LIPODYSTROPHY

PEOPLE LIVING WITH HIV/AIDS
This protocol was created by STD/Aids Coordination of São Paulo City Health Department.

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SECONDARY AND TERTIARY PREVENTION OF LIPODYSTROPHY SYNDROME WITH PEOPLE LIVING WITH HIV/AIDS
The lipodystrophy syndrome consists in anatomical and metabolic alterations that can happen with any individual, though frequent in HIV positive individuals, especially those using Protease inhibitors and stavudine.

Anatomical alterations comprise:
• Facial lipoatrophy (facial fat loss);
• Fat loss from superior and inferior limbs, with prominent superficial veins;
• Fat loss in the hindquarters;
Associated or not with fat deposition in the abdomen, mainly due to visceral fat deposition, fat deposition in the posterior cervical region or fat deposition in the chest, both in men and women.

Metabolic alterations comprise:
• Seric increase of lipids;
• Peripheral resistance to insulin, resulting in Diabetes Mellitus.

The anatomical and metabolic alterations may be associated or not to progressive facial fat loss, due to the decrease of malar fat (Bichat's fat) and temporal and pre-auricular fats, which results in skin indentations with facial wrinkling, sunken areas and evidence of the bony framework.

From a subjective point of view, these alterations can result in self-esteem and self-image problems, considering that PVHA (people living with HIV/AIDS) confront stigmas, prejudice and discrimination. From the affective, social and professional points of view, these alterations can result in sociability damages, in problems seeking and maintaining relationships and in social and affective isolation attitudes
The facial filling procedure used with HIV/Aids carriers consists in the injection of a substance named polymethylmethacrylate (PMMA) into the skin, and looks after redeeming esthetic balance post-facial fat loss.

1- The decision to be subjected to facial fillings must be made by the user, after thorough discussions with the Multidisciplinary Technical team.
2- The most severe cases should have priority.
3- Severity must be analyzed in conformity to physical and psychosocial standards.

**Physical Standards**

Physical lesion evaluation is made according to the same parameter approved by Programa Nacional de DST/AIDS (STD/Aids National Program), named Facial Lipoatrophy Severity Index (ISLA) (Annex I) and elaborated by Dr. Luiza Keiko Matsuda Oyafuso and Dr. Marcio Serra.

ISLA consists in the evaluation of the affected area severity degree multiplied by the affected area extension in the 3 regions to be treated. This evaluation's result is then multiplied by a correction factor: each region has been assigned a specific correction factor, which corresponds to its importance degree to the Facial Atrophy. Finally, the 3 regions' grades are totaled in a final index.

The filling need is evaluated according to this index, and should only occur when ISLA is greater or equal to 6.

**Important Note:** Besides knowing that soropositive individuals with CD4 ≥ 350 and Viral Load lesser than 10,000 copies/ml present lower risk of complications, these two standards cannot be considered as excluding factors to Facial Filling. The exclusion should be a decision taken by the healthcare providers and the multidisciplinary team, who must considerate risks versus benefits for each specific case.
There are no fixed standards or rigid parameters to evaluate psychosocial suffering. The multidisciplinary team work is, in this matter, primary in seeking a broad approach to the users' health. Therefore, we have traced some guidelines based on experiences at the Ambulatório de Especialidades Dr. Alexandre Kalil Yazbek (Ambulatory of Medical Specialties Dr. Alexandre Kalil Yazbek), in partnership with NGOs Grupo de Incentivo à Vida (Incentive to Life Group) GIV São Paulo and Lutando Pela Vida (Fighting for Life) Diadema. This experience evolved to a partnership between the STD/Aids Coordination of São Paulo City Health Department and NGO Instituto Vida Nova (New Life Institute), through the creation of Malhação Vida Nova (Workout: New Life) project. Malhação Vida Nova aims to assist users (children and adults) sent by STD/Aids Specialized Facilities located in the city's East Zone in order to accomplish secondary prevention and harm reduction activities related to lipodystrophy, such as water aerobics, physical exercise, thematic workshops, acceptance of anti-retroviral medicine, nutrition and psychological support.

The following guidelines' aim is not only to help managers and health workers from STD/Aids Specialized Facilities to create activities with individual or group approaches, but also to instruct them to establish partnerships with local governmental establishments (Sport Centers, Socialization Centers, Educational Centers etc.), nongovernmental organizations and other local social institutions.

**Guideline 1**

**User preference due to facial filling procedure orientation**

After multidisciplinary team discussions which should consider not only physical damage evaluation in outcome of tissue loss, but also social, professional, affective and sexual losses, the specialized facilities may instruct users to facial filling procedures. Those cases where fatty tissue loss is not severe must also be considered, when related to social isolation attitudes and psychological suffering such as:
- avoidance of social interaction;
- avoidance of using public transportation;
- avoidance to carry daily activities which imply in self-exposure;
- embarrassment;
- anguish;
- insomnia;
- deep sorrow;
- worthless self-image;
- low self-esteem;
- death thoughts or wishes.
Guideline 2
Important information on users' care

The following aspects should be observed and informed to the users, taking into consideration their expectations and comprehension possibilities:
- facial filling is permanent;
- there are risks of drug interactions;
- one or more new sessions might be necessary;
- nutrition, chewing and swallowing should be observed;
- facial and physical exercises are important;
- mouth hygiene is important.

Guideline 3
Dealing with expectations and feelings

Considering that facial lipoatrophy is a process that can considerably alter someone's image, which in turn can reflect directly on identity matters, it is crucial that the team approaches aspects concerning idealizations, fantasies, taboos, stigmas and other related feelings.

As for image, it is important to highlight that facial filling does not grant image recovering to conditions prior to fat loss or ageing. It is a harm reduction procedure, therefore a tertiary prevention action with patients living with HIV/Aids.

Guideline 4
Group assistance

All actions related to HIV/Aids carriers' acceptance to treatment and services is a process which requires health workers' persistence and comprehension of the objective/subjective underlying factors. Constant dialogue and respect to human diversity are principles to guide the actions. We emphasize that in lipodystrophy prevention/treatment, group activities can provide excellent opportunities to share experience and ideas.

We recommend the maintenance of permanent spaces for reflection activities on lipodystrophy and other subjects related to life quality/health of people living with HIV/Aids.

It is highly recommended that the group sessions at the Orientation Facilities take place during all the user's assistance period, which comprehends pre and post-facial filling.
1. The candidate to facial filling will be identified in his original facility. Thus, the multiprofessional team assisting him must evaluate the most serious cases, according to physical and psychosocial standards.

2. The original facility, that is, the Orientation Facility, must observe the inclusion and exclusion technical criteria and fill out the Orientation Form (Annex II).

3. The Orientation Facility must contact the Facial Filling Reference Facility by phone, to check agenda possibilities. The user should only be oriented after vacancy confirmation.

4. The Reference facilities must fill out a plan (weekly at first) with suggested user's information, which should be then sent to the STD/Aids Coordination of São Paulo City Health Department.

5. The vacancies conceded by the Reference facilities do not necessarily grant that the Facial Filling procedure will be carried out. This should only be put to effect after proper evaluation by the Dermatologist or Plastic Surgeon in charge. After the facial filling procedure, the user must send a Return Orientation Form to his original facility's Orientation team (Annex III).


7. The user must be absolutely aware of his resolution, under the responsibility of the Orientation Facility.

8. All procedures will be registered with photographs, which are to be filed in a medical record (Annex V).

9. These technical guidelines are subject to alterations.
### FACIAL LIPOATROPHY SEVERITY INDEX (ISLA)

#### SCORE DEPTH (P)

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#### SCORE AREA

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#### REGION

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<th>TEMPORAL (T)</th>
<th>PRE-AURICULAR (A)</th>
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#### DEPTH

#### SCORE AREA

#### DEPTH X AREA

\[(\ ) \times 0.7 = (\ ) \times 0.2 = (\ ) \times 0.1 =\]

\[M[\ ]\]

\[T[\ ]\]

\[A[\ ]\]

\[M+T+A= TOTAL:\ [\ ]\]
FACIAL FILLING: ORIENTATION FORM

ORIENTATION FACILITY______________________________________________________________

REFERENCE FACILITY______________________________________________________________

USER NAME__________________________________________________________

NAME OF CHOICE__________________________________________________________

AGE___________       SEX_____________     REGISTER NUMBER_____________________________

CLINICAL INFORMATION

1. DIAGNOSIS:________________________________________________________________________

2. OPPORTUNISTIC INFECTIONS (OIs) IN COURSE:        (  ) YES             (  ) NO
   WHICH ONES?__________________________________________________________________________

3. PRESENCE OF FACIAL CUTANEOUS LESIONS:      (  ) YES              (  ) NO
   WHICH ONES?__________________________________________________________________________

4. ALLERGIES:       (  ) YES              (  ) NO
   WHICH ONES?__________________________________________________________________________

5. AUTOIMMUNE DISEASES: (  ) YES             (  ) NO
   WHICH ONES?__________________________________________________________________________

MEDICATION IN USE:

ANTIRETROVIRAL THERAPY:____________________________________________________________

OTHER MEDICATION:__________________________________________________________________

USING ORAL OU INJECTABLE ANTICOAGULANTS:
(   ) YES                                     (   ) NO

EXAM RESULTS:

CD 4 : _________________            DATE: ___/___/______

VIRAL LOAD _____________           DATE: ___/___/______

COMPLETE BLOOD COUNT: (PLATELETS):_________________________________________________

_____________________________________________

DATE:___/___/______

COAGULOGRAM:_____________________________________________________________________

DATE: ___/___/_____ 

BHCG: _____________________________________________________________________________

DATE: ___/___/_____ 

Stamp/Signature

MULTIDISCIPLINARY TEAM INFORMATION

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

_________________________________________________________________________________

Date: ___/___/______

___________________________________
Stamp/Signature
FLOWCHART

SUPPORT GROUPS

ORIENTATION FACILITY
FACIAL FILLING REFERENCE FACILITY
MULTIDISCIPLINARY TEAM/DERMATOLOGIST/PLASTIC SURGEON AGREEMENT
INFORMED TERM OF AGREEMENT
FACIAL FILLING WITH POLYMETHYLMETHACRYLATE

I, __________________________________________ (user name), below identified and committed, declare to have been clearly informed about all indications, contraindications, main side effects and risks concerning to the polymethylmethacrylate application, recommended to treat facial lipoatrophy related to the side effects of antiretroviral therapy.

The medical terminology has been explained and all my doubts were made clear by doctor _____________________________________ (name of the prescribing doctor).

I also express my agreement and spontaneous wish to submit to the referred treatment, assuming any responsibility and possible undesirable risks.

Therefore, I declare:

That I was clearly informed that the procedure to which I submit myself may have the following benefit:

• Facial Lipoatrophy (resultant from Antiretroviral Therapy side effects) Reduction.

I was also clearly informed about all potential side effects, contraindications and risks concerning to this procedure:

• There are no studies related to this medication usage during pregnancy, breastfeeding or risks to the infant;
• The implant is permanent and has immediate and long term results;
• Despite being permanent, other facial areas can evolve to lipoatrophy due to the continuity of treatment with antiretroviral medication;
• To achieve complete correction, more than one session might be necessary;
• The most common reactions are erythema and edema formation. Other local reactions may include: granulomas, papulae, acne, hardening and painful sensations. Cases of tissue infection and necrosis are rare;
• Contraindicated in cases of hypersensitivity (allergy) to the drug or any other formula ingredients. Allergic antecedents of any nature must be evaluated;
• The procedure may not be realized during the occurrence of treatment with anticoagulants due to risk of bruising and/or hemorrhages;
• The polymethylmethacrylate filling must be performed with caution in the cases of previous treatment with other definitive and/or unknown material and in cases of antecedent autoimmune disease;
• In cases of active cutaneous lesions (viral, bacterial or fungal), the treatment must be postponed until complete cure;
• The procedure is contraindicated during the occurrence of opportunist infections;
• Some kind of discomfort or painful feeling might occur during the procedure, even with the application of ice compresses and topical anesthetics.

I am aware I may suspend the treatment at any time, and that this act will not cause any kind of embarrassment between me and my doctor.

I authorize the Ministry of Health and Health Secretariats to make use of any information concerning my treatment, as long as anonymity is preserved.

I finally declare to have understood and agreed with all terms of this Informed Agreement.

Therefore, I accept it by free-will and conjoint decision with my doctor.
User name: ________________________________________________________________

ID number:______________________________________________________________

Sex: Male ( ) Female ( ) Age:

Address:_________________________________________________________________

City:_______________ Zip Code:_____________ Telephone: (   ) _________________

Legal responsible (if necessary): ____________________________________________

Legal responsible ID number: ______________________________________________

User or legal responsible signature __________________________________________

Responsible Doctor: _____________________________ CRM: _____ State: _______

Address:_________________________________________________________________

City: _______________ Zip Code: ____________ Telephone: (   ) ________________

Doctor signature and stamp: ________________________________________________

Place and date: __________________________________________________________

Comments:

1. The complete filling of this Term and its respective signature are indispensable for realizing the procedure.

2. Two copies of THIS TERM must be filled out one to be filed in the user's Medical Record, and the other one to be kept with the user.
Annex IV

RETURN FORM: FROM REFERENCE FACILITY TO ORIENTATION FACILITY

Procedure: facial filling

FROM REFERENCE FACILITY: ________________________________

TO ORIENTATION FACILITY: ________________________________

USER NAME: ________________________________________________

NAME OF CHOICE: ____________________________________________

AGE: ______________________________________________________

REGISTER NUMBER: _________________________

SEX: _______________________________________________________

Procedure technical information
______________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Multidisciplinary team information
______________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Comments

Date ___/___/____   Signature/Stamp______________________________
TERM OF AGREEMENT

I authorize the Health Facility ____________________________ to follow-up the results of the facial lipodystrophy treatment (filling with polymethylmethacrylate) to which, I, __________________________________________________________________, will be submitted, performing to this purpose photographic registers of each phase pre, during and post-treatment, which will integrate my Medical Record.

São Paulo, _________________________

_________________________________
User signature
BIBLIOGRAPHIC REFERENCES


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