



# 6th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV

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## PROSPECTIVE, PARTIALLY RANDOMIZED, 24-WEEK STUDY TO COMPARE THE EFFICACY AND DURABILITY OF DIFFERENT SURGICAL TECHNIQUES AND INTERVENTIONS FOR THE TREATMENT OF HIV-RELATED FACIAL LIPOATROPHY

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**BACKGROUND:** Autologous fat transfer (AFT) surgery and injection of reabsorbable or non-reabsorbable material into the lipoatrophic areas of the face are the only available treatment for HIV-related facial lipoatrophy. Comparisons between treatment approaches have been limited.

**METHODS:** This is a prospective, multicentre, partially randomized study. Patients with facial lipoatrophy received AFT if residual truncal subcutaneous fat was present as a source of fat graft, otherwise they were randomized to receive filler injections in the cheeks with reabsorbable polylactic acid (PLA) or non-reabsorbable polyacrylamide (PAC). Ultrasound evaluation was used to assess subcutaneous thickness; Visual Analogue Scale (VAS) was utilized to evaluate patient satisfaction. Subjects were followed for 24 weeks following end of treatment.

**RESULTS:** 59 patients were evaluated: AFT (24), PLA (20) and PAC (15). The groups were well balanced for clinical, HIV-related variables, ultrasound measured thickness of cheek fat and VAS measurements. PLA and PAC groups received  $5 \pm 1$  and  $6 \pm 2$  injections, respectively. Six months after end of treatment, VAS had increased in the AFT group from  $24.7 \pm 16.4$  to  $70.2 \pm 21.9$ ,  $P=0.000$ ; in the PLA group from  $20 \pm 20$  to  $82.8 \pm 16.7$ ,  $P=0.001$ ; and in the PAC group from  $25.3 \pm 21.7$  to  $82.8 \pm 17.1$ ,  $P=0.000$ . ANOVA did not show any statistically significant differences among the three groups either for VAS variable ( $F=1.287$ ,  $P=0.288$ ) or for delta thickness of dermal plus subcutaneous layer measured with ultrasound ( $F=0.59$ ,  $P=0.55$ ). Overall cheek thickness increased by a

mean of  $6.4 \pm 7.6$  mm. There was no statistically significant difference in number of injections necessary to reach a satisfactory result (evaluated both by surgeon and patients) between the PLA and PAC groups,  $P=0.083$ . No serious adverse events were observed in the sample.

**CONCLUSION:** All three interventional techniques were highly effective in improving the aesthetic satisfaction of the patients. There were no significant differences in subjective objective variables among the three study arms. Longer follow-up is necessary to discriminate the most suitable treatment in terms of durability.

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