and the patient's ability to be recognized in public and wondered if the patient had adequate supports in place to help them work through these issues.

A few members of the health care team were concerned about the effect that the surgery might have on the patient's identity and "sense-of-self." More commonly however, participants dismissed these concerns as less significant citing that these patients were accustomed to a whole array of unusual problems and reactions from others due to their appearance. One participant viewed it as "restoring" the individual's identity rather than complicating or replacing it.

Perception of facial transplant recipient personality traits. In general, the facial transplant recipients were described as "resilient" and "courageous" individuals by the research participants. They were also described as "inspiring risk takers" who sought to better their own lives but who also contributed to the betterment of society in a tangible way. "There's an undervaluing of the contribution to society that's made through these initiatives" one participant said.

Some participants, who knew several of the patients pre-operatively as well, characterized the patients as possessing similar personality traits. This was described as a balance of resilience and acceptance of their injury which had allowed them to continue to live their lives despite their disfigurement, with an unwillingness to accept that their lives could not be transformed for the better. Others however, cautioned that the risk taking personality trait which seemed inherent to several of the patients may have contributed to the incidences that so severely injured them in the past, and worried how this propensity may impact their long-term outcome. This was visibly

disturbing to those who articulated it and many had great feeling and emotion as they discussed the psychosocial backgrounds of the patients selected.

Perceptions of patient selection. The topic of patient selection for the procedure elicited extensive discussion. Several participants were hesitant to approach the topic even when prompted, while several others asked “permission” to discuss it. Two requested that their comments be kept “off the record.”

The psycho-social background of some of the patients was discussed by many of the participants and they questioned the impact of it on potential outcomes. They reported robust conversations on the topic with their colleagues. In some instances, it was difficult for the participant to articulate why the patient selection criteria for this particular procedure should receive such great emphasis as compared to other procedures, including other organ transplantation. Others speculated that the procedure had been worthy of a “different level of scrutiny” than other procedures because of the “sacrifice” of the donor’s family. In other instances, the participants asserted strong sentiments about the cognitive functioning, social and psychological stability of the patient that should be required for the procedure to be undertaken. In particular, two participants strongly believed that these criteria should play the defining role in establishing candidacy for the procedure. Many other participants reported having similar views in the early stages of the procedure and that extensive discussion with and among their colleagues on this matter were common. They identified the topic as “controversial” and generally theorized that it was because of limited resources, the “ultimate gift” of a face, and the financial liability of the procedure and subsequent treatment. Most significantly, they reported that the conversations amongst their colleagues contained a constant premise and included judgment or bias regarding the nature of the patient's injuries, their psychosocial support systems, and in some cases, the history of risky behavior.

Despite these opinions, the majority of the participants were aware of the extensive screening process undertaken and stated that they “just had to trust” those making the decision regarding

patient selection. One participant asserted a philosophical opposition to "playing God in morally ambiguous situations."

One other topic regarding patient selection that arose was that of blind patients undergoing facial transplantation surgery. Again participants reported robust conversations among their colleagues regarding patient selection if a patient was blind. Overall, participants believed that blind patients were as appropriate for the operation as patients with sight as blind patients could perceive others' reactions to them and therefore their social interactions would be equally enhanced by undergoing the transplant. A few participants believed that blind patients may be more appropriate to receive a facial transplant as a mechanism of support for social interaction.

Perceptions of Potential Donor Family Transformation. In discussing the transformational potential of the surgery, several participants reflected deeply about the "precious and incredible gift" that the patients had received. They expressed hope that the gift was positively transformative to the donor's family as well and pondered whether they could make such a decision. They viewed the patients as having had received a gift of infinite proportion.

Most participants believed that donation of a loved one's face was a "gift" far beyond that of a solid organ and expressed "a tremendous amount of respect for the families that are willing to have their loved one give that kind of a gift." The participants who had cared for one of the donor patients, many of whom had developed longstanding relationships with their family, found the experience to be exceedingly emotional. This was most often described simply as "sad." The most frequent reaction expressed by the participants regarding the family's consent to donation however, was "disbelief."

And I really sat there and thought, 'Oh, my gosh. I can't believe this.' And all the things I thought about before, how much that people had to give up, that the

donor had to give up, and how great the family was to donate the face. And I thought about, ‘How could the family make that decision?’

Many participants expressed similar sentiment and thought that it would be very difficult for families to donate a loved one's face. They were concerned that the impact this may have on future efforts. Several noted that our society's norm of “viewing” the deceased after death may diminish the availability of facial tissue donors.

Interestingly, though the vast majority of participants supported facial transplantation in the theoretical sense, many were unable to readily answer the question about donating their own face or that of the loved ones. Of the 19 participants who had reflected enough on the question of donating their own face, 58% ($n=11$) said yes. The remaining 42% ($n=8$) said no. Perhaps even more striking were the responses to the question regarding donation of a loved one's face. Of the 17 participants who addressed this question, only 29% ($n=5$) said yes. The remaining 71% ($n=12$) had extreme difficulty in conceptualizing such a donation. Despite their active involvement in caring for this patient population, most of the participants acknowledged not having yet had in depth conversations with their family about the topic.

Perceptions of Health Care Team Member Transformation. Many participants described personal transformations as a result of involvement in facial transplantation. They reflected on the transformation of their personal judgments and biases and those made by other members of the health care team. Most participants who admitted that they had expressed reservations about the patients selected for facial transplantation surgery were subsequently introspective about prior judgments however, and only a few participants continued to have reservations about at least some of the patients selected, and two adamantly so. Many expressed that some of the patient outcomes were significantly better than they would have anticipated. One participant reflected on her early opinions and said: “I think, personally, it helped me learn to be careful of your judgments; and to

just try and stay more neutral until you have all the facts, and find out and question things before you form an opinion.”

As one of the participants attempted to explain his personal experience, he said: “these patients speak to us at a very, very core, fundamental, profoundly human level.” As such, an attitude of “how can we not try this” resonated throughout many of the interviews. Many of the participants expressed joy in contributing “even a small role in transforming a life” and others believed that they had been “involved in something very special.” Moreover, when discussing their experience and contribution to the effort, many of the health care team members said that there was a strong spiritual component to the work.

Spirituality. The third subtheme linked to *Individual Sense of Purpose* was *Spirituality*. Self identification of spirituality and religious background of the participants was collected on the demographic questionnaire. Responses to the question “do you consider yourself a spiritual person” were: 19 participants said yes, 4 participants said no, 1 said sometimes, and 2 did not answer the question. Religious background data were: 80.7% Christian, ($n=21$), 3.8% Jewish ($n=1$), 7.7% Christian & Jewish ($n=2$) and 7.7% responded “none” ($n=2$). Five of the participants also added “non-practicing” or “atheist” after their religious background designation.

Twenty-two participants (84.6%) reflected on the impact that involvement in the procedure and/or subsequent patient care had on their spirituality. Sixteen (73%) reported a spiritual component to the work, while six (27%) related no spiritual component. Overall, the healthcare team members involved in the intraoperative care of the patient ($n=8$) expressed a poignant spirituality to the experience ($n=7$; 88%). This was most often related to the transformation of the patient; including the understanding of witnessing the transfer of a “God-made part” from one human being to another. There was consistent description (one exception) with being present in the operating room and viewing the experience as spiritual.

The experience of being in the room, having them roll into the OR with this injury, and then roll out with a face again is an amazing experience that is beyond just the kind of surgical intrigue and technical wonder of -- that we can do this, which is a whole separate topic.

Another described the intraoperative spiritual impact in this way:

Like it's an -- it is one of the most amazing things when the face is first draped over the recipient, and you see this -- you see them become humanized again, in a way. And so, that whole process of seeing the patient transformed is a very -- it is a very emotional, spiritual experience. I'm not really a religious person. But it's a -- it is the closest that I feel to some sense of religion in what we do.

Another described the moment of revascularization of the facial graft:

And that sheer moment when you've -- when you've procured the part, you've washed out all the blood out of it with the very, very cold solutions that we use -- And it's really -- it looks like white marble. And then you bring it to the -- to the recipient, and you join up the first blood vessels, and let the clamps go, and watch that thing come to life. That is a real surreal moment to see that happen, that sort of wave of life just coming to that part; realizing, at the same time, that the donor is -- has expired in the next room, or wherever he happens or she happens to be...because it's on the surface, and you actually kind of can see it and visualize it - - not just imagine it being there -- it just -- it's a very, very rewarding, rich experience.

One intraoperative participant observed that the wide array of surgical skill and talent, compassionate care, and the intellectual capacity exhibited in the operating room denoted a serendipitous type spiritual component for her.

Aside from the operative procedure, spirituality was expressed in a variety of experiences by other members of the health care team. One participant described it as a spiritual experience when a patient saw himself in the mirror for the first time. In this instance the participant defined spirituality as "a desire to maintain his dignity." Many participants also credited the donor families when discussing the spirituality of the experience. They expressed awe and acknowledged the courage that making such a difficult decision requires, while suffering such grief. Few were able to conceptualize what the experience would be like for a family, and marveled at the strength they exhibited.

Esprit de Corps

There was a tremendous enthusiasm and appreciation expressed by the participants at the opportunity to be involved in such an innovative undertaking. They expressed "honor," "pride," and "joy" at being included in something that was "a very big deal scientifically and socially." The participants spoke with fondness and reverence for the leadership of the effort, and were respectful and cognizant of the strength of the inter-disciplinary teams caring for the patients. Additionally, participants believed that the Brigham and Women's hospital provided an environment which exhibited a social, intellectual, and historical architecture supportive of innovation "steeped in history." Together, the subthemes of leadership, teamwork, and environment constitute the theme "esprit de corps:" a positive morale and a capacity of the team members to exhibit enthusiasm and strong regard for a common goal of altruistic and ethical care of the facial transplant patient. Across and within disciplines the thought processes toward positive patient outcomes and a profound level of commitment were shared.

Leadership. The first subtheme identified in the theme *Esprit de Corps* was *Leadership*. The leader of this innovative effort was defined by the participants in terms of a "sincere and ethical desire to help the most severely disfigured patients." One participant described it in this way: "when I asked him questions, I could look into his eyes, and I could see the pain that he

feels for his patients who need help. You could see it. I could feel it.” Without exception, there was a belief in the altruistic motivation of the lead surgeon, which instilled trust in the other members of the healthcare team, caused them to desire involvement in this innovative procedure, and gave meaning and direction to the effort. This meaning and direction allowed the care team members to use their energies to develop care protocols specific to their disciplines, rather than debate the goals, objectives, and ethics of the innovation. Importantly, several participants also articulated the role of the lead surgeon's mentor as an honorable and authentic leader which similarly created an enormous confidence in, and vitality to, the undertaking. One participant explained the mentor's role as the one who “had true faith” that “all of this would work.” Another explained the inherent confidence he instilled in the health care team in this way: “you know that (if) he's behind this, then you have to know that this is good.”

Teamwork. The second subtheme within *Esprit de Corps* was *Teamwork*. All participants were cognizant that a multidisciplinary health care team was involved in facial transplantation surgery and patient care. Most were able to articulate the majority of specialties involved and respectfully acknowledged their contributions. One participant described the team effort in this way: “These are massive undertakings that involve a huge number of people. It's pretty -- it's a logistical circus in the sense -- not in the negative sense. But there's a lot of moving parts.” Most were able to articulate the importance of a team approach to providing optimal care to this patient population. Two types of teams emerged.

The first type of team was intra-disciplinary. In particular, participants from the plastic surgery physician team expressed an exceptional level of collegiality which philosophically and logistically supported the undertaking. Though specifically expressed by members of the division, importantly, the relationships within the division were observed and revered by other members of the health care team as well. This spirit of collegiality contributed to a sense of personal well-being and tremendous cohesiveness amongst many of the participants. The

significance of the role of mentor/mentee and generational support within the division was palpable.

You'd think, in these type of things, there's a lot of egos that would be clashing, and people are kind of muscling in to take different parts of the case. That actually doesn't happen at all. It's pretty seamless... people are willing to help each other out in a very real way here. And it's more than just lip service. It's really kind of an esprit de corps that characterizes the division.

The second type of team that emerged was inter-disciplinary. This type of team was made up of multiple individuals with discipline specific skills which were coordinated to achieve a common goal. One example cited was the collaboration between the clinical staff of the hospital and the New England Organ Bank. One participant noted that other areas of the country have not had this level of cooperation from their regional organ bank, making efforts difficult. Another example of a constructive inter-disciplinary team was the health care team involved in the care of a donor patient and their family in the intensive care unit. The most poignant example of the success of an inter-disciplinary team however was conveyed by several of the participants. This team consisted of those individuals responsible for the intraoperative care of the patients during the facial transplantation procedures. The participants from these teams expressed great reverence for the interdisciplinary teamwork that occurred. Many felt that the commitment and level of teamwork was exceptional and likely atypical of other clinical situations. One member of the intraoperative team described it this way:

I mean, I've been involved with other surgical procedures that have not been the common, everyday thing that I've helped with over the years here; working with different surgical teams. None of those were quite the same as how far out front this was of what we've done here. And I just really love being part of that team.

As the participants reflected on their overall experience of participating on highly functional teams, they discussed activities that ensued during the preparatory and training phase of the procedure, outlined areas for improvement, and made recommendations to enhance the program going forward.

Training. The participants reported varying levels of preparation in anticipation of the first transplant. This created a dual environment of excitement and worry among some disciplines in the clinical setting. Some disciplines were critical of themselves; that they had not done enough preparatory work. Though many of the skills needed were transferable from other complex reconstructive procedures, the participants acknowledged the importance of defining their role in what care for facial transplantation patients would be for the future. In spite of now having cared for four facial transplant patients however, some disciplines admitted to still not yet formalizing written discipline-specific protocols. Additionally, some disciplines struggled during the early phases of the innovation with how many practitioners to involve and train in the care of the patients. Philosophically, some felt that a few specially trained senior level individuals should care for each of the patients. In other areas, an effort was made to train multiple individuals. These philosophical differences became difficult in some settings. Some intra-disciplinary groups acknowledged that these discussions were likely inherent to innovation, though one group rebuked that the revolutionary implications of the procedure gave some the desire to be exclusive.

Recommendations. Many participants described a need for a routine meeting time when the entire healthcare team would confer on the facial transplantation patient's care. Some of the participants feared that the organization of such meetings had eroded over the course of time and that discipline specific meetings had replaced multidisciplinary meetings. Staff on the post-operative unit recommended daily psychiatry and social worker visits to the patients. Others articulated the desire to have a representative of psychiatry attend the multidisciplinary meeting to give guidance

regarding the patient experience; specifically answering the health care team member's questions about how, when, and if, to engage the patient in conversation about his facial graft.

Another area of concern expressed by some disciplines, specifically those who did not have a preoperative role in the patient's care, was the notion that it would be beneficial to meet the patients prior to their transplants. This was particularly true of those responsible for coordinating discharge planning and social and family interactions. In contrast, others reported that not having known the patient preoperatively likely made caring for them postoperatively easier because "they become almost a new person."

A major recommendation among the intraoperative staff was the need to limit the number of people allowed in the operating room. Despite acknowledging the novel nature of the procedure, the institution's philosophy of education and training, and that efforts had been made to involve the security department, there remained considerable concern about infection control and patient privacy issues.

Among the post-operative staff, it was expressed that a more interconnected approach within the nursing units would be beneficial and the formalization of care protocols. The suggestion was made for earlier collaboration between perioperative nursing staff and the intensive care unit, and then between the intensive care staff and the patient floor nursing staff, thereby promoting a more comprehensive care plan for each patient.

Environment. The third subtheme that emerged within *Esprit de corps* was *Environment*. In addition to a strong intellectual environment described earlier in the leadership and teamwork sections, the participants described both the historical and ethical environment at the Brigham and Women's Hospital as providing the architecture for successful innovation. Though these were more intangible elements to the health care team, they were emphasized and recognized as critical elements in a similar way. The value of demonstrated success with innovation at the hospital

throughout its history, and the belief that the work was being undertaken in an ethical environment, was recognized and appreciated by many members of the health care team.

Historical Environment. Many participants acknowledged a historical “aura of support” citing the Brigham’s work carrying out the first kidney transplant as a principle example. One participant explained “We’ve been doing kidney transplants at the Brigham, especially before anyone else. So, there’s more than 50 years worth of patient experience.” Another explained “it’s really good to be at an institution where you have both a historical support, and also an immediate support; that everyone is prepared to pitch in and help, and offers their expertise.”

Likewise, participants were aware that other complex procedures in the field of plastic surgery reconstruction had been successfully undertaken at the hospital “Things that seem sort of odd or unusual are part of the culture here” one participant described. This gave confidence to many members of the healthcare team who described the Brigham as a “natural scientific leader” and hence a likely venue for such work. One participant said:

And from the transplant point of view, I mean, Joseph Murray, who’s actually a plastic surgeon and -- in the -- you know, with his research and his kidney transplant. I mean, he just set the tenor for the place. And that’s kind of been an established fact that the Brigham is a transplant institution. And what followed was all the other types of transplants. And so, it was actually not -- it was certainly understandable that the -- that the non-vital organs, the faces and the hands, would also -- you know, maybe not start here, but certainly really pick up here.

Ethical Environment. No participant expressed concern that the institution’s motivation to undertake the effort was fueled by any factor other than a desire to provide ethical and compassionate care. Participants expressed very few ethical concerns about the undertaking other than those specific to patient selection presented earlier. The participants strongly believed that altruism was the foundation of the innovation at the institution. Participants vehemently dismissed

ego, fame, or fortune as primary motivating factors. In fact, this core belief comforted some who admitted that they were not fully informed about the ethical issues in the literature regarding facial transplantation

Most participants in this study were aware that the procedure had been regarded as ethically controversial when it was in the conceptual phase. Most were also able to affirm that they were aware of the individual issues when they were presented to them. None of the participants however reported any of the ethical concerns mentioned were troubling enough to them to give them pause or tempt them to choose not be involved. Some participants were aware of colleagues who had chosen not to participate in the care of this patient population based on ethical issues, though importantly this was not wide-spread, nor did they speculate on the reasons.

In general, the participants could be separated into two groups with regards to knowledge about ethical issues: those who had been fully informed and those who had been arbitrarily informed. The level to which the participant was informed was generally reflective of their role on the healthcare team and the length of time of that involvement. Those who had been involved in the planning stages of the procedure, had cared for the patients over a long period of time, and those responsible for releasing information to the general public were able to articulate a wide range of issues in the literature and fluently offered explanations of how each issue had been addressed within the institution. This group of participants was aware of IRB restrictions and requirements regarding patient selection and clearance, that the current IRB approval had evolved from an earlier version which had narrowed the patient inclusion criteria to those who were immunosuppressed, and believed that efforts had been made to protect the patient's autonomy regarding decision-making. They were well-informed about a range of ethical issues: immunosuppression, the question of an ability to obtain a fully informed consent, potential challenges with identity, the necessity to have an alternative plan should the

graft fail, and the economics of the procedure. They were also able to speak to the future implications of the procedure for a broader group of patients and hence believed they had an ethical responsibility to assure its development. There was a degree of comfort among them this group and believed the patient selection process had been fair, patient-centric, and ethical. Overall it was clear that this group of participants had spent considerable time reflecting and discussing the ethical issues inherent to this surgical innovation.

The other group of participants, those who had been arbitrarily informed of the ethical issues focused on a few select issues, specifically: patient selection criteria and the finances supporting the effort. When questioned, these participants believed that the patient's were well informed- to the extent possible- of the postoperative course and lifelong medication regimens. They expressed concern and fear however that some of the patients might be unable to adhere to the complicated postoperative care routine and that some of the patients appeared to have limited social supports in place to assist them. Many expressed dire concern about the financial responsibility of such lifelong care. One participant said:

And then there's a notion of kind of larger societal concerns about allocation of finite resources, and whether it makes sense to spend the money that we have -- what little of what we have right now on facial transplantations, when that money could be spent to take care of 100 diabetes patients, for example.

Participants widely acknowledged that the surgical team and the hospital had received extensive positive publicity following the procedures however this was not viewed as a motivating factor in the effort. Most speculated that all who were involved in the procedure, as well as the hospital's administration, were likely "quite pleased." One participant described it as:

At the same time, I think a lot of good will and a lot of good press was obtained by the hospital. So, it's kind of a win/win situation. But the most critical thing is, the patient is

the one that win/wins. And as a by-product of that, I think everyone involved with it has a positive outcome, including the hospital.

There was a great deal of discussion among the participants about the media coverage of each of the patient's hospitalization, and public disclosure of the nature of the patient's injuries which illuminated potential ethical concerns on the part of some of the participants. Some denounced the media as intrusive and a violation of the patient's privacy and therefore presented ethical concerns. Though the participants understood why the recording of a historical procedure might be an important undertaking, many expressed frustration and viewed this element as a risk to patient care. This was particularly true of the operating room staff who was concerned about asepsis and patient privacy.

Media coverage took several forms, and some participants wondered if one particular media event that had taken place, and resulted in extensive national coverage, was really in the best interest of the patient. Others wondered if the patient really understood the implications of involvement or felt coerced to participate, though none indicated that they believed that was the case. Several participants wondered if the same type of publicity would have occurred if the outcomes had not been positive. Some surmised a delay in the media releases until the patients were assuredly more stable, so that the surgeon's could tell a "confident story," and wondered if this could be interpreted as a maneuver to control facts and therefore a potential ethical problem. One participant believed the delay was appropriate: "there's a positive side to -- you're not just showing off. You're actually telling a very interesting story, with the hope that more people may become donors. And so, it would help other people."

In spite of the perceived media intrusion, there was an aura of respect and appreciation for the efforts of the hospital community to respect the patient's privacy immediately prior to and after the transplant procedures. Most participants expressed amazement at the ability of the hospital community to maintain a level of secrecy about these procedures during the immediate

perioperative period. The participants were complementary of the institution as a whole around this, though a few caregivers expressed concern that lines of communication were at times too constrained and inhibited planning patient care.

Summary

Twenty-six members of the health care team were interviewed to explore their experiences of involvement in facial transplantation surgery and related patient care. Two main themes, “individual sense of purpose” and “esprit de corps,” emerged from the data.

The theme “individual sense of purpose” was comprised of three subthemes: “getting it right,” “transforming a life” and “spirituality.” Descriptively, their experiences were defined with a seriousness of purpose to “get it right” in order to assure that the patient would have a positive “transformation of (his/her) life.” They exhibited vigilance to be attentive and thorough in their care. In examining the influence of this innovative event on their lives, they often acknowledged a significantly heightened sense of spirituality. Together, these factors yielded a personal and professional “individual sense of purpose” for the participants.

The theme “esprit de corps” also encompassed three subthemes: “leadership,” “teamwork,” and “environment.” Throughout the individual interviews the participants collectively expressed intense “honor,” “deep pride,” and “awe” at the opportunity to be involved in this innovative undertaking. They also articulated intense trust in the leadership, and acknowledged the institution’s motivations as being ethical. They viewed the experience as transformative to the patients, to the donor families, and to themselves, which consequently impacted them at an intensely spiritual level.

Chapter 5

Discussion

Introduction

The purpose of this study was to explore the experiences of the health care team involved in facial transplantation surgery and related patient care utilizing a qualitative descriptive method. The main findings were that the participants found the experience to be personally and professionally rewarding on an individual basis and recognized that the commitment and collaboration of the entire health care team had been extraordinary. As such, most participants believed that the overall experience of this innovative procedure exceeded other novel undertakings with which they had been involved in terms of spiritual impact and intrinsic rewards. This was expressed through a regard for the quality of the effort's leadership, through deep reflection on the value of being involved in the profound transformation of another human being, and through an awareness of the strength of the institution's intellectual, ethical, and historical environments where the procedures occurred.

First, these findings will be discussed in relation to the study's conceptual framework: Moore's "Ethical Criteria for Surgical Innovation" (1970, 1988, 1989, 2000). Importantly, this chapter will include a suggested framework modification applicable to innovative efforts that represent major paradigmatic shifts in both scientific effort and social philosophy as epitomized by facial transplantation. This framework modification will introduce the concept of a "Surgical Innovation Cluster." Second, the study's major findings will be compared to prior empirical evidence. Finally, the chapter will present implications for practice and health policy, propose areas for future research, and summarize the study's limitations.

Conceptual Framework: “Moore’s Criteria for Ethical Acceptability of Surgical Innovation

Moore’s “Ethical Criteria for Surgical Innovation” provides four conditions to evaluate when determining the ethical acceptability of an innovative procedure or technique (1970, 1988, 1989, 2000) (Figure 2). The criteria are: the scientific background of the innovation, the skill and experience of the team (“field strength”), the ethical climate of the institution, and the extent to which public and professional evaluative discussions have occurred (Moore; Wiggins et al., 2004, p. 7).

The Specific Aims of this study reflected these criteria. Specific Aim #1 sought to describe the skill-set, attitudes, and experiences of the multi-disciplinary health care team members involved in facial transplantation surgery and patient care. Specific Aim #2 sought to describe the ethical impact on the multi-disciplinary health care team members involved in facial transplantation surgery and patient care.

When appraised according to Moore’s framework, the health care team members who participated in this study confirmed the ethical acceptability of facial transplantation surgery and patient care in their setting. Data analyses validated that the participants believed that the surgical team had been congruent with the tenants of the framework: there was an established scientific basis for the procedure (“scientific background”), the health care team possessed the intellectual and technical skill set required (“field strength”), and the effort was supported by an institutional climate which was grounded in beneficence (“ethical climate of the institution”).

The major findings of this study are encompassed within two main themes: individual sense of purpose and esprit de corps. It is within selected subthemes of each of these that a direct alignment with Moore's framework is exemplified. Specifically, the participant’s expression of confidence, and their ability to give specific examples of the health care team’s intellectual and technical capacity to undertake the innovative procedure (subthemes "getting it right" and “teamwork”), along with their strong desire for positive patient outcomes (subtheme “transforming a life”), exemplifies two major

concepts depicted within Moore's framework: "scientific background and field-strength" (1970, 1988, 1989, 2000). The subtheme "environment" includes data that describes the ethical impact of the procedure on the individual health care team members, the motivational climate of the undertaking at the institution, and the extent to which the effort was evaluated and critiqued on a scientific, ethical, and social basis. These concepts are depicted in Moore's framework: "ethical climate of the institution" and "open display and discussion."

Conceptual Framework Modification: "Surgical Innovation Cluster"

Although Moore's framework provided an appropriate foundation by which to assess the ethical acceptability of this innovative surgery, it does not go far enough to reflect all of the elements ascertained as essential components to the surgical innovation in this study. These components, derived as concepts from the experiences of those involved in facial transplantation surgery and related patient care, are suggested as necessary to frame an innovative effort which stretches the boundaries of a surgical innovation to extraordinary levels. In these circumstances, the boundaries of innovation exceed what is commonly expected in "cutting edge" efforts. As such, there is a shift in the paradigm of what is commonly accepted as surgically possible, often providing revolutionary outcomes for science and society. Markedly, these efforts also generate wide-spread human interest, and have the potential to create fascination and intrigue through a wide variety of media formats. Consequently, those who participate in the innovation's development and implementation have a potential for astonishing personal experiences and outcomes. A brief overview of surgical innovation and an introduction to "Cluster Theory" and their applicability in this setting, are presented here.

Surgical Innovation. The interest in, and study of, innovation in the science of surgery is not new. Nonetheless, the field of surgery presents an interesting dichotomy with regards to its evolution. Surgical expertise is dependent on continuous evolution and refinement of techniques and innovative technologies, yet it is steeped in tradition and reverent towards the contributions of

those who have gone before. This dichotomy was exemplified as a valued premise within the findings of this study.

Cluster Theory. The concept of a “cluster” has been described by Michael Porter (2001, 2006, 2008), Professor at the Institute for Strategy and Competitiveness at Harvard Business School. Porter is the foremost authority on clusters as they apply to business strategy and competitive theory (Harvard Business School, n.d.). Porter broadly defines a cluster as “a geographically proximate group of interconnected companies and associated institutions in a specific field based on commonalities and complementarities” (Harvard Business School, n.d.). A cluster avails “access to specialized inputs, services, employees, information, institutions, and public goods (e.g. training programs)” resulting in “specialized knowledge creation” with increased efficiency and productivity (Porter, 2006). Cluster theory has been applied in relation to global economic development (Ketels, 2003). Other examples include the automotive industry, the media industry in Hollywood, and the fashion and textile industries of Northern Italy (Ketels).

The productivity potential of a “cluster” has been otherwise applied. The accomplishments in Concord, Massachusetts, during the mid 1800s when Ralph Waldo Emerson brought together a group of intellectuals (Henry David Thoreau, Louisa May Alcott, Nathaniel Hawthorne, Henry James, Oliver Wendell Holmes, Henry Wadsworth Longfellow, Horace Mann) resulting in our country’s great American literary works is a poignant illustration (Cheever, 2006).

Innovation Cluster. The concept of “innovation clusters” has been also described by Michael Porter. According to Porter (2006), innovation is “stimulated and enabled” by comprehensively assembled “clusters” as they encourage a broad interpretation of opportunities, provide multiple sources of knowledge, and capitalize on available resources, supplies, and technology within a given geographic region. Less broadly, the concept of “innovation clusters” has been pragmatically applied in medicine in the settings of the life sciences (Massachusetts Life Sciences Collaborative, 2008), biotechnology, pharmacology, and medical device development (Porter, 2001). Still more situation-

specific is the concept of a “surgical innovation cluster,” as depicted in Figure 3. Surgical innovation clusters have not been previously described in the literature.

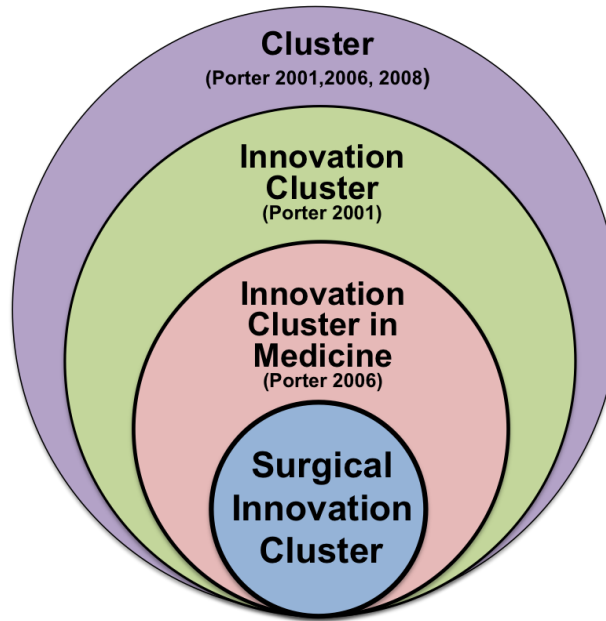


Figure 3. Cluster Theory and Innovation Clusters (Porter, 2001)

Surgical Innovation Cluster. The synthesis of the findings of this study suggest that a comprehensive set of conditions- a “surgical innovation cluster”- enabled the successful implementation of facial transplant surgery at Brigham and Women’s Hospital. These circumstances include: a valid, evidence-based, scientific background for the procedure and highly-skilled multi-disciplinary individuals. These individuals formed multiple, highly functioning inter and intra-disciplinary teams. Importantly, these teams were guided by a shared mental model of transforming the quality of life of a human being in an extraordinary way. Furthermore, there was evidence of a comprehensively sound ethical environment during the procedures’ planning and implementation, and was led by individuals who were trusted and admired by those involved. Together, these conditions were supported by a history of successful institution-based innovative undertakings in the field of organ transplantation. These conditions characterize a “surgical innovation cluster.”

The components of a surgical innovation cluster which were not previously described within Moore's ethical criteria for surgical innovation are: the extension of "field strength" to include health care teams which represent esprit de corps, the importance of an historical influence within the institution's environment which supports innovation, and the critical role of leadership are illustrated in Figure 4.

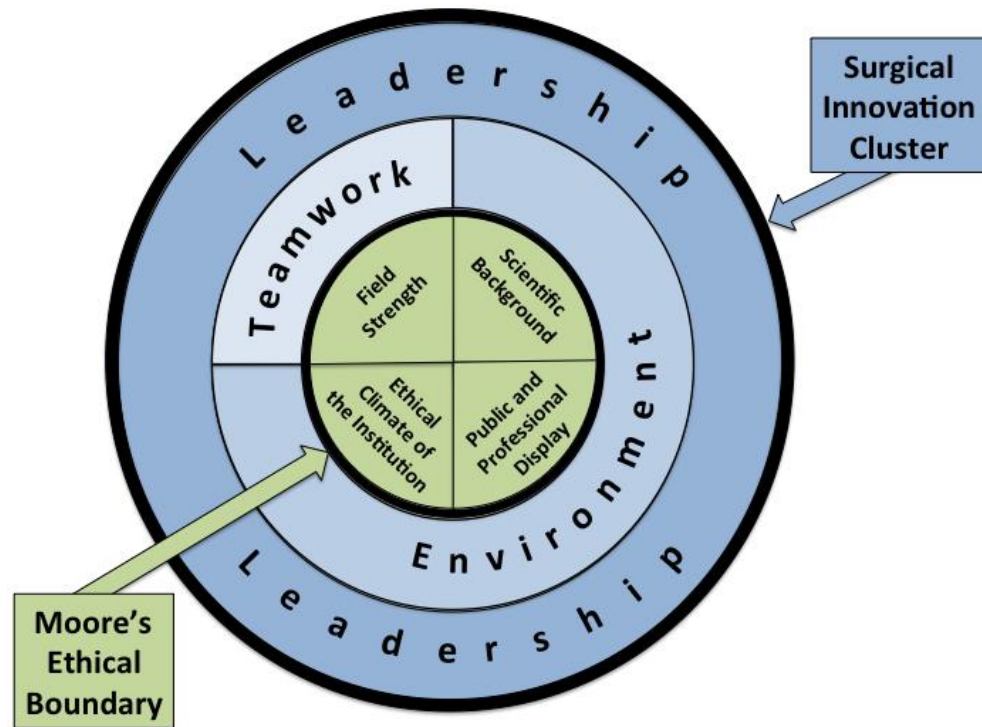


Figure 4. Surgical Innovation Cluster

Consequently, a surgical innovation cluster has the potential to transform the life of the patient in an extraordinary way, and for the health care team, may result in expressions of personal transformation and expressions of spiritual growth. These components will be further defined as they are proposed within a "surgical innovation cluster."

Teamwork. The teams involved in an effort encompassed in a "surgical innovation cluster" reflect individuals that are not only highly skilled, but are often "best in class." Moreover, the development of highly effective inter-disciplinary and intra-disciplinary teams which possess confidence, commitment, and a common morale of beneficence while exhibiting a determination to

“do the right thing,” are foundational to the concept. These qualities were evident in the experiences of the health care team members participating in this study.

Environment. A well-defined intellectual and ethical architecture within an institution is an essential component for successful innovative efforts. The health care team members in this study however, described an additional environmental domain which influenced the confidence and commitment of those involved. This realm consisted of a historically-based precedent specific to successful innovation in the field of organ transplantation at their institution, and likely provided intangible support for the confidence of the team undertaking the innovative effort.

Historical influences have been previously suggested when discussing the results of talented individuals who have congregated geographically and temporally close and achieved extraordinary things. The idea that “genius attracts genius” has been described in reference to the work of the great philosophers Plato, Aristotle, Aeschylus, Aristophanes, Euripides and Sophocles (Cheever, 2006). In ancient Rome, there was “speculation that geniuses inspired envy, which attracted younger men in two ways: they came for inspiration, and they came in the hope of equaling and surpassing those who would teach them” (Cheever, p.5). As such, the historical significance of other successful innovative efforts in the field of transplantation at Brigham and Women’s Hospital likely had a positive effect on those involved in the facial transplantation effort.

Leadership. A surgical innovation cluster must be led by an individual(s) that imparts integrity, humility, and dedication in the setting of comprehensive risk-benefit analysis, while imparting a sense of purpose, meaning, and direction to all involved. These important characteristics of leadership have been extensively outlined by Warren Bennis (1985, 1997) and accurately depict the views of the participants in this study. These qualities are essential to “translate intention into reality and sustain it” (Bennis, 1985, p. 64). Bennis also describes the importance of leadership as it applies to the incorporation of the media, “as it is available to those people who oppose a particular decision as well as those who support it” (p. 64-65). This is one particularly critical role of the leader

in a surgical innovation cluster, as the innovative undertaking approaches extraordinary boundaries and elicits significant fascination and public interest. Such was the case with facial transplantation.

Spirituality. The findings of this study support the premise that extraordinary innovative efforts in surgery may impact the health care team's personal perception of involvement on a spiritual level. It is emphasized here however, that an effort developed and implemented by a "surgical innovation cluster" has the potential to exhibit expressions of "awe" by those involved, while recognizing that the experience exceeds the spiritual experience of other novel undertakings.

Summary. The findings of this study support the development of a new conceptual framework useful in guiding innovative efforts which represent major paradigmatic shifts in both scientific effort and social philosophy. The framework represents a "Surgical Innovation Cluster." A "Surgical Innovation Cluster" consists of the following components: Moore's four criteria for the ethical acceptability of an innovation (scientific background, field strength, ethical climate of the institution, and public critique of the innovation) undergirded by an esprit de corps that includes exceptional teamwork, an environment which is strengthened by a history of successful innovation, and guided by exceptional leaders. The innovative effort often results in spiritual reflection by those who participate in the undertaking.

A "surgical innovation cluster" then, is operationalized as: the leveraging of a knowledge base grounded in superior theoretical and clinical expertise, energized by an infrastructure rich in extraordinary technical skills and advanced surgical technologies, and fostered in a patient-centric, ethically sound environment whose foremost focus and motivation is on positive patient outcomes. The outcome measures of the efforts of a "surgical innovation cluster" are a transformed quality of life for the patient following a novel surgical intervention, and a profound personal- often spiritual- experience for members of the health care team (Figure 5). An innovative surgical procedure may be appraised using this framework not only to evaluate its ethical comportment, but in terms of its process, implementation, and outcome evaluations for patient and

members of the health care team as well.

Relationship to Prior Empirical Evidence

As reported by Hibbert (1995,) Regehr, Kjerulf, Popova, & Baker (2004) and Wang & Lin (2009), the professional caregiver's perception of involvement in solid organ procurement and transplantation procedures has been found to be morally complex and deeply important. Prior to this study, the impact of facial transplantation surgery on the healthcare team had not been explored. This study confirmed that the health care team's experience with facial transplant surgery was viewed as similarly important, and in some cases, the participants believed that it exceeded the level of significance of other organ transplantation procedures. Among the similar findings to Hibbert's study were: an overall positive perception of the experience of involvement in transplantation surgery, and an identified need for stress debriefing sessions to express feelings. Unlike Hibbert's study however, in which the participants were specifically involved with the organ donation process and the resultant stress around grief in anticipation of death, the participants in this study expressed stress in regards to providing clinical care which would maximize positive patient outcomes for the transplant recipient.

Siminoff, Arnold, & Caplan (1995) found a relationship ($r=.62$; $p=.000$) between a healthcare provider's attitude and effects on organ donation; specifically in relation to requesting donation. Based on these findings, the attitudes of the health care team regarding facial transplant may also affect the number of available donors. As many participants in this study reported hesitation in agreeing to donate their own or their loved ones face should the circumstance arise, this may represent implications for the number of available donors. Additionally, if the healthcare team members who have had generally positive experiences with facial transplantation remain hesitant about donation, the general public's hesitation to donate may be of even greater magnitude.

The first facial transplant surgery occurred in 2005. Studies addressing the attitudes and opinions of healthcare team members toward facial transplant surgery and ethical questions have

been conducted (Clarke, Simmons, White, Withey, & Butler, 2006; Clarke et al., 2007; Mathes, Kumar, & Ploplys, 2009; Prior & Klein, 2011; Vasilic et al., 2008). However, all were done during the conceptual phase of facial transplantation surgery and therefore based on speculation, rather than experience. This study found that many of these potentially controversial topics were mitigated by an overwhelming sense of desperation of the participants to help patients with complex cosmetic, functional, and mechanical facial deficits. The participants in this study unanimously believed that the risk-benefit ratio of the procedure overwhelming supported its implementation.

The findings of this study are in contrast to some early critics of the procedure during the conceptual phase who argued that facial transplant surgery was not “life-saving” in the same manner as heart, lung or kidney transplants (Morris et al., 2004; Strong, 2010). Many participants in this study felt that the “life-giving” nature of this procedure made it an even more important undertaking than other organ transplantation efforts they had been involved with, supporting the published views of proponents of the procedure (Alexander et al., 2010; Clarke & Butler, 2009; Pomahac, 2011).

Several other ethical issues during the conceptual phase of facial transplantation were presented which assessed whether the benefits of the procedure outweighed the risks including: the risks of lifelong immunosuppressive therapy and potential medical complications (O’Neil, 2009; Powell, 2006; Renshaw, 2006; Wu, Xu, Ravindra, & Ildstad, 2009), the ability to obtain a fully informed consent and assure patient autonomous decision-making due to the innovative nature of the procedure (Reitsma & Moreno, 2006), the financial burden for such procedures is absorbed by the health care system (Kalliainen, 2010), and situations whereby the patient might fail to comply with necessary treatment to preserve their transplant which would result in a burden to the health care system, including subsequent surgical interventions and treatment. The participants in this study believed that the risks of long-term immunosuppression following a facial transplant, though concerning, were acceptable to them. This was dependent on the patient being fully informed of the risks however. The participants in this study believed that the patients they had cared for seemed to

have a thorough understanding of their options, and that each patient appeared to understand the risks inherent to the undertaking, to the extent possible given the innovative nature of the procedure.

One area illuminated by the current study, which did not receive wide critique during the conceptual phase of the procedure was that of patient selection. These concerns were specifically related to psychosocial factors including the nature of the injury, past evidence of risky behavior by the recipient, and the strength and availability of psychosocial support systems for the post-transplant phase. These concerns were intertwined with the financial burden of the procedure and the risks associated with non-adherence to postoperative medical regimes which are currently absorbed by the health care system.

Implications for Practice

As this is the first study which explores the personal attitudes and experiences of the healthcare team members involved in facial transplantation it expands a narrow evidence base. Importantly, it supports the Institute of Medicine's recommendation of a focus on inter-professional practice and education (Perlman, 2009).

The healthcare team members in this study identified areas of practice in need of further development. These included learning to become more comfortable with discussions about the "new" face with the patient; and in particular, about sensitive topics such as how one might want to deal with past photos, a blended hair color, and the patient's ability to be recognized in public. Though multidisciplinary protocols for facial transplantation are now found in the literature and provide guidance for program development (Bueno, Diaz-Siso & Pomahac, 2011; Siemionow & Gordon, 2010a), there exists a need for discipline-specific protocols to be reported as well. Though the discipline of medicine has now reported extensive case reports and other short-term findings related to facial transplantation, few other disciplines, including nursing, have done likewise.

The concept of “surgical innovation clusters” has not been previously described. Development of the concept may have implications by which to assure successful development and implementation of innovative techniques and procedures in a variety of clinical settings.

Implications for Research

Although early empiric data are now available regarding the technical, immunological and psychological aspects of facial transplantation, long-term results are as yet unknown. Research must now focus on the long-term functional, mechanical, and psychosocial ramifications of the surgery and related treatment in order to fully assess risk/benefit ratios. The experience of the patients and the quality of life measurements related to the transplant must be longitudinally explored. Additionally, the participants in this study voiced concern about the recipient patient’s psychosocial characteristics and questioned whether a relationship between the nature of the patient’s original injury and long-term outcomes may exist.

The impact of facial tissue donation on the donor family on both the short and long term grieving processes must be understood. Assessing the type of social supports needed and other beneficial interventions to support these family members would be important to explore. Assessing this in regards to long-term outcomes may help to assure positive outcomes, including the potential for other families to consent to donation in the future.

The concept of innovation clusters has not previously applied in the surgical setting and as such, the concept has not been empirically tested, developed, or refined. Outcome measures of surgical innovation clusters, including productivity, efficiency, and patient and health care team member experiences should be further explored.

Implications for Health Policy

Currently, facial transplantation is regarded as an experimental protocol and as such, is regulated by an institution's IRB. Because the surgical procedure and perioperative care are complex, and postoperatively the patient will require lifelong immunosuppression, financial implications of

the procedure are significant. Both private insurance plans and public subsidies will be required to address these issues in the future. Additionally, criteria for the distribution and priority of donations must be developed.

Limitations

The study's limitations are primarily reflective of the rare and innovative nature of facial transplantation. As such, transferability of findings may be limited. Additionally, data collection activities were limited to one setting. Significantly, at the time of data collection the participant's exposure had been with generally positive patient outcomes. It is unknown if participant views would be different if any patient had had negative results. It is also unknown if those who received an invitation to participate but did not respond, or chose not to participate, did so because of negative perceptions about the procedure. Therefore the results may reflect only those with positive perceptions.

The notoriety and media interest of the procedure may have influenced participant's responses. Though no indication of such was evident, participant's responses may have been influenced by their employment status and a potential fear of retribution. A potential conflict of interest exists for the researcher who was formally an employee of the institution where the data collection occurred, a former colleague of some of the participants, and who also participated in the intraoperative care a patient involved in facial transplantation.

Conclusions

The attitudes and experiences of the health care team members involved in facial transplant surgery and patient care were explored in this study, which utilized a qualitative descriptive method. The Specific Aims of the study and the interview questions were guided by "Moore's Ethical Criteria for Surgical Innovation." Overall, the participants believed that the risk-benefit ratio of facial transplantation favored proceeding with the procedure in the clinical scenarios with which they had been exposed. The participant's experience was challenging and rewarding, and they

expressed personal fulfillment from the opportunity to be involved in the transformation of another human being's life. Moreover, the entire effort exhibited highly effective team work which displayed esprit de corps, was guided by superior leadership, and illuminated the importance of the clinical, intellectual, and historical environment of the institution where the procedures took place. These components represent a "surgical innovation cluster," a proposed framework for guiding surgical innovative efforts which represent major paradigmatic shifts in both scientific effort and social philosophy.

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Appendix A

Timeline: The development of composite tissue transplantation

Date	Event
348 _{AD}	Legendary account of the transplantation of leg by Cosmos and Damian
Late 16 th century	Transplantation of a nose by Gaspare Tagliacozzi
Early 20 th century	Canine limb transplant by Carrel
Early 20 th century	Heterotopic allotransplantation of the heads of dogs by Guthrie
1956	First successful human kidney transplant. Donor and recipient were identical twins mitigating risk of rejection
1963	First human hand transplant. Experience acute rejection. Removed 3 weeks after transplant in Equador
1994	Re-plantation of full-facial tissue (autotransplant) in India
1998	Second-ever human hand transplant performed in France. First to survive more than two years. Eventually rejected and removed because of non-compliance.
1999-2011	62 hand transplants in 46 patients. No mortality reported. Multiple episodes of rejection- successfully reversed with medication management
November, 2005	First human facial transplantation
2006-2011	Sixteen total additional facial transplantation procedures performed worldwide in France, China, Spain and the United States. Two of the sixteen patients undergoing facial transplants have died
2009	US Department of Defense acknowledges facial transplant as a research priority in effort to care for wounded soldiers

Appendix B
Facial transplantation procedures 2005-2011

Date	Patient	Location	Lead Surgeon	Mechanism of Injury
November, 2005	38 yr. old female	Amiens, France	Lantieri	Dog bite
April, 2006	30 yr. old male	Xi'an, China	Hui	Bear attack Died July, 2008 presumably after stopping immunosuppressants
January, 2007	29 yr. old male	Creteil, France	Lantieri	Neurofibromatosis
December, 2008	46 yr. old female	Cleveland, OH, USA	Siemionow	Gun Shot Wound
March, 2009	28 yr. old male	Creteil, France	Lantieri	Shooting accident
March, 2009	30 yr. old male	Creteil, France	Lantieri	Burn Died of a heart attack during subsequent surgery for an infection
April, 2009	59 yr. old male	Boston, MA, USA	Pomahac	Fall/Traumatic injury
August, 2009	43 yr. old male	Valencia, Spain	Cavadas	Radiation for tumor
Fall, 2009		Amiens, France		
September, 2009	39 yr. old male	Creteil, France	Lantieri	Shooting accident
January, 2010	34 yr. old male	Madrid, Spain	Gomez Cia	Congenital disease ->deformities
April, 2010	male	Barcelona, Spain	Barret	Shooting accident
June, 2010	35 yr. old male	Creteil, France	Lantieri	Genetic
March, 2011	25 yr. old male	Boston, MA	Pomahac	Traumatic Injury/Burn
April, 2011	30 yr. old male	Boston, MA	Pomahac	Car Accident
May, 2011	57 yr. old female	Boston, MA	Pomahac	Animal Attack
Jan., 2012	19 yr. old male	Turkey	Ozkan	Burn

Appendix C

Participant Demographic Form

1. Age:_____
2. Gender:_____
3. Race:_____
4. Ethnicity:_____
5. Religious background:_____
6. Discipline:_____
7. Role:_____
8. Years working in your discipline:_____
9. Years of education:_____
10. Highest academic degree held:_____
11. Number of face transplant patients cared for_____

Appendix D
Participant Demographics

Category	Total Participant Response	Percent
Age <ul style="list-style-type: none"> • 26-35 • 36-45 • 46-55 • 56-65 	<i>N</i> =26 <i>n</i> = 3 <i>n</i> = 9 <i>n</i> = 7 <i>n</i> = 7	11.6% 34.6% 26.9% 26.9%
Gender <ul style="list-style-type: none"> • Male • Female 	<i>N</i> =26 <i>n</i> = 7 <i>n</i> = 19	27% 73%
Race <ul style="list-style-type: none"> • Caucasian • Asian 	<i>N</i> = 26 <i>n</i> = 25 <i>n</i> = 1	96% 4%
Role <ul style="list-style-type: none"> • Registered Nurse • Physician • Clinical Support Services <ol style="list-style-type: none"> 1. Occupational Therapist 2. Speech Therapist 3. Physical Therapist 4. Nutritionist 5. Social Worker 6. NE Organ Bank • Patient Care Support Services <ol style="list-style-type: none"> 1. Surgical Technologist 2. Patient Care Assistant 3. Security 4. Public Affairs 5. Administration 	<i>N</i> = 9 <i>N</i> = 5 <i>N</i> = 7 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 2 <i>N</i> =5 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1 <i>n</i> = 1	34.6% 19.2% 27% 19.2%
Years working in discipline <ol style="list-style-type: none"> 1. 1-10 years 2. 11-20 years 3. 21-30 years 4. 31-40 years 	<i>N</i> = 26 <i>n</i> = 9 <i>n</i> = 6 <i>n</i> = 6 <i>n</i> = 5	34.6% 23.1% 23.1% 19.2%
Highest academic degree <ul style="list-style-type: none"> • High school diploma • Associate's degree • Bachelor's degree • Master's degree • Doctoral degree 	<i>N</i> = 26 <i>n</i> = 2 <i>n</i> = 1 <i>n</i> = 6 <i>n</i> = 10 <i>n</i> = 7	7.7% 3.9% 23% 38.4% 27%
Number of facial transplant patients or procedures <ul style="list-style-type: none"> • One • Two • Three • Four 	<i>n</i> = 4 <i>n</i> = 3 <i>n</i> = 5 <i>n</i> = 14	15.4% 11.5% 19.2% 53.9%