

A Prospective Randomised Double-Blind Dose-Comparative Clinical Investigation Evaluating Skin Mechanical Property Alterations after Botulinum Toxin Type a Injections for the Treatment of Forehead Rhytides

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INTRODUCTION: Few insights into the mechanical properties of skin have been made, and clinical evidence regarding the outcomes of interrupting the cholinergic system in human skin remains lacking.

Objectives: We prospectively investigated the alterations in the mechanical properties of the skin of patients who received intramuscular injections of botulinum toxin A (BTX-A) for forehead rhytides and compared two injection doses.

MATERIALS AND METHODS: Of the 42 enrolled patients, one randomly assigned half received intramuscular injections of two units (group I), and the other half received four units (group II) of BTX-A in each injection point. The baseline and post-treatment skin mechanical parameters, including gross elasticity (R2), net elasticity (R5), viscoelastic ratio (R6) and biological elasticity (R7), were measured using the Cutometer® and compared.

Results: Treatment with BTX-A resulted in significant overall alterations in the mechanical properties of skin at the injection sites of both treatment groups during the 16-week period, and no significant differences were observed between groups. Significant decreases in biological elasticity, net elasticity and viscoelasticity properties were observed at two weeks follow-up and began to recover at that time. All of the skin mechanical properties recovered to baseline levels by 16 weeks of follow-up in both dosage groups, which indicates that the higher dosage (4 units) did not delay relapse compared to the two-unit dosage.

CONCLUSION: We concluded that intramuscular injections of BTX-A significantly regulated the gross elasticity, net elasticity, functional elasticity and viscoelastic elasticity at the injection point over a radius of 1.5 cm at two weeks, four weeks and eight weeks follow-up. The potency had completely diminished by the 16-week follow-up.

REFERENCES:

1. Kurzen H, Schallreuter KU. Novel aspects in cutaneous biology of acetylcholine synthesis and acetylcholine receptors. *Exp Dermatol* 2004;13:27–30.
2. Xiaoxue W, Xi C, Zhibo X. Effects of botulinum toxin type A on expression of genes in keloid fibroblasts. *Aesthet Surg J*. 2014 Jan 1;34(1):154-9.

FIGURE LEGEND:

Figure 1. The injection points and diffusion areas

Table 1. Patient characteristics