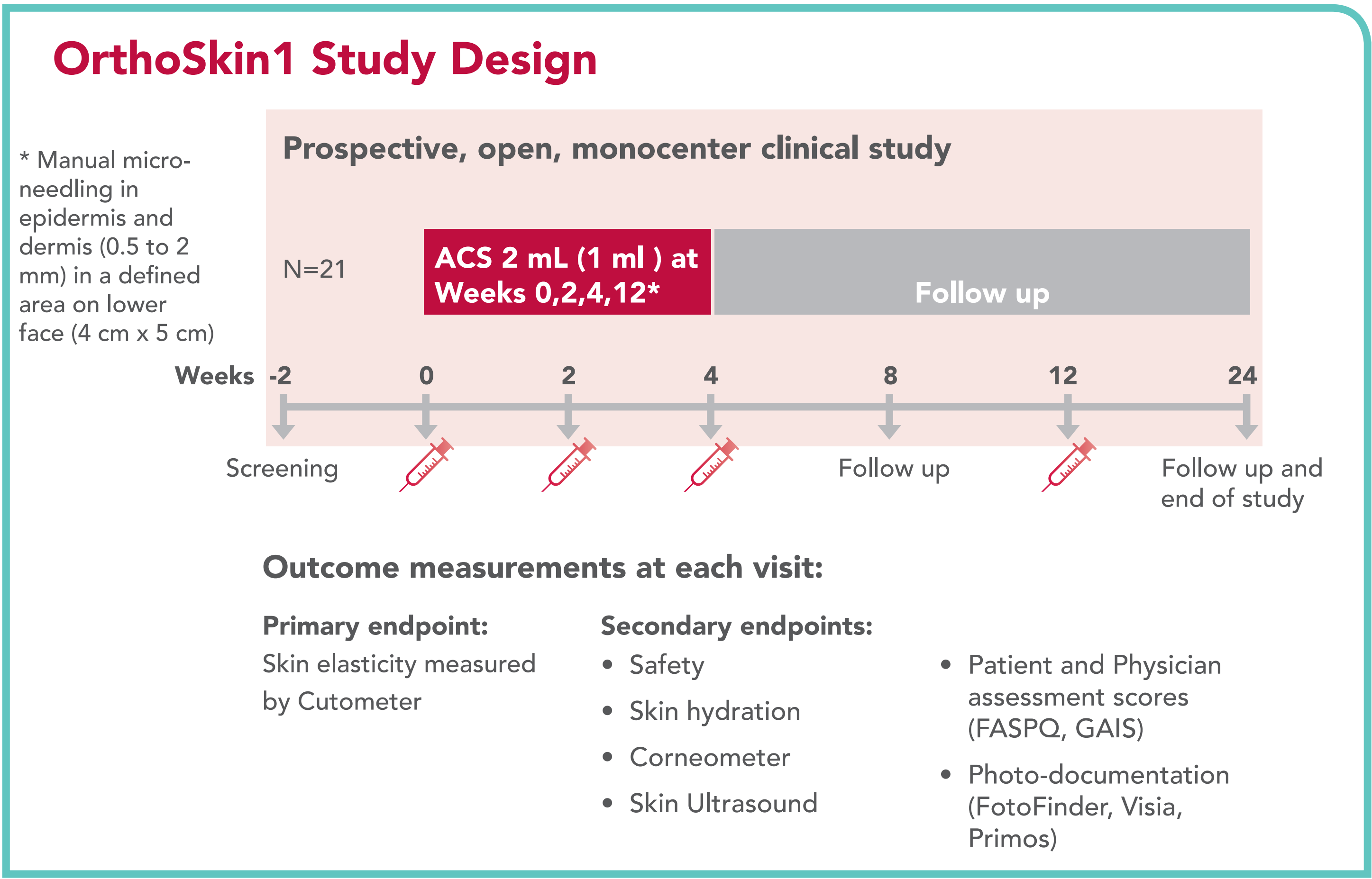


Cell-free Autologous Conditioned Serum (ACS) improves skin elasticity: Results of an Investigator Initiated Clinical Trial OrthoSkin I

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Background

The therapeutic safety and efficacy of ACS has been shown in controlled clinical trials for knee osteoarthritis and lumbar radiculopathy¹. ACS's efficacy has been ascribed to increased levels of anti-inflammatory cytokines and growth factors (e.g. TGF- β , IGF1, IL-1Ra), achieved through incubation - which distinguishes ACS from PRP². Increase of collagen type I has been shown histologically in animals treated with ACS³. Skin damage due to extrinsic factors increases oxidative stress, which leads to a reduced TGF- β level and collagen neosynthesis in skin^{4,5}. We hypothesized that substitution with autologous TGF- β in ACS may increase skin elasticity and have a rejuvenative effect.

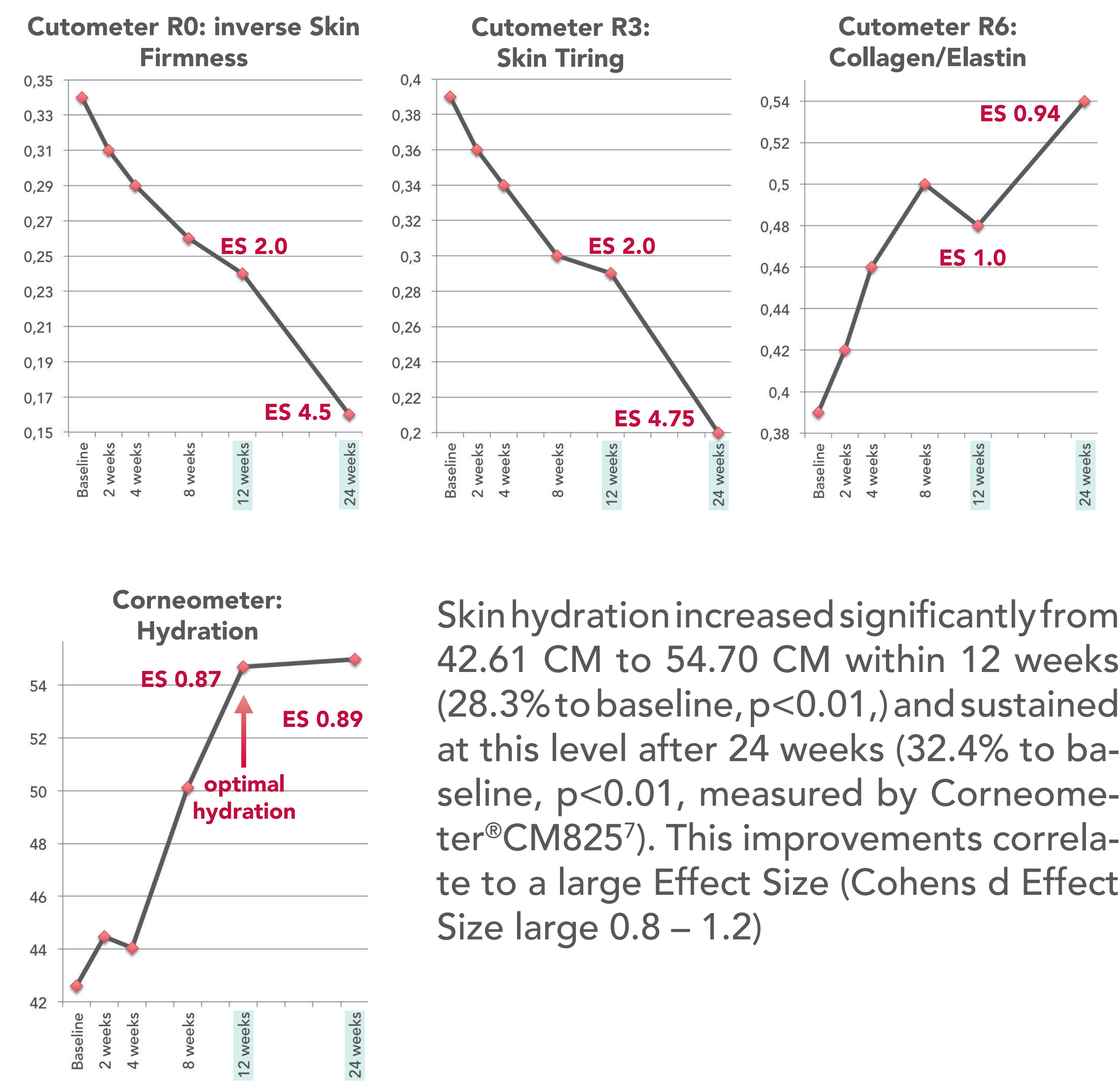
Methods

21 female patients (age 35-55) with reduced facial skin elasticity were treated via manual micro-needling with cell-free ACS in four sessions at day 0, after 2, 4 and 12 weeks in an open, monocenter, prospective 24 weeks clinical trial approved by the ethical committee. The primary endpoint was skin firmness and elasticity measured by Cutometer[®] after 12 and 24 weeks. Validated questionnaires and skin hydration were secondary parameters. All measurements were performed under standardised conditions. Safety has been evaluated at each visit.

Results

Changes in skin characteristics measured by Cutometer[®] and Corneometer[®]

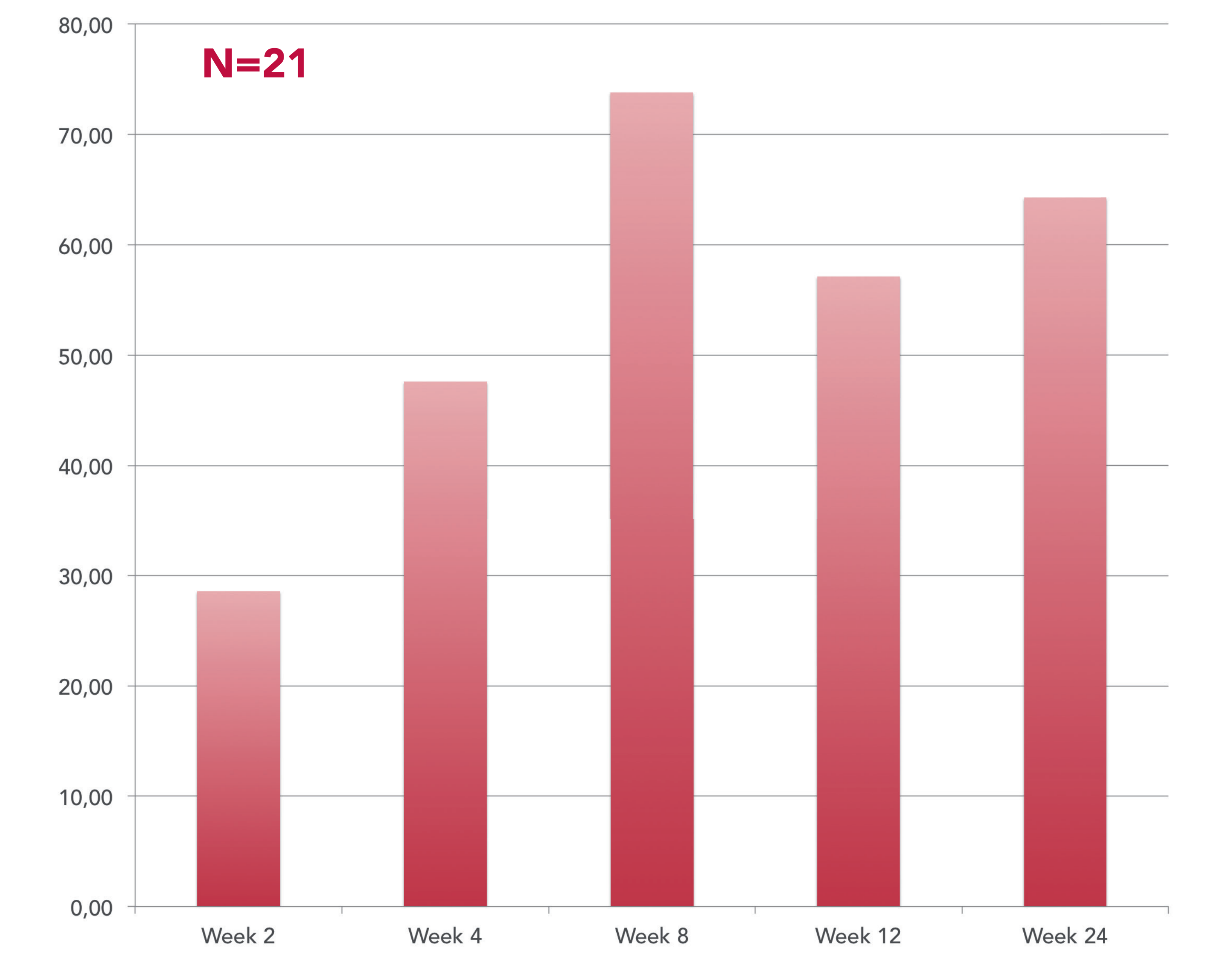
Skin firmness (R0) improved with a very large Effect Size (ES) at week 12 (2.00) and increased to a huge ES at week 24 (4.50, measured by Cutometer[®] dual MPA 580). The increased skin elasticity was confirmed with reduction of skin tiring measurements shown in R3 parameter. R6 parameter showing collagen / elastin ratio increased with a large ES and was consistent at week 12 and 24 (1.0 and 0.94).



Effekt Size: ES, Cohens d Effect Size is expressed as small (0.2 – 0.5), medium (0.5 – 0.8), large (0.8 – 1.2), very large (1.2 – 2.0), huge (> 2.0).

Patient-Reported Outcomes: Global Aesthetic Improvement Scale (GAIS)

Patient's satisfaction with the treatment has been assessed at every visit using the Global Aesthetic Improvement Scale (GAIS). Increasing number of patients expressed aesthetic improvements over the time, reaching a level of 73.8%.



Conclusions

- Cell-free ACS treatment leads to significant increase in skin elasticity quantified by Cutometer[®] and coincides with increase in hydration of the skin after 12 and 24 weeks.
- The significant increase in skin firmness which was confirmed by high reduction of skin tiring may be caused through increase of collagen type I in the ACS treated skin.
- Quantitative improvements were confirmed by patient's self-perception questionnaires.
- No adverse events besides small transient hematomas were observed in the study
- ACS has the potential to be the first cell-free biological skin enhancer from patient's own blood. Further clinical investigations are ongoing for better understanding of the underlying mechanisms.

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Disclosures

M. Kerscher: Consultancy to ORTHOGEN AG at the Skin Advisory Board.
D. Nachtweide: No conflicts.
Drabik: Consultancy to ORTHOGEN AG.
T. Kaptan: Employee of ORTHOGEN AG.

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