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## ***Skin elasticity and regional differences using instruments: implications for clinical trials***

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### **1. Introduction**

Skin ageing is inevitable in the life of human beings, leading to several undesirable features such as loss of elasticity [1]. Several skin care routines have been developed and marketed to either slow the rate at which this phenomenon happens, or reverse the process. These range from traditional skin care practices to advanced treatment regimens involving the use of drugs and technological advances [2-4]. But to confirm such efficacy claims in clinical studies, one of the main challenges remains the use of reliable and objective evaluations [5]. This need is driven by increased legislative demands in terms of evidential support, as well as a better informed consumer market [6].

Coupled with clinical assessments, instrumental measurements are more frequently being adopted as part of the methodologies in the clinical trials; the industry strongly advocates for these methods given the sensitivity and objectivity of such techniques [7]. A skin elasticimeter is commonly employed in clinical studies to assess the anti-ageing claims for cosmeceuticals. However, there is still a need to further understand the behaviour of the skin elasticimeter readings on various areas of the body, given inherent biological differences and exposure to environmental conditions [8].

In a study among Korean women, Ryu et al. [9] reported regional body differences in terms of several parameters derived from Cutometer measurements, a commonly used elasticimeter [10]. The degree of correlation between age and derived readings from the Cutometer measurements varied considerably depending on the body part investigated. Overall elasticity ( $U_a/U_f$ ) and the ratio of immediate recovery to total deformation ( $U_r/U_f$ ) had substantially higher levels of correlation with age on the face. In a relatively similar study [8], but with a more important sample size ( $n=120$ ), the same parameters correlated more strongly with age on the cheek, forearm, and neck.

When assessed in a population of 50 healthy Iranian volunteers [11], the skin surrounding the neck area was found to be the most elastic, while the leg was the least elastic. Ishikawa et al. [12] reported higher elastic properties on the chest compared to the

finger, hand and forearm, in a clinical trial conducted in Japan involving 191 healthy individuals. In another study among Korean females [13], the neck was found to be more elastic than the forearm and cheek.

This study thus further explores the regional differences on the body in terms of skin elasticity, measured with a Cutometer, in a multi-ethnic population. Building on previous literature on the topic and a novel clinical study, it guides the conduct of prospective clinical trials by contrasting age related differences on various body sites, and the choice of sensitive parameters.

## 2. Materials and Methods

In this single center, open and intra-individual study, the skin elasticity for  $n=298$  participants was measured using a skin elasticimeter, namely the Cutometer Dual MPA 580 (Courage Khazaka Electronic GmbH, Cologne, Germany) with a 2mm diameter probe at constant 300mbar suction. Evaluations were done on a single day, under controlled environmental conditions, bare skin, on three zones of interest: the face, thigh and forearm. All subjects provided informed consent, and the study was approved by an Independent Ethics Committee (IEC).

Only the following relative parameters were of interest in this study: Ua/Uf (overall elasticity), Ur/Ue (pure elasticity), Ur/Uf (ratio of elastic recovery to total deformation), and Uv/Ue (ratio of viscoelastic to elastic extension).

Numerical values were summarized using the mean and standard deviation, while categorical variables using frequencies and percentages. The formal comparison of anatomical sites was performed, by parameter, and using a one-way ANOVA, after verification of underlying assumptions, including normality and homogeneity of variances.

## 3. Results

The studied panel comprises mostly female subjects (83.6%,  $n=249$ ). The majority were of phototypes IV to V (89%,  $n=265$ ), a greater portion of them categorised as having a mixed race (56.7%,  $n=169$ ).

On the face, Ua/Uf differed considerably between age categories; averages dropping systematically from 0.890 in the youngest group to 0.700 in the oldest (Table 1). Similar observations were noted in terms of Ur/Ue and Ur/Uf; elastic properties reduced in a linear fashion when moving from upper to lower age categories.

On the forearm, Ua/Uf differed substantially only when comparing the top three to the last two age categories (means of 0.904, 0.895 and 0.882 compared to 0.828 and 0.834 respectively). Ur/Ue showed limited discrimination between the 26-35 and 36-45 age categories, but fairly captured the differences between the other age groups. Ur/Uf decreased systematically with age, with an approximately constant magnitude of reduction.

On the thigh, the youngest two categories were able to distinguish themselves from the last three in terms of Ua/Uf, yielding mean values of 0.925 and 0.922 compared to 0.879, 0.877 and 0.874 respectively. Similarly, for Ur/Uf, the means for the top two categories were relatively close, compared to the values for the bottom three categories. On the other hand, Ur/Ue tended to display a relatively linear reduction when shifting from the younger to older age categories.

The ratio of elastic recovery to total deformation (Uv/Ue) demonstrated an increasing trend from the 18-25 group to the older groups. However, beyond 36-45, on the face,

the mean values appeared to stabilize or decrease. This observation is true on the forearm, and the thigh as well, except that the shift occurred beyond the age group of 46-55.

**Table 1:** Comparison of anatomical sites, by parameter and age group.

N=298			Age				
			18-25 (n=48)	26-35 (n=93)	36-45 (n=85)	46-55 (n=43)	56+ (n=29)
Ua/Uf	Face	Mean	0.890	0.831	0.802	0.767	0.700
		SD	0.070	0.101	0.117	0.118	0.139
	Forearm	Mean	0.904	0.895	0.882	0.828	0.834
		SD	0.084	0.068	0.078	0.095	0.083
	Thigh	Mean	0.925	0.922	0.879	0.877	0.874
		SD	0.096	0.168	0.120	0.114	0.152
	<i>p</i> -value		0.122	<0.001	<0.001	<0.001	<0.001
	Face	Mean	0.945	0.834	0.795	0.670	0.582
		SD	0.107	0.148	0.176	0.171	0.181
	Forearm	Mean	1.068	1.016	1.012	0.956	0.879
		SD	0.149	0.138	0.181	0.201	0.139
Ur/Ue	Thigh	Mean	1.020	0.995	0.958	0.983	0.903
		SD	0.202	0.173	0.256	0.259	0.197
	<i>p</i> -value		0.001	<0.001	<0.001	<0.001	<0.001
	Face	Mean	0.302	0.321	0.367	0.344	0.367
		SD	0.116	0.171	0.166	0.102	0.165
	Forearm	Mean	0.322	0.325	0.371	0.397	0.372
		SD	0.131	0.119	0.149	0.170	0.093
	Thigh	Mean	0.310	0.315	0.375	0.427	0.382
		SD	0.154	0.183	0.239	0.233	0.149
	<i>p</i> -value		0.759	0.917	0.970	0.092	0.918
Uv/Ue	Face	Mean	0.730	0.641	0.590	0.501	0.436
		SD	0.100	0.132	0.142	0.136	0.156
	Forearm	Mean	0.812	0.767	0.741	0.683	0.644
		SD	0.093	0.084	0.114	0.111	0.111
	Thigh	Mean	0.781	0.771	0.705	0.692	0.659
		SD	0.117	0.144	0.158	0.155	0.155
	<i>p</i> -value		0.001	<0.001	<0.001	<0.001	<0.001
	Ur/Uf						

#### 4. Discussion

Ageing manifests across all organs, with the earliest signs often visible on the skin [14]. The changes in skin appearance, including elasticity, are not homogenous across all body parts. Despite considerable attempts to document skin ageing features using elasticimeters on different body sites, some patterns yet remain to be uncovered. This study strengthens past findings documented in the literature, extending the

generalisability of the findings to populations with a more diverse demography, while focusing on the most popular relative parameters Ua/Uf, Ur/Ue, Ur/Uf and Uv/Ue.

Ua/Uf, convincingly sensitive to age [7,8] tends to exhibit a linear diminishing pattern when moving from lower to upper age categories on the face. But on the forearm and thigh, the top and bottom two or three categories produced relatively similar values. This aligns very much with the previous findings from Krugger *et al.* [7], except that the linear fashion was less obvious when shifting age categories in non-facial areas. This pattern is relevant in clinical trials, in the sense that in a study for anti-ageing efficacy claims, only minimal changes are likely to be observed on these non-facial sites, to the extent of not achieving significance for low sample sizes. It is worth noting that the facial skin does not posit itself as the area with highest levels of elasticity [14], despite its ability to discern more easily between age groups.

Similarly, Ur/Ue, representing pure elasticity, showed comparable results to Ua/Uf on the facial skin. Implying that this parameter recorded consistent reduction when shifting from younger to older individuals on the face, even if the change differed in terms of magnitude when compared to Ua/Uf. This trend was also true on the thigh. However, on the forearm, Ur/Ue was less sensitive to differences between the two younger groups, though it effectively distinguished among the older individuals, corroborating prior findings [8].

Ur/Uf reduced systematically from lower age groups to the upper ones, both on the face and the forearms. This finding matches with Cua *et al.* [15], suggesting that the differences are primarily attributable to alterations to the elastic fiber network. However, on the thigh, the same parameter did not effectively demarcate between adjacent age groups found at the extremities, even when separated by a decade.

The ratio of viscoelastic to elastic extension (Uv/Ue) should be interpreted with caution, since the change observed when shifting from one age group to another exhibited a curvilinear behaviour, with specificities within each region of the body. On the face, the highest average Uv/Ue was recorded within the 36-45 age group, compared to the 46-55 group for the non-facial sites. Thus, the corresponding results have to be interpreted both depending on the age group being studied and the anatomical location.

## 5. Conclusion

It is expected that in a prospective clinical study aimed to evaluate the anti-ageing efficacy of skin care products on the face, all relative parameters would exhibit a relatively similar linear behaviour with age, except Uv/Ue. On the thighs and forearms, the upper and lower age categories tend to cluster in terms of the relative parameters, in particular, Ur/Ue and Ur/Uf, implying that no significant differences would be expected for products with only moderate efficacy. Detectable differences, if any, will be obvious only for treatments capable of setting back the skin elasticity features by 10+ years, with higher chances of success when enrolling participants from the older groups.

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