Measurement of soft tissue deformation at discomfort and pain threshold in different regions of the head

Parth Shah [1,2]
[1] School of Design, The Hong Kong Polytechnic University, Hong Kong Special Administrative Region.
[2] Laboratory for Artificial Intelligence in Design, Hong Kong Science Park, New Territories, Hong Kong Special Administrative Region.

Yan Luximon* [1,2]
[1] School of Design, The Hong Kong Polytechnic University, Hong Kong Special Administrative Region.
[2] Laboratory for Artificial Intelligence in Design Hong Kong Science Park, New Territories, Hong Kong Special Administrative Region.

Ameersing Luximon [3]
[3] EMEDS Ltd., Hong Kong Special Administrative Region.

Abstract

Understanding of product-soft tissue interface and related discomfort is essential while designing wearable devices. Although pressure thresholds at the perception of discomfort and pain have been measured in the past, associated tissue deformation are yet to be studied. This data can provide a holistic understanding of user discomfort and be a valuable reference for ergonomic product design. Hence, in the current study, tissue deformation at discomfort and pain threshold was measured using an ultrasound indentation device at eighteen landmarks for sixty Chinese adults on the head and face. Results show that deformation was higher in the facial region than the scalp and forehead, with maximum deformation in the cheek area and minimum in the forehead region for both thresholds. Also, for most landmarks, the tissue deformation data showed no significant relationship with age and Body Mass Index (BMI). Nearly half of the landmarks exhibited significant gender-based differences. Overall, the measured data showed acceptable within-session and between-session reliability.

Keywords: Human head, anthropometry, soft tissue deformation, discomfort, pain.

Practitioner Summary: In this study, tissue deformation was measured in different head regions for discomfort and pain thresholds, and corresponding deformation maps were developed. Measured tissue deformation data showed no significant relationship with BMI and age. This data can be a useful reference in product design, testing, and evaluation of headgears.

1. Introduction:

In product design, ergonomics and human factors play a significant role as they throw light on users' capabilities and limitations and can, thus, help designers to make necessary modifications in the product design to improve and enhance user experience (Chapanis, 1995; Sagot, Gouin, & Gomes, 2003; F. Zhang, Yang, & Liu, 2014). Wearable products related to the head and face, which perform functions like protection or are used for healthcare purposes, need to have a close fit with the corresponding soft tissue surface to ensure they perform their required functions effectively (Shah & Luximon, 2018). The close fit of the product may result in the application of some pressure in the contact region, leading to soft tissue deformation in that region. Several studies(De Looze, Kuijt-Evers, & Van Dieen, 2003; Helander & Zhang, 1997; Vink & Hallbeck, 2011) have suggested discomfort to be primarily associated with physical attributes. Hence, it is imperative to understand the product-soft tissue interface to understand user discomfort, to design better ergonomic products (Shah, Luximon, & Luximon, 2017).

Engen(1988) suggests that the stimulus threshold is a psychophysical assumption and refers to it as the weakest stimulus that an individual can detect. Based on this approach, several researchers(Maquet, Croisier, Demoulin, & Crielaard, 2004; Melia et al., 2019; Xiong, Goonetilleke, Witana, & Rodrigo, 2010; Y. Zhang et al., 2013) have defined the term Pressure Discomfort Threshold (PDT) and Pressure Pain Threshold (PPT) as the minimum amount of applied pressure on a specific region which leads to discomfort or pain respectively. Past studies(Fischer, 1986; Jensen, Andersen, Olesen, & Lindblom, 1986; Schoenen, Bottin, Hardy, & Gerard, 1991) conducted to measure PDT and PPT have mainly focused on the identification of clinical issues like muscle/tissue hypersensitivity, muscle pain or dysfunction, muscle/tissue tenderness. Some researchers(Shah et al., 2017; Xiong et al., 2010) have suggested that pressure sensitivity maps developed from such data can also be handy in the field of product design. Even though much work has been done to investigate the pressure threshold parameter in prior studies, the associated tissue deformation caused due to pressure exerted on soft tissues is yet to be studied.

Recently, during the time of the COVID-19 pandemic, it was observed that the front line healthcare workers had to wear Personal Protective Equipment (PPE) for an extended period of time, leading to several soft tissue related issues and even skin damage problems, which have been reported in several studies (Gefen & Ousey, 2020; Lee & Li, 2020; Moore et al., 2021). Gefen and Ousey (2020) argue that one of the critical reasons for the soft tissue and skin damage was the ill-design of PPE. Their study has developed a damage spiral of a device-related pressure ulcer (DRPU) formation. According to this cycle, they have explained how sustainable tissue deformation is the triggering event and driving cause for primary tissue damage, which over a period of time can cause pressure ulcers or DRPU. Hence, it is crucial to study the tissue deformation parameter not only for medical products but for other head-related close-fit products too and further incorporate it in the future product design process to avoid such issues. The current study was planned to measure soft tissue deformation in different regions of the head and face and further evaluate any possible relationship with other key parameters like gender, age, and Body Mass Index (BMI). For this study, the definition adopted for the discomfort and pain threshold is similar to past studies.

2. Methods:

2.1 Study Design

A within-subject experimental study was planned for this research, where tissue deformations at key anatomical landmarks on the head and face region of healthy Chinese adult volunteers were measured at discomfort and pain threshold level. A counter-balanced approach was adopted while measuring the data to avoid any time-based bias. Statistical analysis was performed to get the deformation values range and detect relationships with other demographic parameters like age, BMI, gender, and location. A within-session and between-session reliability analysis was conducted to test the repeatability of measured data.

In the current study, an ultrasound indentation device was used to manually apply force on the head and face region's soft tissues, and the associated tissue deformation was measured. The tissue thickness was considered the distance between the skin surface and the underneath bony surface, and the tissue deformation was measured using the time of flight principle at discomfort and pain threshold levels. Figure 1 provides a visual representation of the terminologies used in this paper.

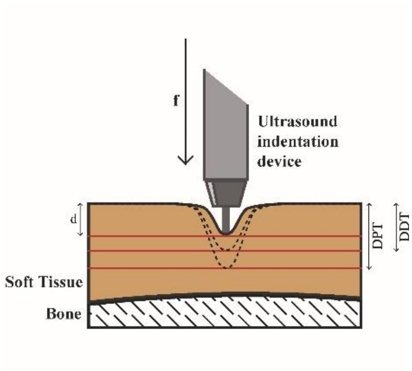


Figure 1. Visual representation of the terminologies used in this study: f- applied force, d- tissue deformation, DDT- tissue deformation at discomfort threshold, DPT- tissue deformation at pain threshold

2.2. Participants

Eighty-three healthy Chinese adult participants (43 males and 40 females) with no visible facial soft tissue or bony deformities or previous history of facial trauma were invited to participate in this study. The mean age of male participants was 32.6 years with a standard deviation of 15.0 years, and that for female participants was 31.0 years with a standard deviation of 13.7 years. Body height and body weight were measured for all the participants using a stadiometer (Model: HM 200P, Charder Electronic Co. Ltd., Taiwan) and a digital body fat and water monitor (Model: WS-004, OTO Bodycare, Singapore), and these data were used to calculate BMI. The mean BMI for male participants was 23.01 kg/m^2 with a standard deviation of 2.79 kg/m^2, and that for female participants was 20.82 kg/m^2 with a standard deviation of 2.49 kg/m^2. Even though the study population can be considered as lean by international standards (very low BMI), but based on the reference values recommended by the report (World Health Organization, 2000) by WHO Western Pacific Region for Asian adults and the standards (Underweight: BMI<18.5, Normal: 18.5<BMI<22.9, Overweight: 23<BMI<24.9 and Obese: BMI>25) accepted by The Centre for Health Protection, Department of Health, The Government of the Hong Kong Special Administrative Region, the study tried to include participants in all the BMI groups. The age and BMI distribution of the participants are shown in Figure 2.

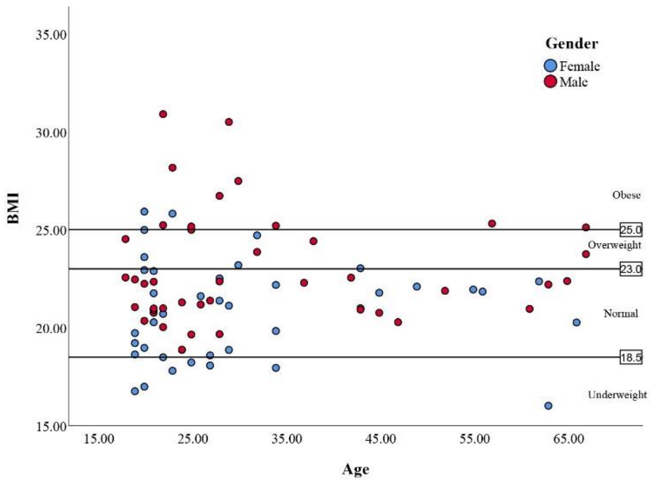


Figure 2. Participant's age and BMI distribution

2.3. Equipment and software

Some of the previous studies (Dohi, Mochimaru, & Kouchi, 2004; Xiong, Goonetilleke, & Jiang, 2011; Xiong et al., 2010) conducted to measure pressure threshold in flat body parts like limbs have tried to use a fixed indentation system where the indentation rate was kept constant using stepper motors. However, the head's geometry is very complex, making it very difficult to develop a fixed system that can help acquire tissue deformation data in all the different regions. Hence a handheld indentation device, shown in Figure 3, was used in this study.

Figure 3. Ultrasound indentation system

The handheld ultrasound indentation probe comprising of an ultrasound transducer (Model: V129-SM, Panametrics, Olympus, MA, USA) with a frequency of 10 MHz was developed based on the established principles presented in previous studies (Zheng, Choi, Wong, Chan, & Mak, 2000; Zheng & Mak, 1996; Zheng, Mak, & Lue, 1999) used for the assessment of soft tissue properties. In a study conducted to measure the pressure sensitivity of the hand by Fransson-Hall and Kilbom (1993), it was observed that while using the contact surface with a perpendicular edge, the subjects felt high pressure mainly at the surface edge. This could lead to a premature perception of discomfort or pain, resulting in misleading measurements. A pilot study conducted with two different indenter sizes showed a similar phenomenon with the soft tissues in the facial region. However, with the indenter having a smaller radius, it was observed that this concern was nearly obliviated. Hence, an indenter tip with a radius of 1.5mm was considered for this study. Also, the smaller tip size makes it suitable for usage in different head and face regions with complex and sharp contours. An ultrasound pulser/receiver was used to drive the ultrasound transducer and amplify the received signal, whereas a high-speed A/D converter was used for digitizing the amplified ultrasound echo train. The velocity of ultrasound was assumed to be 1540m/sec, which is equivalent to the velocity of ultrasound in water/body tissue. To ease the operation, a footswitch was used to start sampling of the ultrasound data. Although the indentation rate was not controlled due to the setup's complexities, care was taken that the indentation rate was maintained at less than 2mm/sec, as suggested in previous studies(Xiong et al., 2011; Xiong et al., 2010). The ultrasound sensor's accuracy in measuring thickness was checked by comparing the measurements with those acquired from the digital Vernier caliper for different silicon phantoms. The mean error in thickness measurement was found to be 0.08±0.33mm.

To record the instances of discomfort and pain thresholds, a keypad switch was interfaced with the system, and participants were asked to press specific buttons on the perception of discomfort or pain. Ultrasound gel was applied to the skin as a coupling medium to ensure continuous contact between the indentation probe and the skin surface. A custom-designed program developed in Microsoft VC++ was used for data collection and analysis. The data recorded during the experiment were analyzed offline to acquire the tissue deformation measurements. A custom-made MATLAB GUI was developed to export the tissue deformation data at the discomfort and pain threshold and to visualize the deformation data. A schematic representation of the setup used for the experiment is shown in Figure 4.

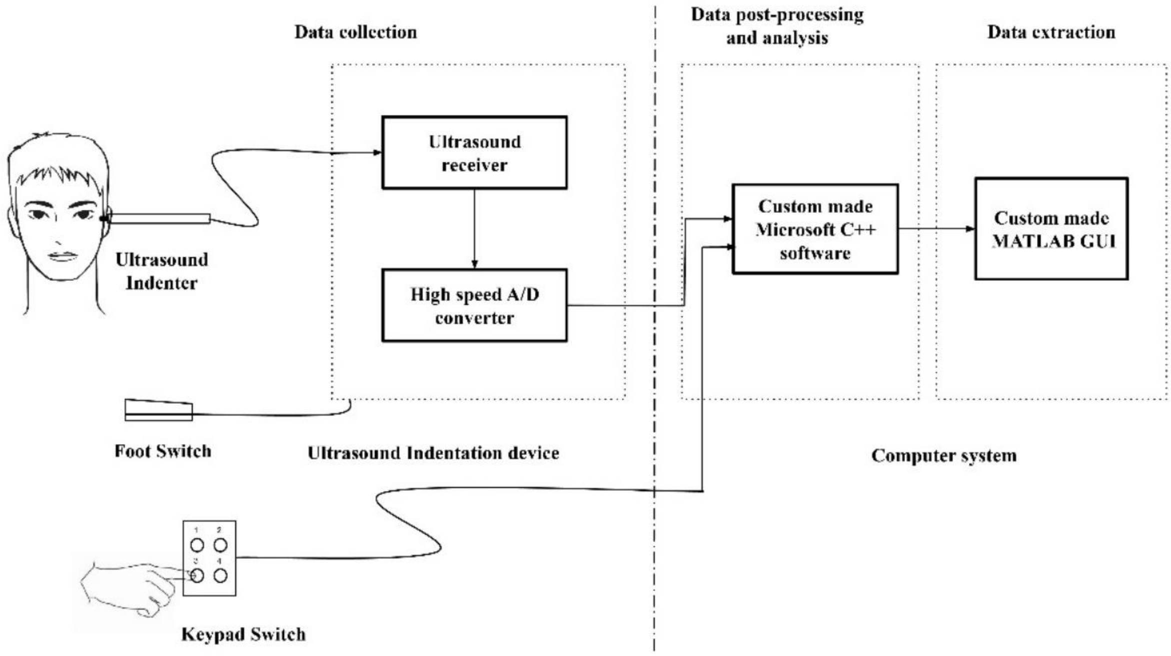


Figure 4. Schematic representation of the setup used for the current study

2.4. Landmarks

A total of eighteen landmarks were selected for this study, which were studied using a counter-balance approach. The landmarks were selected on key anatomical locations for ease of identification. As previous studies(De Greef et al., 2006; Jia et al., 2016; Torres, Cantín, Pérez Rojas, & Suazo, 2011) suggested negligible asymmetry of craniofacial soft tissue thickness, landmarks were only considered on the right side of the face and the facial midline. Figure 5 shows the locations of the landmarks.

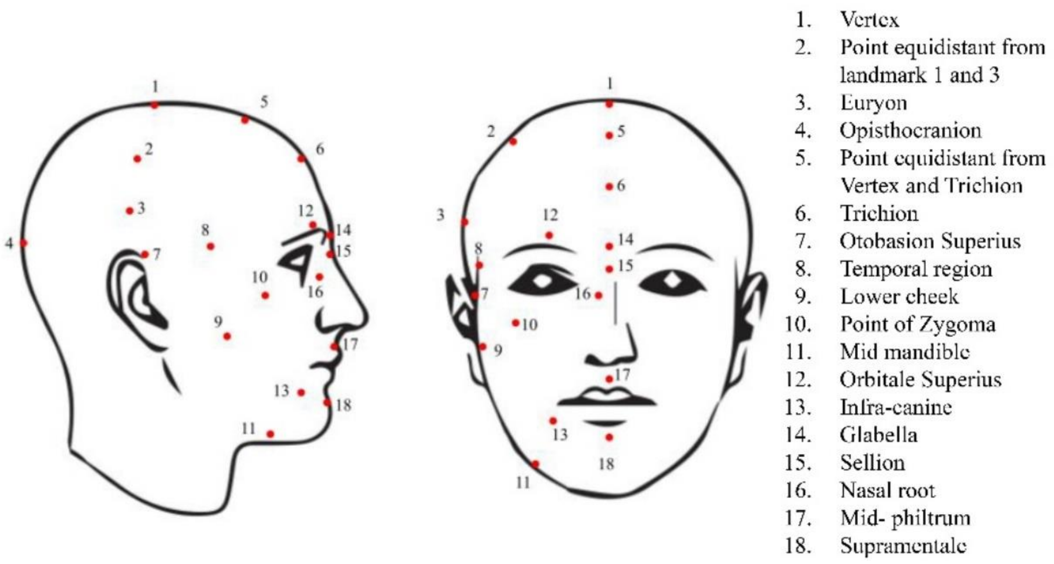


Figure 5. Location of landmarks selected for the study

2.5. Procedure

This study's ethical approval was acquired from University Human Subjects Ethics Committee. Participants were informed in detail about the experimental procedure, and their signed consent was obtained before starting the experiment. Participants were asked to remove any facial makeup before the beginning of the experiment. Around five to eight practice trials were performed before starting the actual experiment to help participants get acquainted with the experimental setting. During the experiment, participants were asked to sit on a comfortable table and rest their heads on a head mount. Head mount was used to keep the head still during the experiment and to minimize errors caused by head movement.

While performing the experiment, a small quantity of ultrasound gel was placed on the landmark using a syringe to ensure continuous contact between the indentation probe and skin surface. The ultrasound indentation probe was placed perpendicular to the skin surface and adjusted until a clear echo was received. Then gradual loading was applied on the soft tissue surface manually by slowly pushing the indentation device. The participants were informed about pressing button 1 when the researcher would say "start," representing the start of loading, and then press buttons 2 and 3 when they felt the onset of perception of discomfort and pain, respectively, after which the load was removed gradually. These button presses were recorded as a marker in the system representing the discomfort and pain thresholds. For every landmark, two cycles of loading were performed. In case of any movement or error, additional trials were conducted. There was a time gap in between the two trials for the skin to regain its initial position. Also, the soft tissue thickness before loading was measured before start of loading for both the cycles at all the landmarks; the measured value of tissue thickness showed excellent repeatability (Intraclass correlation coefficient >0.900).

2.6. Data processing

Individual cycles for loading at every landmark were separated and processed offline after the data collection was completed in a custom-designed Tissue Ultrasound Palpation System (TUPS) program developed in Microsoft VC++, using the time of flight principle. To acquire the deformation signal, a window was selected around the initial echo in the first frame of the data. This echo represented the tissue thickness and reflected the ultrasound signal from the bony surface below the soft tissue and the skin surface. Then, the deformation data were acquired by tracking the echo for every frame of the collected ultrasound data, as shown using a schematic in Figure 6. The figure shows the ultrasound echo recorded at the skin surface and the shifted echo at the second instant on the application of force. The difference in the echo position was measured in the developed program, and a deformation curve was generated. The entire data was manually cross-checked, and three (0.2% of the entire data) erroneous data due to unclear signal or error in the signal recording were eliminated.

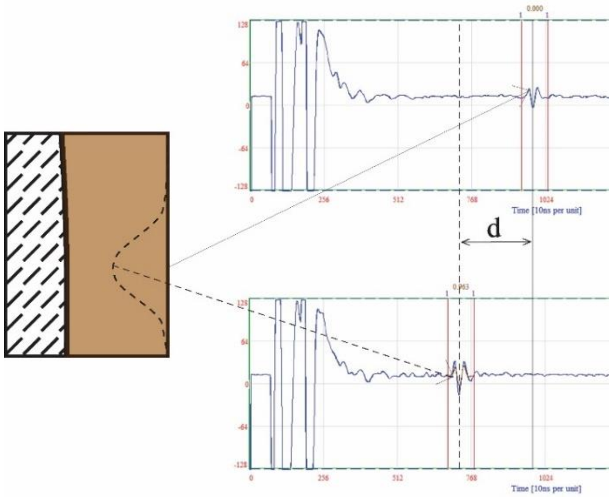


Figure 6. Tracking of ultrasound echo signal for the acquisition of tissue deformation(*d*)

The processed data were exported from the TUPS software along with the time markers for both the thresholds and the required tissue deformation data at discomfort and pain threshold was further extracted from it using a GUI developed in MATLAB.

2.7. Reliability Analysis

Since the perception of discomfort and pain threshold is subjective in nature, it was important to test the acquired data's reliability (interchangeably used as repeatability in the literature). In the literature (Knapstad et al., 2018;

Paungmali, Sitilertpisan, Taneyhill, Pirunsan, & Uthaikhup, 2012; Shah & Luximon, 2021; Tabatabaiee, Takamjani, Sarrafzadeh, Salehi, & Ahmadi, 2020; van Wilgen, Van der Noord, & Zwerver, 2011; Xiong et al., 2010) Intraclass correlation coefficient (ICC) ?? has been used widely to measure the reliability of measured psychometric data for pressure thresholds. Hence, in this study, ICC was used to test the within-session and between-session test-retest reliability in the measured DDT and DPT data.

For evaluating within-session reliability, the measured DDT and DPT at cycle one and cycle two during the experiment session at every landmark for all the participants were evaluated. To assess the between-session reliability of the acquired data, eleven participants (four male and seven females) who participated in the experiment, were invited to redo the experiment after a time interval of two months. The entire experimental procedure was repeated as conducted before by the same experimenter, and the DDT and DPT values were acquired for two cycles of loading at every landmark. ICC was used to measure the between-session reliability by comparing the mean values of DDT and DPT, measured during the first and the second instance. Also, the difference between the measured DDT and DPT values within-session and between-session were examined to understand the phenomenon of (de)-sensitization or habituation.

2.8. Data Analysis

The mean values for both DDT and DPT at both cycles were used for the data analysis process. The statistical analysis was performed using IBM SPSS Statistics Version 22 software. Descriptive statistics of DDT and DPT were calculated for male and female participants to understand the range of measured deformation values at every landmark for both the discomfort and pain thresholds. Independent sample t-test was used to estimate the gender-based difference amongst the measured DDT and DPT data. Paired sample t-test was used to test if there was a significant difference between measured DDT and DPT values. The intraclass Correlation model (3,1) was used to measure the within-session test-retest reliability of DDT and DPT measurement between the two cycles performed during the same session. The ICC analysis was based on two-way mixed effects and tested for absolute agreement, as suggested in the literature (Koo & Li, 2016; Trevethan, 2017). To examine the between-session test-retest reliability ICC model (3.2) was used, where the mean DDT and DPT values measured during two sessions conducted two months apart were tested. The ICC analysis was based on two-way mixed effects and tested for absolute agreement. The mean difference between the values of DDT and DPT measured within-session and between-session were calculated to understand the phenomenon of (de)-sensitization.

3. Results

The mean values of tissue deformation measured at discomfort and pressure thresholds, recorded for two cycles at every landmark for every participant, were computed and used for analysis. IBM SPSS Version 22 software was used to perform statistical analysis. Table 1 and Table 2 present the results of descriptive statistics for tissue deformation at every landmark for male and female participants along with the results of independent sample t-test, which was used to evaluate gender-based differences for discomfort and pain threshold, respectively. The results of paired sample t-test, used to test for significant differences between DDT and DPT measurements for male and female participants, are presented in Table 2.

Table 1. Measured tissue deformation data at the discomfort threshold (DDT)

Landmarks	Male				Female				Results of Independent sample t-test	
	Min. (mm)	Max. (mm)	Mean (mm)	Std. Dev. (mm)	Min. (mm)	Max. (mm)	Mean (mm)	Std. Dev. (mm)	*t*-value	*p*-value
1	0.54	2.71	1.35	0.50	0.53	3.11	1.42	0.63	-0.532	0.596
2	0.47	3.42	1.70	0.67	0.47	4.10	1.38	0.79	2.005	0.048*
3	0.32	3.77	2.03	0.75	0.48	5.35	1.64	0.92	2.117	0.037*
4	0.40	3.95	2.18	0.94	0.75	4.93	2.22	1.08	-0.221	0.826
5	0.18	3.86	1.44	0.69	0.54	3.38	1.60	0.78	-0.998	0.321
6	0.27	2.31	0.97	0.45	0.31	2.20	0.75	0.40	2.387	0.019*
7	0.58	5.77	2.51	1.26	0.75	5.08	2.40	1.00	0.408	0.685
8	1.00	4.08	2.26	0.78	0.82	3.33	2.00	0.65	1.638	0.105
9	1.02	13.71	8.26	2.89	3.50	12.99	8.12	2.14	0.243	0.809
10	1.37	6.64	3.15	1.12	1.05	5.33	3.12	1.12	0.147	0.884
11	1.25	7.95	3.83	1.58	0.68	9.07	4.66	1.83	-2.209	0.030*
12	0.77	2.95	1.75	0.49	0.14	2.24	1.23	0.49	4.851	0.000*
13	1.72	11.91	5.77	2.63	1.44	12.00	4.79	2.29	1.807	0.074
14	0.32	2.82	1.61	0.55	0.18	2.74	1.07	0.56	4.375	0.000*
15	0.90	3.78	1.92	0.63	0.40	2.44	1.34	0.58	4.390	0.000*
16	0.42	3.21	1.37	0.63	0.45	3.01	1.46	0.59	-0.684	0.496
17	2.63	8.00	4.76	1.21	1.71	7.76	4.36	1.09	1.611	0.111
18	1.26	8.22	4.96	1.64	1.23	7.91	4.22	1.37	2.231	0.028*

* Significant gender-based difference in tissue deformation data at the discomfort threshold

The amount of deformation acquired at the discomfort threshold for the landmarks in the scalp region (landmark 1-5), forehead region and nasal region (6-8, 12, 14-16) was in the range of 0.75 to 2.50 mm. The lowest mean soft tissue deformation was measured at Trichion (landmark 6) for both genders. However, the landmarks on the facial region (landmarks 9-11, 13, 17-18) showed a higher amount of tissue deformation at the discomfort threshold. The maximum amount of deformation was recorded in the cheek region (landmark 9). The results of Independent sample t-test suggest a statistically significant difference in measured deformation value at the discomfort threshold for eight landmarks (Landmark 2, 3, 6, 11, 12, 14, 15, and 18). All the other landmarks showed no significant differences in the tissue deformation values at the discomfort threshold between genders.

Table 2. Measured tissue deformation data at the pain threshold (DPT)

Landmarks	Male						Female						Gender-based difference	
	Min. (mm)	Max. (mm)	Mean (mm)	Std. Dev. (mm)	Difference between DDT & DPT (Results of paired sample t-test)		Min. (mm)	Max. (mm)	Mean (mm)	Std. Dev. (mm)	Difference between DDT & DPT (Results of paired sample t-test)		Results of Independent sample t-test	
					t-value	*p*-value					*t*-value	*p*-value	*t*-value	*p*-value
1	0.69	3.07	1.59	0.52	-16.582	0.000#	0.66	3.37	1.64	0.66	-17.073	0.000#	-0.435	0.664
2	0.70	3.71	1.92	0.69	-17.429	0.000#	0.59	4.51	1.55	0.84	-13.454	0.000#	2.149	0.035*
3	0.45	3.97	2.23	0.75	-16.865	0.000#	0.59	5.68	1.83	0.95	-10.588	0.000#	2.122	0.037*
4	0.50	4.14	2.45	0.98	-12.426	0.000#	0.87	5.16	2.40	1.09	-8.053	0.000#	0.206	0.837
5	0.37	4.18	1.63	0.72	-16.285	0.000#	0.74	3.54	1.78	0.79	-15.995	0.000#	-0.874	0.384
6	0.44	2.51	1.10	0.45	-12.786	0.000#	0.35	2.31	0.84	0.41	-12.319	0.000#	2.692	0.009*
7	0.67	5.91	2.73	1.28	-7.292	0.000#	0.86	5.13	2.69	1.02	-7.372	0.000#	0.136	0.892
8	1.43	4.61	2.81	0.76	-13.233	0.000#	0.95	4.46	2.51	0.80	-10.194	0.000#	1.783	0.078
9	4.46	15.01	10.14	2.45	-12.214	0.000#	5.22	13.69	9.42	1.93	-9.648	0.000#	1.458	0.149
10	1.83	8.02	3.87	1.29	-10.928	0.000#	1.12	5.74	3.54	1.06	-6.349	0.000#	1.258	0.212
11	1.54	8.60	4.64	1.49	-8.462	0.000#	0.76	9.64	5.18	1.88	-8.643	0.000#	-1.465	0.147
12	0.93	3.07	1.96	0.51	-13.115	0.000#	0.20	2.42	1.36	0.52	-12.077	0.000#	5.313	0.000*
13	2.75	12.35	7.02	2.50	-9.439	0.000#	2.68	13.09	6.12	2.30	-9.902	0.000#	1.702	0.093*
14	0.70	3.30	1.79	0.58	-11.996	0.000#	0.23	2.91	1.18	0.58	-12.105	0.000#	4.735	0.000*
15	1.13	4.10	2.16	0.62	-9.468	0.000#	0.50	2.71	1.48	0.61	-9.058	0.000#	4.977	0.000*
16	0.63	3.32	1.52	0.61	-11.669	0.000#	0.51	3.20	1.65	0.62	-8.876	0.000#	-0.963	0.338
17	3.40	8.42	5.56	1.14	-8.064	0.000#	2.23	7.94	4.89	0.97	-6.733	0.000#	2.834	0.006*
18	2.71	8.68	5.79	1.38	-9.330	0.000#	2.26	8.68	4.87	1.34	-6.813	0.000#	3.080	0.003*

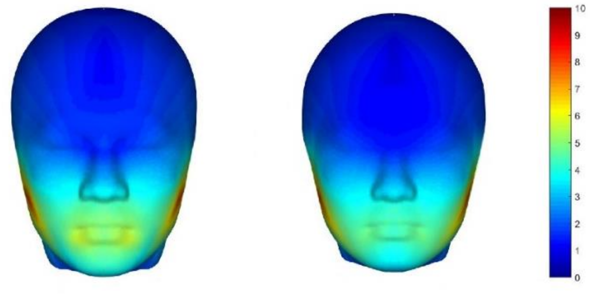
Significant difference in measured value of tissue deformation at discomfort and pain threshold

* Significant gender-based difference in tissue deformation data at the pain threshold

The deformation data for the pain threshold in Table 2 shows a pattern similar to the data for the discomfort threshold. The deformation in the facial region is comparatively higher than that in the scalp or forehead region. The minimum deformation was observed at landmark 6 in the forehead region, whereas maximum deformation was observed at landmark nine, located in the cheek region of the face. The results of Independent sample t-test suggest a statistically significant difference between both genders in measured deformation value at pain threshold for nine landmarks (landmark 2, 3, 6, 12, 13, 14, 15, 17, and 18). All other landmarks showed no significant differences in the tissue deformation values at the pain threshold between both genders.

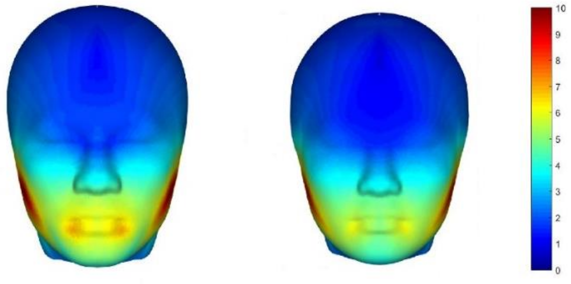
It was essential to assess if the difference between deformation at discomfort and pain threshold were significantly different or the deformation measurements at pain threshold would be redundant. It was tested using paired sample t-test. Since the measured DDT and DPT data were significantly different at half of the landmarks, they were tested separately. The results in Table 2 suggest that for both male and female participants, the mean value of DDT and DPT had a statistically significant difference at all the landmarks.

Based on the average soft tissue deformation data acquired from the eighteen landmarks, deformation maps at discomfort and pain threshold of head and face region for male and female Chinese adults were developed as shown in Figures 7 and 8. For developing these deformation maps, the tissue deformation values on the contralateral side of the face were assumed to be the same as the measured side. Mean values for deformation at all the landmarks were first plotted, and the values at the regions between the landmarks were interpolated using the natural neighbor interpolation technique using MATLAB software. Although the interpolated values may not be accurate, the simulated interpolated deformation maps help visualize the data, making it easy to interpret.



(a) (b)

Figure 7. Simulated average tissue deformation map at discomfort threshold (DDT) for (a) male (b) female. Deformation values are in mm



(a) (b)

Figure 8. Simulated average tissue deformation map at pain threshold (DPT) for (a) male (b) female. Deformation values are in mm

Spearman's correlation analysis was used to investigate the relationship between the measured tissue deformation data, age and BMI. The results of correlation analysis are summarized in Table 3. For male participants, there was a statistically significant correlation between age and DDT at five landmarks (landmarks 1, 2, 5, 6, and 17) and with DPT at four landmarks (landmarks 2, 5, 6, and 17). For the female participants, the deformation data showed a significant correlation with age at three landmarks (landmarks 9, 15, and 17) at the discomfort threshold and four landmarks (landmarks 9, 14, 15, and 17) at the pain threshold. For all the other landmarks, there was no statistically significant correlation between deformation data and age.

It was observed that there was no stastically significant correlation between deformation at discomfort threshold and BMI for both male and female participants. However, for the pain threshold, landmark 18 for male participants and landmark 8 for female participants exhibited a significant correlation between deformation and BMI. For all the other landmarks, there was no significant correlation between the deformation data and BMI.

Intraclass correlation was used to test the within-session and between-session test-retest reliability of DDT and DPT measurements. For within-session reliability measurement, the DDT and DPT data for both the cycles measured in the same session were analyzed for all the participants (n=83) at every landmark using ICC (3,1) model. The results of within-session test-retest reliability are presented in Table 4, along with the 95% Confidence interval limits. Based on the accepted standards in the literature (Cicchetti, 1994; Fleiss, 2011) for clinical studies, it was observed that for DDT, measured deformation data exhibited excellent reliability at nine landmarks, good reliability at eight landmarks, and fair reliability at only one landmark. The deformation measurements showed excellent reliability at thirteen landmarks and good reliability for the remaining five landmarks for the pain threshold. While comparing the mean values of the difference in measured DDT and DPT between the two loading cycles, it was observed that the measurements were generally higher for the first trial for the head region. However, the measured value at most of the landmarks for the second trial was slightly lower than in the first cycle in the facial region.

Eleven subjects who participated in the study were invited to redo the entire experiment after two months to evaluate the between-session test-retest reliability of the measured DDT and DPT data. The intraclass correlation model (3,2) was used to examine the reliability of the mean values of DDT and DPT measured at all the landmarks during both sessions. The results have been presented in Table 5. For DDT, excellent reliability was observed at four landmarks, good reliability at seven landmarks, fair reliability at five landmarks, and poor reliability at two landmarks. For DPT, excellent reliability was overserved at five landmarks, good reliability at seven landmarks, fair reliability at three landmarks, and poor reliability at three landmarks. It was observed that for most landmarks, the measured value at the second instance was higher than at the first instant for both DDT and DPT data..

Table 3. Results of correlation analysis between Deformation at discomfort and pain threshold, age and BMI

Landmarks	Male								Female							
	DDT				DPT				DDT				DPT			
	Correlation with Age		Correlation with BMI		Correlation with Age		Correlation with BMI		Correlation with Age		Correlation with BMI		Correlation with Age		Correlation with BMI	
	r-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value
1	-0.360*	0.018	0.107	0.496	-0.298	0.053	0.170	0.277	-0.122	0.453	0.184	0.255	-0.118	0.468	0.232	0.150
2	-0.317*	0.038	0.025	0.872	-0.325*	0.033	0.012	0.941	0.031	0.852	0.118	0.474	0.076	0.647	0.156	0.344
3	-0.188	0.228	0.144	0.358	-0.166	0.288	0.144	0.357	-0.082	0.614	0.024	0.883	-0.020	0.903	0.060	0.715
4	-0.223	0.150	0.255	0.099	-0.234	0.130	0.275	0.074	-0.070	0.670	-0.013	0.935	-0.081	0.618	0.049	0.766
5	-0.390**	0.010	0.208	0.181	-0.414**	0.006	0.214	0.168	-0.238	0.140	-0.074	0.649	-0.216	0.181	-0.018	0.914
6	-0.402**	0.007	0.172	0.269	-0.396**	0.009	0.200	0.198	-0.018	0.912	0.169	0.298	0.043	0.793	0.241	0.135
7	-0.087	0.581	-0.099	0.527	-0.084	0.591	-0.073	0.640	0.098	0.546	0.006	0.970	0.240	0.137	0.080	0.625
8	0.108	0.492	0.090	0.565	0.172	0.270	0.027	0.863	0.138	0.395	0.304	0.056	0.137	0.398	0.341*	0.031
9	-0.113	0.482	-0.067	0.678	-0.167	0.298	-0.006	0.972	-0.343*	0.030	-0.097	0.552	-0.343*	0.030	-0.145	0.373
10	-0.134	0.393	0.144	0.356	-0.002	0.989	0.214	0.168	-0.090	0.582	0.083	0.611	-0.042	0.798	0.238	0.138
11	-0.029	0.851	0.049	0.755	0.199	0.201	0.200	0.199	-0.088	0.588	0.085	0.600	-0.007	0.967	0.149	0.358
12	-0.152	0.332	0.155	0.320	-0.132	0.399	0.204	0.190	-0.211	0.192	0.122	0.455	-0.153	0.347	0.135	0.405
13	0.067	0.670	-0.185	0.236	0.082	0.601	-0.107	0.494	-0.071	0.663	0.082	0.613	-0.044	0.787	0.107	0.511
14	-0.248	0.109	0.299	0.051	-0.241	0.120	0.298	0.053	0.274	0.087	0.128	0.431	0.321*	0.044	0.166	0.307
15	0.159	0.307	-0.001	0.995	0.255	0.099	0.109	0.487	0.321*	0.043	0.102	0.529	0.340*	0.032	0.099	0.543
16	-0.249	0.107	-0.173	0.268	-0.234	0.131	-0.197	0.206	-0.109	0.502	-0.047	0.774	-0.041	0.800	0.038	0.817
17	-0.484**	0.001	0.037	0.812	-0.537**	0.000	0.187	0.229	-0.366*	0.020	-0.044	0.785	-0.347*	0.028	0.051	0.756
18	0.053	0.736	0.182	0.243	-0.009	0.956	0.308*	0.044	-0.128	0.432	-0.059	0.716	0.016	0.922	0.021	0.899

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 4. Results of ICC analysis for testing within-session test-retest reliability

Land marks	ICC results for DDT			ICC results for DPT			Difference between measurement in both the cycle			
	Intraclass Correlation	95% Confidence Interval		Intraclass Correlation	95% Confidence Interval		DDT (mm)		DPT (mm)	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound	Mean	Std. Dev.	Mean	Std. Dev.
1	0.720	0.254	0.873	0.791	0.481	0.899	0.31	0.36	0.24	0.33
2	0.792	0.625	0.878	0.836	0.733	0.897	0.23	0.46	0.17	0.44
3	0.853	0.707	0.919	0.879	0.799	0.925	0.23	0.43	0.16	0.42
4	0.805	0.690	0.876	0.834	0.748	0.891	0.23	0.63	0.17	0.60
5	0.762	0.492	0.875	0.791	0.570	0.887	0.30	0.47	0.27	0.45
6	0.658	0.502	0.770	0.683	0.547	0.783	0.13	0.38	0.09	0.38
7	0.845	0.770	0.897	0.857	0.787	0.905	0.03	0.66	0.02	0.65
8	0.658	0.517	0.764	0.752	0.641	0.832	0.08	0.66	-0.05	0.60
9	0.673	0.522	0.781	0.690	0.502	0.805	-0.69	2.16	-0.80	1.77
10	0.800	0.707	0.866	0.815	0.728	0.877	-0.01	0.75	-0.04	0.76
11	0.779	0.669	0.855	0.792	0.691	0.862	-0.36	1.19	-0.30	1.13
12	0.555	0.387	0.687	0.604	0.449	0.724	-0.06	0.59	-0.08	0.59
13	0.691	0.558	0.789	0.748	0.624	0.833	-0.48	2.11	-0.55	1.79
14	0.845	0.770	0.897	0.854	0.782	0.904	-0.05	0.35	-0.08	0.36
15	0.747	0.626	0.832	0.765	0.635	0.849	-0.14	0.50	-0.18	0.49
16	0.678	0.536	0.782	0.703	0.563	0.801	-0.15	0.52	-0.16	0.50
17	0.656	0.514	0.763	0.750	0.637	0.832	-0.07	1.06	-0.19	0.82
18	0.771	0.667	0.846	0.806	0.716	0.870	-0.16	1.11	-0.08	0.94

Sample size (n) = 83

Table 5. Results of ICC analysis for testing between-session test-retest reliability

Land marks	ICC results for DDT			ICC results for DPT			Difference between measurement in both the cycle			
	Intraclass Correlation	95% Confidence Interval		Intraclass Correlation	95% Confidence Interval		DDT (mm)		DPT (mm)	
		Lower Bound	Upper Bound		Lower Bound	Upper Bound	Mean	Std. Dev.	Mean	Std. Dev.
1	.620	-0.296	0.895	.748	0.146	0.930	0.22	0.61	0.30	0.52
2	.864	0.404	0.965	.877	0.383	0.969	0.36	0.49	0.40	0.50
3	.438	-0.549	0.833	.525	-0.342	0.860	0.47	0.80	0.51	0.78
4	.688	-0.070	0.914	.778	0.239	0.939	0.25	0.71	0.35	0.65
5	.707	0.040	0.918	.710	-0.039	0.922	0.30	0.56	0.45	0.55
6	.646	-0.166	0.901	.694	0.003	0.914	0.27	0.63	0.31	0.60
7	.505	-0.622	0.862	.720	0.036	0.923	0.30	0.77	0.44	0.63
8	.426	-1.097	0.845	.417	-1.090	0.842	0.34	1.20	0.41	1.37
9	.470	-0.597	0.857	.384	-0.964	0.836	-1.67	2.98	-1.05	2.22
10	.622	-0.481	0.900	.588	-0.520	0.889	-0.19	1.16	-0.33	1.29
11	.726	0.058	0.925	.718	0.061	0.922	-0.88	1.29	-0.67	1.48
12	.839	0.298	0.959	.868	0.082	0.970	0.26	0.34	0.31	0.28
13	.510	-0.534	0.861	.682	-0.060	0.912	-1.35	2.99	-1.81	2.43
14	.705	-0.016	0.919	.741	0.129	0.928	0.23	0.65	0.36	0.63
15	.783	0.260	0.940	.789	0.270	0.942	0.26	0.56	0.30	0.55
16	.343	-1.957	0.831	.391	-1.686	0.843	0.02	0.59	-0.03	0.56
17	.352	-0.517	0.793	.205	-2.352	0.793	-0.52	0.68	-0.15	0.79
18	.764	0.147	0.936	.822	0.336	0.952	-0.41	1.58	-0.25	1.43

Sample size (n) = 11

4. Discussion

Understanding product-soft tissue interface is essential for designing ergonomic products. Hence, products related to the head and face, which are the most sensitive part of the body, need to be designed carefully to ensure minimal user discomfort. In order to address this, a few studies (S.-C. Chung, Kim, Kim, & Murphy, 1993; S.-C. Chung, Um, & Kim, 1992; Fernández-de-Las-Peñas, Cuadrado, Arendt-Nielsen, Ge, & Pareja, 2007; Jensen et al., 1986; Schoenen et al., 1991) have been conducted in the past to better understand the pressure sensitivity in different regions of the head by measuring pressure thresholds at discomfort/pain. However, the tissue deformation parameter has been mostly ignored. Hence is this study, tissue deformation at eighteen landmarks in different head and face regions was measured at discomfort and pain threshold for eighty-three healthy Chinese adults using an ultrasound indentation device. The ultrasound indentation device used the time of flight principle for measuring the soft tissue deformation.

In the past, several researchers have used different techniques like ultrasound (Chan, Listi, & Manhein, 2011; Jia et al., 2016) or medical imaging data like Computed tomography (J.-H. Chung, Chen, Hsu, Huang, & Shaw, 2015; Deng et al., 2020; Dong et al., 2012; Kim et al., 2005) or Magnetic Resonance Imaging (Chen et al., 2011; Johari, Esmaeili, & Hamidi, 2017; Sipahioğlu, Ulubay, & Diren, 2012) for measuring soft tissue thickness at different regions of the head and face and tried to investigate the influence of age, gender, and BMI. Based on the results of the study and considering the data acquired in these studies, it is quite evident that tissues in the scalp and forehead region where the thickness of the soft tissue is less, the tissue deformation is lower, whereas in the regions of the face where the tissue thickness is comparatively higher the deformation is higher.

The head's scalp region comprises a fibrous muscle, Occipitofrontalis, with a significantly less amount of fat. Hence this tissue is very stiff, and the tissue deformation in this region is very less even with the application of a large amount of force. Also, the temporal region has a thin Temporalis muscle covered with a tough fascia, whereas the Procerus is a small pyramid-like muscle in the forehead region that occupies the Glabella area. The tissue stiffness in this region is comparatively less than that of the scalp region. There are several muscles in the facial region, major ones being Buccinator, Orbicularis Oris, Masseter. The soft tissues in this region are comparatively less stiff compared to those in the scalp and forehead region; hence they can deform more even at the application of low pressure. Since the tissues in the different regions of the head and face are not homogenous and isotropic in nature, the deformation pattern in the different regions varies accordingly. In the stiffer regions like the scalp of the head and forehead region, the amount of soft tissue deformation measured at discomfort and pain threshold was lower than that of less stiff regions in the facial region. Although in this study, tissue stiffness was not evaluated, it would be interesting to evaluate region-specific biomechanical properties of the soft tissue of the head and evaluate their influence on tissue deformation.

The measured tissue deformation at discomfort and pain threshold in the head and forehead region for both male and female participants follow a similar pattern across the different regions of the head and face. The amount of tissue deformation at discomfort and pain threshold in the scalp and forehead region, with less tissue thickness and high stiffness, was comparatively lower than that in the facial region, where the tissues are thicker and less stiff. The tissue thickness in the hairline region is significantly less, which was reflected in the tissue deformation measurement at Trichion (landmark 6), being the minimum. Maximum tissue deformation was observed in the cheek region of the face for both genders.

The results of Independent sample t-test showed a statistically significant gender-based difference at nearly half of the landmarks (8 for deformation threshold and 9 for pain threshold). Overall, the value of tissue deformation for male participants was comparatively higher than that of female participants. A similar trend is also seen in previous studies(Chesterton, Barlas, Foster, Baxter, & Wright, 2003; Fischer, 1986; Hogeweg, Langereis, Bernards, Faber, & Helders, 1992; Jensen et al., 1986; Vanderweeen, Oostendorp, Vaes, & Duquet, 1996) related to the measurement of pressure threshold, where it has been observed that pressure threshold for male participants is found to be higher than that of female. Also, it was essential to know if the DDT and DPT values varied significantly, or else the DPT measurement would not be helpful. Since the measured DDT and DPT varied significantly between the genders for nearly half of the landmarks, the DDT and DPT values for both the genders were evaluated separately. Results of paired sample t-test indicated that for both genders at all the landmarks, the mean values for DDT and DPT values varied significantly. In the past, several studies related to assessment of pressure threshold have only focused on measuring the values at pain threshold, but the significant difference between the perception of discomfort and pain thresholds suggests the need for measurement at both thresholds for better understanding while designing ergonomic products.

The correlation analysis results show a significant relationship between measured tissue deformation at discomfort and pain threshold and demographic parameters like age and BMI only at a few landmarks. However, the correlation coefficient was very low. Overall considering all the landmarks, there were no significant correlations between tissue deformation, age, and BMI. The age and BMI of the participants involved in this study were not normally distributed (nor are they in the real world). Hence, the correlation results may have some bias, so the results from this study cannot be generalized for the entire population. However, the results provide a general overview of their influence on deformation recorded at discomfort and pain threshold.

Discomfort and pain thresholds being subjective perceptions may vary depending on various physiological and psychological parameters, making it crucial to check the repeatability in the measurement. Terms repeatability and reliability have been interchanged and used in the literature. Reliability is defined as“the extent to which measurements can be replicated” (Daly & Bourke, 2008). A within-session and between-session test-retest reliability was measured using ICC in this study. For within-session test-retest reliability, all the landmarks for DDT and DPTshowed good or excellent reliability (except one for DDT, which showed fair reliability). For between-session test-retest reliability, most of the landmarks showed acceptable reliability. However, two landmarks for DDT and three for DPT showed poor reliability. One of the key reasons for this could have been that the measured DDT and DPT value at the second instance was found to be higher than the first instance for most of the landmarks. While comparing the DDT and DPT measurement between both the cycles in the within-session study, it was found that for the landmarks in the head scalp region where the sensitivity is comparatively lower, the measurement for the second cycle mainly was higher. This could indicate (de)-sensitization or habituation effect as reported in the literature (Arntz, Merckelbach, Peters, & Schmidt, 1991; Ernst, Lee, Dworkin, & Zaretsky, 1986; LeBlanc & Potvin, 1966). However, for the facial region, which is more sensitive, it was observed that the measurements for the second cycle did not vary a lot, and, for most of the cases, the measured value for the second cycle was smaller than the first measured value. Also, for the between-session study, it was observed that the mean values for both the cycles for the majority of landmarks in head and forehead regions for the second instant were higher than at the first instance. On the facial region, however, the values for the second trial were nearly similar or smaller than at first instance, just like the observations from the within-session study. This further supports the argument that the sensitivity in the scalp region is comparatively lower than in the facial region, and the habituation effect is more common in stiffer tissues than more elastic sensitive tissues.

The data acquired in this study can help better understand the amount of deformation in different head and face regions at the perceptions of discomfort and pain. This data can be a valuable reference in all the key stages of the human-centred product design process while designing head-related wearable products. A generic process for a new product design using a human-centric approach and step-wise application of the measured deformation data are summarized in the schematic shown in Figure 9.

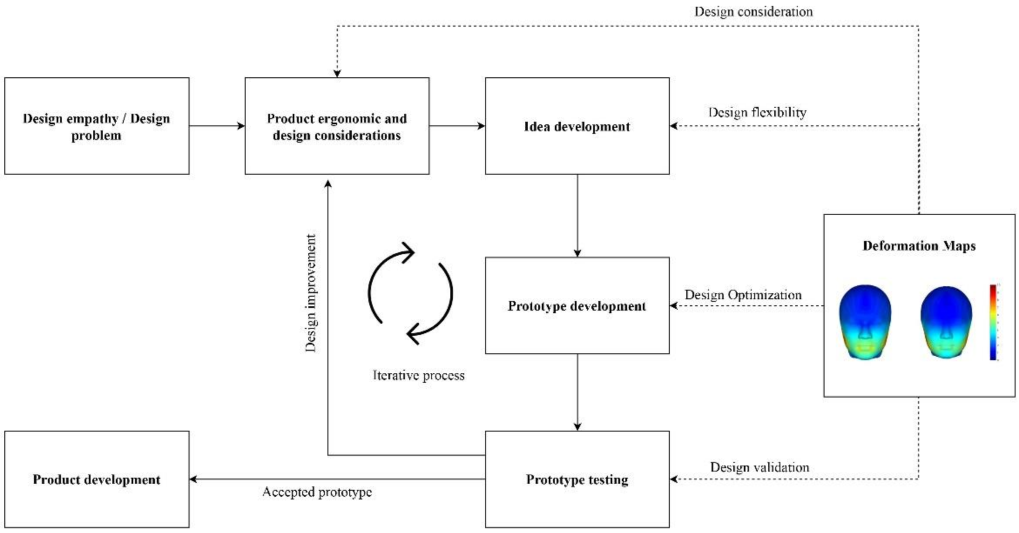


Figure 9. Application of deformation data in the generic process for a new product design

At the beginning stage of the design process for a new product, an empathetic approach has to be adopted, and the existing problems, needs and opportunities have to be evaluated. At this stage, the designer can look for visible deformation marks on the soft tissues because of continuous usage of the product and further discuss the issue in detail with the users using interviews or focused group studies. Based on the results of such studies and with the reference of the deformation maps generated from the acquired data in this study, the designer can deduce key design considerations for the new product. During the ideation and brainstorming process, the deformation maps can serve as a good reference for deciding the allowance and flexibilities in different regions for tissue deformation so that users can experience better comfort while using the product. Consideration of deformation maps and pressure threshold data can help a designer come up with a more feasible design that can yield better comfort. Once a prototype is ready, with simulation techniques like Finite Element Analysis, where deformation analysis can be simulated, virtual testing of the product can be conducted. At this stage different design elements, like size, shape, weight andmaterials, can be simulated, and corresponding deformation maps can be generated and collated with the developed deformation maps. In case of discrepancies, the design can be further improved, and necessary changes in different parameters can be made. Considering this cyclic process, the process would follow an iterative ideate-design-test-validate loop to help achieve an optimal ergonomic product design.

One of the critical limitations of the current study was that the indenter size was kept small to avoid the premature perception of discomfort or pain due to higher pressure at the edge in the case of a bigger sized indenter tip. Hence there is a further need to conduct a detailed study to test the influence of indenter tip size and shape, on the tissue deformation at discomfort and pain threshold. However, even with a different sized indenter, the relative sensitivity in different head regions should still follow the same trend even if the deformation values vary significantly. Hence, the current data can provide an good relative understanding of tissue deformation and human perception of discomfort and pain in different head and face regions for product design.

Human errors in data collection and processing could have introduced some errors in the measured data. Kouchi and Mochimaru (2011) have already established that there are human errors caused in anthropometric measurements during landmarking. To keep these errors minimal, the entire data collection was done by only one researcher, and also, the researcher underwent thorough training in landmarking using 3D printed head models. In addition, the landmarks were primarily selected in the key anatomical region, making them easy to identify using tissue palpitation. On initial contact of indenter with the soft tissue at the start of the experiment, to ensure a proper echo, there could have been a small amount of deformation of the soft tissue, which cannot be avoided. However, care was taken to ensure that the indenter was just touching the skin surface at the start of the experiment with no force applied. To restrict the errors caused due to the motion of the head during the experiment, a head mount was used. Also, the participants were asked to sit stable during the experiment to reduce errors due to movement. However, errors could have also been introduced due to the misalignment of the indenter. Studies conducted by Zheng et al.(1997) show that a misalignment range of 0 to 12.5 degrees could lead to an approximate error of around 2% in thickness measurement for a similar setup. One of the other limitations of the current study is that the indentation rate was not constant due to complexities in measurement setup; however, based on the suggested range from previous studies(Xiong et al., 2011), care was taken that the indentation rate was less than 2mm/sec. A counter-balanced approach was used in landmark selection during the experiment to avoid the time-based influence on the results.

In the current experiment, DDT and DPT were sequentially measured for every cycle of loading. An ideal approach for measurement would have been where both the data were acquired separately. This might have caused overlapping between DDT and DPT values at some instance and could have also reduced the upward bias of the pain threshold measurements. However, it would have increased experiment time significantly, leading to fatigue resulting in a possible bias in the measurements. Also, the nature of the experiment meant that there was a personal interaction between the investigator and the subject, which could have also influenced the results. It has been well documented in the literature that the gender of the investigator may influence the response of pain tolerance of the participant. For this study, the experimenter was a male researcher, and it might have influenced the male participants to tend to reveal a higher pain threshold to express their masculinity, leading to overall higher values for deformation at both the threshold. However, no such evident scenario was observed by the experimenter.

Along with the deformation, the influence of time also has to be examined to have a more holistic understanding. Understanding the amount of deformation caused by various products with time is another crucial area that has not been explored. This can help provide further insights into product-tissue interface-related bruises, rashes, or swelling and can be very helpful for ergonomic product design.

5. Conclusion

Although pressure measurement at discomfort and pain thresholds have already been investigated, associated tissue deformation has not yet been studied. Consideration of soft tissue deformation can help in providing a better and holistic understanding of the soft tissue interface. Hence in the current study, an ultrasound indentation device was used to measure the amount of tissue deformation in different regions of the head and face for eighty-three healthy Chinses adult participants. The acquired data showed that the deformation in a similar anatomical region like the scalp, forehead, or cheek region has a similar deformation pattern for both genders. High tissue deformation was recorded in the facial region, compared to the scalp and forehead region for both the thresholds.

A significant gender-based difference was observed at nearly half of the landmarks. Also, a significant difference was measured between DDT and DPT values indicating the need for measurement at both thresholds. The results of correlation analysis suggested no significant relationship between DDT, DPT, age and BMI except for a limited number of landmarks. The overall within-session and between-session reliability was found to be acceptable. The results also indicated a habituation effect based on higher measurement values at the head and forehead region during the second instance.

The measured deformation data, along with pressure threshold data, can be a valuable reference while designing wearable products in identifying proper allowance, testing new prototypes and identifying the optimal size, shape, weight, and material for the product. By ensuring a good balance between these parameters, the user comfort can be improved, and their experience can be enhanced.

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