## Experiences over 11 years subcutaneous testosterone implants in hypogonadal men

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## Congress Abstract

Testosterone pellets seem to be an androgen formulation with a long biological action and a strong pharmacodynamic efficacy. We performed this investigation to establish detailed data about the pharmacokinetics, the efficacy and side-effects of subcutaneously implanted testosterone (T) pellets in a single center between 1994 and 2005. In an open-label, non-randomized study, 6 T-pellets, each containing 200mg of fused crystalline T, were implanted in the subdermal fat tissue of the lower abdominal wall of 100 hypogonadal men over 5 years. All patients (mean age  $39.7\pm13.4 \text{ yr}$ ; BMI  $28.1\pm5.6\text{kg/m}^2$ ; T <4.7 nmol/l; mean±SD) suffered from primary (n=34) or secondary hypogonadism (n=66). Blood samples for determination of T, hemoglobin, PSA, lipid parameters and bone mineral density (BMD) at the lumber spine 2–4 were obtained over 5 years. T kinetics was revealed over 7 months after implantation. The pharmacokinetic study in 100 hypogonadal men revealed an initial short-lived burst release of T with a peak concentration of 25.5±8.9 nmol/l after 2 months which was followed by a decline after 4 months (14.7±6.7 nmol/l), 5 months (11.8±5.8 nmol/l), 6 months (7.8±3.2 nmol/l) and 7 months (5.5±3.0 nmol/l). After a period of 5 years hemoglobin (14.6±1.6 to 15.1±1.3g/dl; p=0.03) and BMD of the lumbar spine 2–4 (1090±175 to 1263±203g/cm<sup>2</sup>; p=0.003) increased. PSA (1.12±1.0 to 0.76±0.64 ng/ml; p=0.16), total cholesterol, HDL, LDL and triglycerides did not changes. The only side-effects observed during 1100 implantations in the total group were 20 local infections (1.8%) and the extrusion of 82 pellets.

In conclusion, subcutaneous testosterone implants in hypogonadal men revealed a well tolerated treatment and should be performed with an interval of 5 months. After 5 years bone mineral density increased without changes of lipid parameters and PSA. After launch of the 3-months-injection with testosterone-undecanoat, testosterone pellets were less implanted.