

FACIAL LIPOATROPHY AND RECONSTRUCTIVE TREATMENTS IN THE CANADIAN CONTEXT

A BRIEF GUIDE



CANAC
Canadian Association
of Nurses in AIDS Care

ACIIS
Association canadienne
des infirmières et infirmiers
en sidologie

Introduction

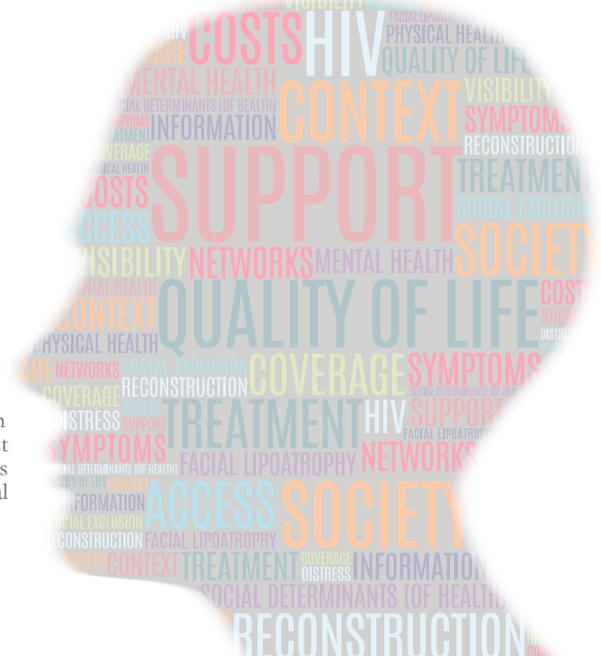
In recent years, dermal fillers such as poly-L-lactic acid (New-Fill or Sculptra) or polyalkylimide (Bio-Alcamid) have been increasingly used for the treatment of facial lipoatrophy in Canada and other countries such as Australia, Brazil, Germany, France, Spain, Italy, the Netherlands, and the United States. In Canada, both of these dermal fillers have been approved for the treatment of facial lipoatrophy but neither one is publicly insured. The first objective of this guide is to provide an overview of reconstructive treatments currently approved for facial lipoatrophy in the Canadian context. The second objective is to build on previous research conducted by the primary author with people who suffer lipodystrophy (including facial lipoatrophy) (see Gagnon & Holmes, 2011, 2012; Gagnon, 2012) to support and encourage nurses to adopt a more comprehensive approach to the care of people who suffer from facial lipoatrophy.

Background*

Facial lipoatrophy is characterized by “loss of the buccal and/or temporal fat pads, leading to a facial skeletonization with concave cheeks, prominent naso-labial folds, periorbital hollowing, and visible facial musculature” (Guaraldi, Fontdevilla, Christensen, Orlando, Stentarelli et al., 2011, p.1). In the weeks or months after initiating antiretroviral combination therapy or changing pharmacological regimen, individuals who suffer from facial lipoatrophy will manifest a progressive loss of subcutaneous adipose tissue in the malar, buccal, and nasolabial areas (Funk, Brissett, Friedman & Bessler, 2007). As the condition progresses to the periocular and temporal regions, individuals will report that their underlying facial musculature is becoming more visible and that the bone landmarks around their orbits and temples are becoming much more prominent (Funk et al., 2007). Studies suggest that the severity of facial lipoatrophy varies from one individual to another, although at present, there is neither a standardized tool to measure the varying degrees of facial fat depletion nor concise parameters that could be used in the clinical setting (Guaraldi et al., 2011). While a number of severity scales have been proposed (Fontdevilla, Berenguer, Prades, Pujol, Guisantes et al., 2007; Funk et al., 2007; James, Carruthers & Carruthers, 2002), more work needs to be done in order to ensure that facial lipoatrophy is properly assessed, documented and reported by clinicians based not only “measured” severity but also on the subjective assessment of severity by the patient.

The occurrence of facial lipoatrophy is well documented in people living with HIV, although at present, it remains difficult to determine exactly how many suffer from this condition. In 2005, it was estimated that 50% or more of people living with HIV develop signs of facial lipoatrophy during the course of their treatment (Jones, 2005). A number of factors have contributed to the rising incidence of facial lipoatrophy in the first decade of the HAART era, in particular the cumulative exposure to thymidine analogue nucleoside reverse transcriptase inhibitors (NRTIs) such as stavudine (d4T or Zerit) and zidovudine (AZT or Retrovir). These antiretroviral agents are no longer prescribed in first line combination therapies and as a result, it is believed that the number of people who suffer from facial lipoatrophy will decrease in the coming years (Guaraldi et al., 2011). While this may be true in industrialized countries, stavudine (d4T) continues to be widely prescribed in developing countries as part of a combination therapy called Triomune. And so, researchers are now reporting a high prevalence of facial lipoatrophy (and other body fat changes) in many sub-Saharan countries (see Gagnon & Holmes, 2010). Other contributing factors include: age, genetic profile, sex, ethnicity, lipid profile, body mass index, nadir CD4+ count, stage of HIV infection, and duration of treatment (Jones, 2005) - none of which have been proven to be as instrumental in the development of facial lipoatrophy as thymidine analogue NRTIs (Guaraldi et al., 2011).

* Sections of the background and summary of the literature were reprinted in this guide with the permission of Elsevier, International Journal of Nursing Studies (June 17, 2013). It was first published in Gagnon, M. (2012), Understanding the Experience of Reconstructive Treatments from the Perspectives who suffer from Facial Lipoatrophy: A Qualitative Study. International Journal of Nursing Studies, 49 (5), 539-548.

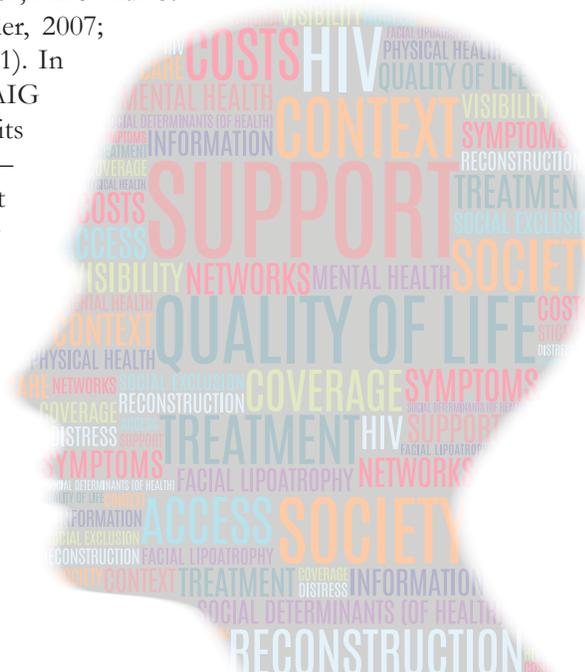


Summary of the Literature*

Unfortunately, to date, no pharmacological treatment has proven effective in the clinical management of facial lipoatrophy. For this reason, there has been a vast interest in reconstructive treatments because they allow for facial contours and facial fullness to be restored while being minimally invasive (Carey, Liew & Emery, 2008). A wide range of dermal fillers are available for the correction of facial lipoatrophy – some of which provide more satisfactory results than others. In Canada, two dermal fillers have been approved for the treatment of facial lipoatrophy, namely poly-L-lactic acid (New-Fill or Sculptra) or polyalkylimide (Bio-Alcamid). The following sections summarize the state of the literature on these dermal fillers in the context of HIV.

Poly-L-lactic acid (PLLA) biodegradable gel contains particles of poly-L-lactic acid which “trigger the host tissue to produce a foreign body response, which eventually stimulates the connective and fat tissue fibroblasts to produce collagen, and this de-novo collagen production is responsible for the filling effect” (Guaraldi et al., 2011, p.4). The injections are usually performed over the course of multiple sessions (3-5 sessions every 4-6 weeks) so that tissue augmentation can be achieved progressively (Rotunda & Narins, 2006). The effectiveness and safety of PLLA has been widely studied in the treatment of people who suffer from facial lipoatrophy. Overall, researchers agree that PLLA is successful at restoring facial volume and improving the facial contours of people who suffer from this condition (Barton, Engelhard & Conant, 2006; Carey, Baker, Rogers, Petoumenos, Chuah, Rogers et al., 2007; Hanke & Pagliai Redbord, 2007; Loufty et al., 2007). Studies indicate that both physical and psychological benefits of PLLA are sustained at 48 weeks (Carey et al., 2007), 72 weeks (Moyle et al., 2006), 96 weeks (Valantin et al., 2003) and much longer with additional treatment sessions (up to 3 years as suggested by Levy, Pagliai Redbord & Hanke, 2008). Here, it is important to highlight that the effects of PLLA are temporary and can only be maintained if the gel is re-injected ideally within two years after the last completed treatment procedure (Levy, Pagliai Redbord & Hanke, 2008). In general, PLLA is well tolerated even though it is known to cause injection-related adverse events such as bruising, edema, discomfort, hematoma, and localized inflammation (Barton, Engelhard & Conant, 2006). Occasionally, PLLA may lead to the formation of small subcutaneous micronodules and/or the appearance of an inflammatory granulomatous reaction at the injection site (Barton, Engelhard & Conant, 2006). There is limited knowledge on the mechanisms responsible for these complications. Wildemore and Jones (2006) suggest that perhaps PLLA “should not be considered entirely biologically inert” (p.1407) which could, in part, explain the granulomatous inflammatory response observed in some patients. Others insist that improvements in injection techniques and postinjection care could significantly reduce the risk of developing micronodules which affect nearly half of people who are treated with PLLA (Sturm et al., 2009). Further investigation into these complications is thus warranted.

Polyalkylimide nonbiodegradable gel (PAIG) is a synthetic polymer composed of 4% polyalkylimide and 96% non-pyrogenic water (Loufty et al., 2007). Once PAIG has been injected into the subcutaneous place, it triggers a host tissue response which is then responsible for the formation of a collagen capsule (Guaraldi et al., 2011). According to Antoniou, Raboud, Kovacs, Diong, Brunetta and colleagues (2009), “the formation of a fine (0.02 mm) collagen capsule around the injected polymer isolates it from host tissue and renders the product easily removable should the need subsequently arise” (p.1247). Because the effects of PAIG are permanent, further treatment sessions are usually not necessary once the first set of injections has been performed and the patient is satisfied with the outcomes of the procedure (Antoniou et al., 2009). However, follow-up sessions are highly recommended because of the risk of delayed adverse reactions, including inflammation, hardening of the capsule, migration, nodule formation, and infection (Guaraldi et al., 2011). A number of case reports have been published on these adverse reactions which tend to occur months and up to several years after treatment (Alijotas-Reig, Garcia-Gimenez, Miro-Mur & Vilardell-Tarres, 2008; Jones, Carruthers, Fitzgerald, Sarantopoulos & Binder, 2007; Karim, Hage, Rozelaar, Lange & Raaijmakers, 2006; Nelson & Stewart, 2011). In Canada, two studies were conducted on the safety and effectiveness of PAIG (Antoniou et al., 2009; Loufty et al., 2007). Both concluded that the benefits of this reconstructive treatment were maintained at the time of follow-up – 48 weeks and 96 weeks postinjection. Even though these studies did not report severe adverse reactions such as the ones listed above, they suggest that further



Implications for Nursing Practice

Drawing on a social ecological perspective, we argue that nursing care provided to people who suffer from facial lipoatrophy should incorporate multiple levels simultaneously.[†]

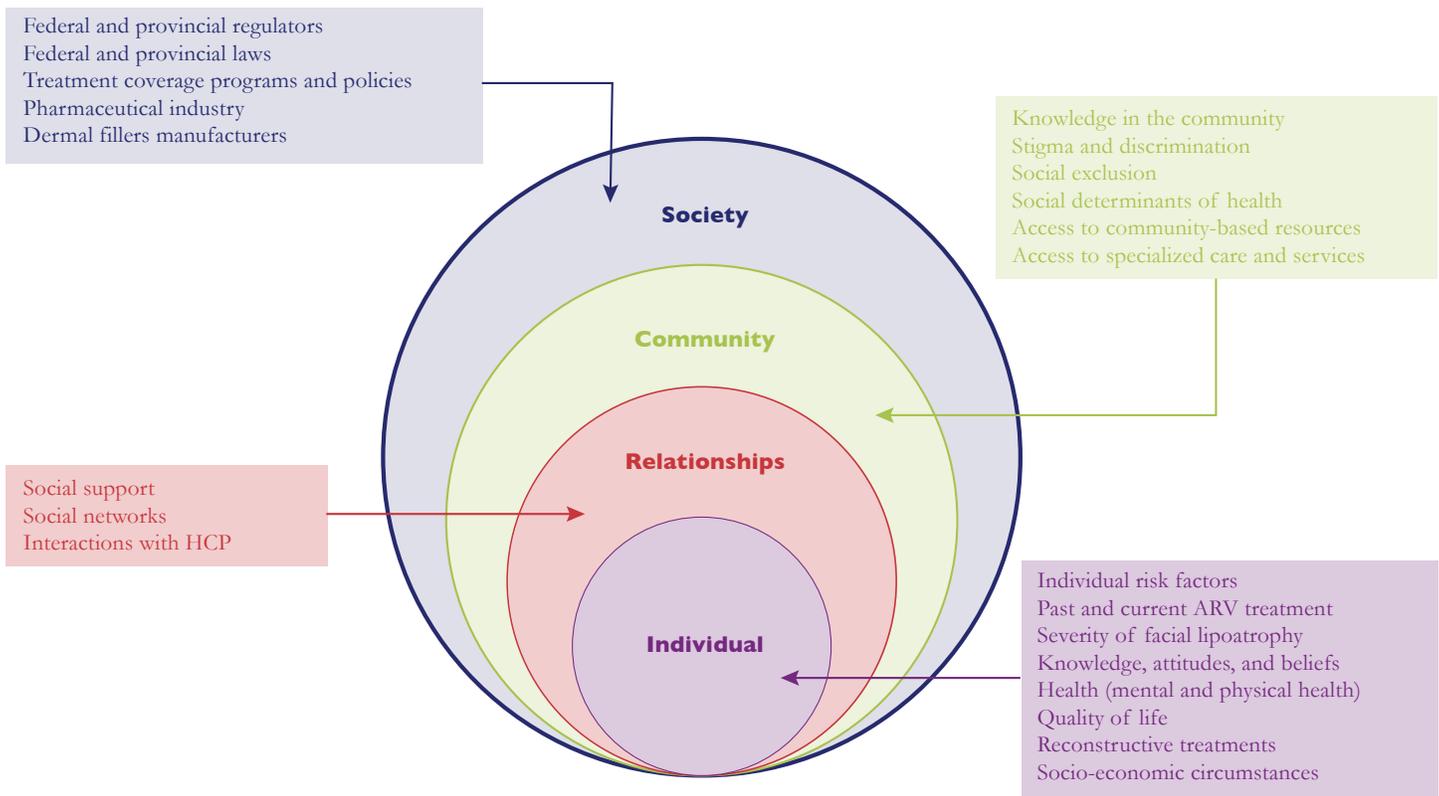
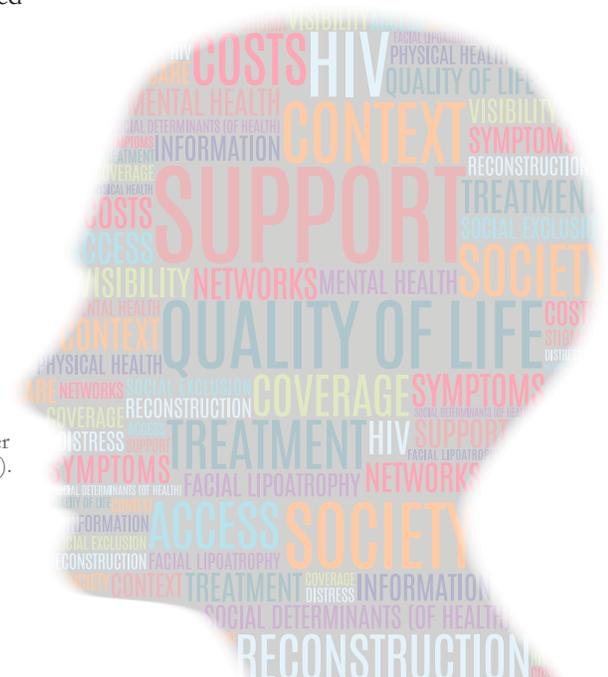


Figure 1. Social ecological model adapted to facial lipoatrophy

Adapted from Byrne, J.M. & Stowell, J. (2007). Examining the link between institutional and community violence: Toward a new cultural paradigm. *Aggression and Violent Behavior*, 12, 552-263.

At the level of the individual, nurses should take into account the medical history of the patient, including individual risk factors as well as past and current antiretroviral combination therapies. Knowledge, attitudes and beliefs should also be explored because they impact the way patients perceive, understand and deal with facial lipoatrophy. Furthermore, nurses should assess for quality of life and health issues. People who suffer from facial lipoatrophy report high incidences of psychological and social distress which make them particularly vulnerable to develop mental health problems and experience social isolation. However, it is important for nurses to remain cautious when conducting their assessment and acknowledge the risk of overpathologizing emotions, reactions, and symptoms by seeing them as more severe or clinically indicative of a mental health problem than it truly may be (Jacob, Gagnon & McCabe, ePub Ahead of Print).

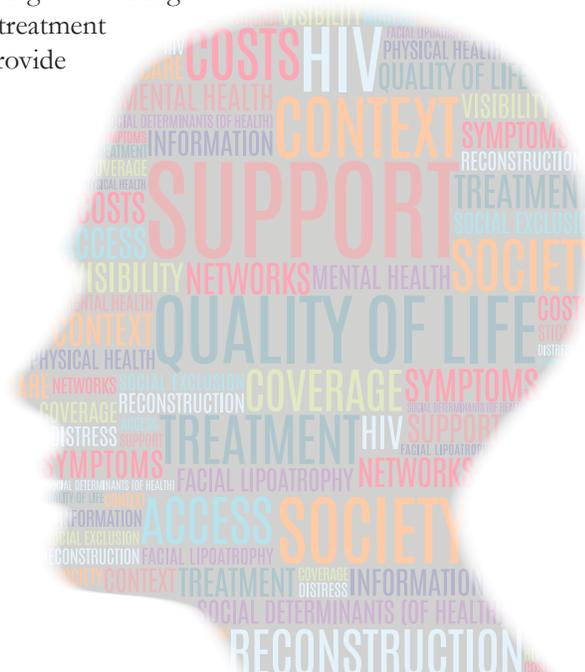
[†] This section draws on findings of previous research conducted with people who suffer lipodystrophy (including facial lipoatrophy) (see Gagnon & Holmes, 2011, 2012; Gagnon, 2012).



Overpathologization may, in fact, accentuate the burden of disease by situating the problem at the individual level, rather than engaging in the difficult task of addressing the relational, societal, and contextual elements that may be at the source of distress (Jacob, Gagnon & McCabe, ePub Ahead of Print). These elements not only impact the quality of life and overall health of people who suffer from facial lipoatrophy but also affect their desire and decision to seek reconstructive treatments. While research demonstrates the positive impact of reconstructive treatments on the lives of people who struggle with the visibility and the full scope of psychosocial effects of facial lipoatrophy, these treatments may not be accessible due to costs constraints. In fact, socioeconomic circumstances have more influence on access to reconstructive treatments than other factors at the relational, community, or societal level.

At the level of relationships, nurses should assess the level of social support reported by the patient as well as existing social networks. Here, social support should be understood as emotional, instrumental, and informational support provided by various members of existing social networks (e.g., family members, relatives, friends, colleagues, etc.) (Due, Holstein, Lund, Modvig & Avlund, 1999). People who suffer from facial lipoatrophy may report lower levels of social support or precarious social relations for various reasons; they feel exposed and stigmatized when they go out in public, they prefer to avoid certain social situations and isolate themselves, and they are fearful of involuntary disclosure and negative experiences (such as discrimination, rejection, violence, etc.). Nurses may consider the following questions when assessing social support and social networks: Do you have someone to talk to if you feel troubled? Do you have friends or family who can provide some assistance (practical, financial, informational) in your everyday life? Have you encountered relationship problems or conflicts with partner, family, friends, and colleagues? Who are the closest persons to you and who provides the most support in your everyday life? Do you belong to groups or formal social networks? (Due et al., 1999). When providing care to people who suffer from facial lipoatrophy, not only is it important to recognize that social support has health promotion and health protective effects, but also it is equally important to understand that social support (especially practical and informational support) has implications for treatment access. In order to have access to reconstructive treatments, most people who suffer from facial lipoatrophy have to be resourceful and every so often borrow money from friends or family. This form of support may be helpful at first but it may eventually put a strain on some relationships.

Relationships with health care providers are also important to consider at this level. These relationships shape the experience of people who suffer from facial lipoatrophy in various ways – they can be supportive and informative but they can also be invalidating and frustrating. Incidentally, it is not uncommon for people living with HIV to report that body changes associated with lipodystrophy (including facial lipoatrophy) are minimized or dismissed by health care providers (for example, also see Collins et al., 2000; Power et al., 2003; Reynolds et al., 2006). It is also not uncommon for people to learn about facial lipoatrophy and reconstructive treatments through friends, peers, information booklets, and the internet rather than through health care providers or learning resources in the clinical setting. Both of these issues raise questions for health care providers who work in the field of HIV/AIDS: Do health care providers have adequate knowledge about this topic to provide up-to-date and relevant information in clinical practice? What are the attitudes and beliefs of health care providers toward facial lipoatrophy and reconstructive treatments? What are the taken-for-granted assumptions about facial lipoatrophy and reconstructive treatments? Is there room for people who suffer from facial lipoatrophy to share their concerns, ask questions, and express their emotions freely in the clinical setting? Nurses have a key role to play in addressing these questions and improving the care provided to people who suffer from facial lipoatrophy. A good starting point would be to critically examine how discourses of HIV treatment, treatment adherence, and treatment side effects inform the way nurses engage with and provide care to people who suffer from facial lipoatrophy.



At the community level, nurses should understand that people who suffer from facial lipoatrophy are very concerned with and affected by the visibility of their condition – which makes them more prone to experience stigma, discrimination, and social exclusion. In some communities where the baseline knowledge about HIV is higher than the general population, they may consider themselves recognizable and potentially identifiable as a person living with HIV or they may experience involuntary disclosure in social situations. In other communities, they may be more concerned with being seen as “sick-looking” or “unwell” because of the loss of facial fullness which, in the general population, is not recognized as a sign of facial lipoatrophy but rather as a sign of disease. Thus, access to community-based recourses and psychosocial support in the community should be considered when providing care to people who suffer from this condition. Other social determinants of health (such as income, income distribution, unemployment, job security, employment, working conditions, food insecurity, housing and so on) should also be considered. Social security and financial hardships not only result in lower health outcomes but also act as a barrier to the access of reconstructive treatments. Additionally, the availability of and proximity to specialized care and services for facial lipoatrophy can act as a barrier to the access of reconstructive treatments. Physicians who practice aesthetic medicine in certain communities may not be experienced with the use of dermal fillers for facial lipoatrophy. For this reason, access to specialized care and services should be facilitated by nurses and/or other members of the health care team.

At the societal level, three levels of influence must be taken into account when providing care to people who suffer from facial lipoatrophy; (1) Federal and provincial regulators who are responsible for approving pharmaceutical drugs and dermal fillers for the treatment of facial lipoatrophy, (2) Federal and provincial laws, programs, and policies that determine which pharmaceuticals or products should be publicly insured and coordinate adverse reaction reporting, and (3) Pharmaceutical industry and dermal fillers manufacturers who are responsible for demonstrating the safety of their respective products, for price-setting and marketing, and for providing information and training to health care providers. More central to this practice brief is the second level – at this level, medical procedures associated with the use of these fillers are seen as elective aesthetic procedures and dermal fillers are defined as cosmetic rather than reconstructive. It should be noted that the approval of dermal fillers (level 1) for the treatment of facial lipoatrophy is not sufficient enough to secure access for people who suffer from this condition. Likewise, it should be noted that while pricing of pharmaceuticals or products (such as dermal fillers) plays a role in public programs and policies in the Canadian context, universal coverage of medically necessary care and treatment is a cornerstone of our health care system (Charles, Lomas & Giacomini, 1997). At the core of any debate regarding the coverage of reconstructive treatments for facial lipoatrophy is the assumption that these treatments are not medically necessary despite the fact that this condition is caused by antiretroviral combination therapy. This assumption should be challenged by nurses who are best positioned to advocate for the dignity of people who suffer from facial lipoatrophy and access to reconstructive treatments that can dramatically improve their lives.



