A new testosterone transdermal delivery system, TDS®-testosterone, is superior to existing transdermal preparations in healthy males.

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Testosterone replacement therapy is problematic because oral testosterone is substantially metabolised by the liver. Other routes of testosterone replacement include intramuscular, implantation and transdermal. We reported a pharmacokinetic study of a new transdermal formulation to deliver testosterone. The TDS®-testosterone preparation is a solution which can be applied on the skin via a metered pump spray. The concentration of testosterone is five-fold greater than a commercially available topical testosterone preparation (Androgel®, 1% topical testosterone gel). An open label, comparative, randomised placebo-controlled study involving three topical treatments was conducted in twelve healthy male subjects: 50 mg TDS©-Testosterone (5% solution); 50 mg Androgel® (1% gel); and, TDS®-Placebo. Blood samples were obtained at baseline and then multiple time points after application and assayed for serum testosterone [Chik et al, Br. J. Clin. Pharm. In press 2006]. In this abstract, we report a further pharmacokinetic analysis of these data. The data were corrected using three methods: 1) the mean of the pre-treatment testosterone levels at t=-0.5-h and t=0 was subtracted from each post-dose value; 2) endogenous testosterone levels were modelled from the placebo data using a polynomial equation and subtracted from the measured treatment values; 3) testosterone concentrations on the placebo day were subtracted from the active treatment day concentrations. The largest difference was seen with method 1: TDS©-Testosterone, mean corrected area under the curve from 0 to 12 hours (corrAUC) 7.47 ng/ml.h and maximum corrected testosterone concentrations (corrCmax) 1.69 ng/ml compared to Androgel, corrAUC 2.57 and corrCmax 1.09. Similarly, the other correction methods showed higher values for TDS©-Testosterone: method 2, corrAUC 13.61, corrCmax 2.42, versus corrAUC 9.98, corrCmax 1.87; and method 3: corrAUC 13.86, Cmax corr2.88, versus corrAUC 10.65, corrCmax 2.48. Thus, data corrected for baseline or endogenous serum testosterone concentrations showed increased testosterone profiles for TDS®-Testosterone compared to Androgel, corrAUC by 36 to 190% and corrCmax by 29 to 55%, depending on the method of correction. We conclude that the TDS®-Testosterone preparation can deliver testosterone systemically in healthy males more effectively than an existing topical delivery gel, and in a smaller and more convenient volume of solution.