METHODOLOGY
This study was conducted at the department of Orthodontics, College of Dental Surgery, B.P. Koirala Institute of Health Sciences, Dharan, Nepal from January 2011 to November 2012. However the translation and validation of some psychometric instruments was done before that. This was a cross sectional comparative study. Ethical clearance was obtained from institutional ethical review board and principles from declaration of Helsinki were followed. This study was conducted in two steps. The first step included translation and validation of the instruments-Psychosocial Impact of Dental aesthetic Questionnaire (PIDAQ), Derriford Appearance Scale (DAS 59) and Patient Expectation of Orthodontic Treatment Questionnaire in the target population. The second step included the main study in patients with craniofacial anomalies reporting for orthodontic treatment using these validated instruments. These steps are described below for three instruments – DAS-59, PIDAQ and Expectation from orthodontic treatment.

1. PIDAQ- Psychosocial Impact of Dental Aesthetic Questionnaire
Development of the Translated Version of PIDAQ: The series of event that lead to the translated final version involved are represented in Fig 1. (Gjersing, 2010) The first step was to assess conceptual and item equivalence in the target settings, this was done by discussing the findings of the literature with subject experts and representatives from the target population. The second step was translation into the target language. Two English teachers in local, government Art College produced the initial translation independently. It was then synthesized into a final version by a third independent translator again an English teacher by profession. This version was then back translated again by two independent translators who were good in original language and had sufficient knowledge of the target language. Similarly a final synthesized version was developed by a third independent translator. This was presented to the expert committee comprising of translators, orthodontist and representatives of the target population. The committee assessed that if words/sentences represent the similar idea in both original and translated version of questionnaire. The instrument was modified with the consensus of the committee members. This was followed by a pretest of the questionnaire on 50 respondents. The participants were asked to rephrase each item in their own words so as to identify that each item is understood. A final semantic
adjustment was made. The instrument was then tested for operational equivalence using literature and expert opinion. Again after due consensus the final version was developed.

FIGURE1. The steps that are involved in the development of final Nepali translation of PIDAQ

The aesthetic component of the Index of orthodontic treatment needs:
This scale measures the self perception of subjects in regards to their dental attractiveness. The subject is asked to rate himself/herself against 10 black and white photographs and asked to pick the photograph that resembles his/her dentition the most.(Brook & Shaw, 1989) This scale has been used extensively in various studies in various regional and ethnic settings.(Mattrick & Gordon, 2004; Bourne et al, 2010; Albarakati, 2007; Aikins et al, 2012; Mugonzibwa et al, 2004).
The Perception of Occlusion Scale:
This scale has been used previously for assessment of self perception of occlusion and arrangement of teeth. There are six items that refer to the occlusal traits of upper and lower teeth and the responses are recorded for each item on a 0 to 4 likert scale.(Epseland, 1991).

Sample size calculation:
The sample size was calculated by using Bonnett’s Formula (Peker, 2011, a sample size of 102 subjects would be required. In order to allow a 10% missing data, at least 112 subjects should be invited. For validity the Kaiser –Meyer-Okin measure of sampling adequacy was assessed for the sample of 252 (planned sample size). The value was 0.878 and suggested that sample size is adequate for such calculation.

Ethical clearance was obtained from institutional ethical research committee and guidelines from declaration of Helsinki were followed.

Administration of the Nepali PIDAQ Questionnaire:
The Final Nepali PIDAQ version with addition of demographic data were administered to 252 young adults, 126 males and equal number females with an age group from 18 to 29 years (Mean 22.33 with SD 2.114). We employed convenience sampling and all the participants were from BP Koirala Institute of Health Sciences, Dharan, Nepal. Inspite of convenience sampling our samples represented different parts of Nepal as this is the institute of national importance and is one of few government medical universities in Nepal. There is a national level entrance for selection and we have adequate cultural and ethnic diversity among our students and staffs. Dental students and staff were excluded from the study. Similarly patients with missing or fractured teeth, moderate to severe discoloration in anterior region and with severe craniofacial anomalies or craniofacial disfigurement and those with previous orthodontic treatment or undergoing orthodontic treatment were also excluded. The Questionnaires were administered by Author 1 who is well trained in the use of orthodontic indices and has good experience with questionnaire administration. In addition the participants were asked regarding demand for orthodontic treatment.
The questionnaire consisted of
1. Nepali version of PIDAQ consisting of 23 items arranged in four domains. Each item response is marked based on a likert scale from 0 to 4 with 0 indicating not at all and 4 indicates very strongly.
2. Index of Orthodontic Treatment Needs Aesthetic Component (IOTN-AC) consisting of 10 standard photographs of malocclusion arranged according to severity. The respondent was asked to tick the photograph that resembles his/her arrangement of teeth.
3. The perception of occlusion scale (POS) consisting of six items. Each item response is marked based on likert scale from 0 to 4 with 0 indicating not at all and 4 indicates very strongly.

Fifty participants out of total were randomly selected using table of random numbers for checking test retest reliability after a interval of 4 weeks.

**Statistical analysis:**
The data was entered in Microsoft excel sheets and later transferred to SPSS Version 19(Statistical Package for Social Science, IBM corporation, NY, USA) for statistical analysis. Reliability of the scale was tested by Cronbach’s alpha coefficient and coefficient of correlation. The retest reliability was also tested using correlation coefficient between items and scale.

Construct validity was tested by carrying out factorial analysis. Criteria validity by assessing the association of PIDAQ with POS and IOTN-AC scales using Kruskal-Wallis Test. Responsiveness was checked by analyzing the differences between the group having demand and no demand using the Mann-Whitney test.

2. DAS- Derriford Appearance Scale -59

**Translation of DAS59:**
The DAS59 is copyright protected and translation procedure to be followed is listed in the website. First of all permission is taken regarding translation from the developer then the tool was subjected to conceptual, semantic and society equivalence. This was done by a committee comprising of a clinical psychologist, orthodontist, general surgeon, Public health
specialist, members of the civil society and members of the target population. The committee suggested following changes: 1. Change the options in the question "your ethnic background" as Nepal has different ethnicity than UK. 2. To add religion also, because many religious practices are so unique here that it can affect the outcome. 3. To include Caste also according to demographics of Nepal. 4. Question 37 refers to “the beach”, Nepal is a land-lock country with no seashores, and instead we replaced it by “swimming”. However there was a repeat [HOW DISTRESSED DO YOU GET WHEN, item 37 “you go to swim” (as modified from “you go to the beach”) [HOW DISTRESSED ARE YOU BY, item 45 “Not being able to go swimming”], but the committee felt that both sections are different and repetition of “swimming” can be justified, as the meaning of the question changes in each section. The first section is concerned with self consciousness around bodily exposure associated with swimwear. The second section emphasizes the stress which he/she gets when he/she is not able to go to swimming due to his/her "feature".

A discussion was organized with the committee members and members of the target population to finalize these changes and communicate to the developer of the scale for final approval. We followed the standard translation – back translation procedure, the first step encompassed translation by an individual whose first language is English but has good knowledge and command of Nepali language. This was facilitated by the fact that Dharan, Nepal is the hub of British Gurkhas and as many of them has been settled in the UK for generations. Two individuals did translation independently and then it was synthesized by an independent third translator. The next stage encompassed back translation from Nepali to English by two individuals independently whose first language is Nepali, but is well versed in English. For this process, three English language teachers from local Nepali colleges were employed. Two of them did the back translation independently, and the third synthesized it into one version. This version was compared with original translation for conceptual and semantic equivalence and with discussion with committee members, translators, and original scale developer. This final version was then pretested in the target population, two interviewers – one orthodontist and clinical psychologist administered the questionnaire to 50 individuals from both the groups. We asked each individual to read each item and try to
explain the interviewer about their interpretation of that question. There were no confusing items and the subjects were readily able to understand all items.

**Administration of the Nepali Version of DAS59:**

**Derriford appearance Scale (DAS59):**

The scale consists of an introduction which collects necessary demographic features and also the feature of appearance that concerns the person most. It also asks the participant about other areas of concern regarding to appearance. Later part of the scale has 59 items which have the responses in a likert format. The scale ensures that it is equally applicable to those who have appearance concerns and those who do not have. The DAS59 consists of 59 items with each item having a response in the format of likert scale (almost never to almost always) for distress (not at all distressed to extremely distressed). Clear cut instructions and simple format makes it easier to administrate.

Actually this questionnaire is designed as a self-report questionnaire to be completed without supervision but in this study subjects were asked to complete the questionnaire in the presence of administrator, however the administrator did not interfere with privacy of the patient. The DAS59 produces six measurements of psychological distress and dysfunction and one measure of physical distress and dysfunction (items 25 and 26). The five domains are 1. General self-consciousness of appearance (GSC), 2. Social self-consciousness of appearance (SSC), 3. Sexual and body self-consciousness of appearance (SBSC), 4. Negative Self concept (NSC), 5. Facial self-consciousness of appearance (FSC) (Harris et al, 2004)

**General Health Questionnaire (GHQ12):** This is a 12 item scale that is used to assess mental health status especially in detection of emotional disorders such as distress. The scoring is done on a likert scale. The translated and validated Nepali version is available (Koirala et al, 1999)

**Beck’s Anxiety Inventory (BAI) and Beck’s Depression Inventory (BDI):** These 21 item scales are used to assess depression and anxiety symptoms. Items are scored on a likert scale. The translated and validated Nepali version is available (Kohrt et al, 2002, 2003)

The questionnaire pack thus consisted of
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1. Nepali version of DAS consisting of 59 items. Each item response is marked based on a likert scale from 1 to 4 with 1 indicating “almost never” and 4 indicate “almost always”.
2. General Health Questionnaire (GHQ12) consisting of 12 items. Each item response is marked based on a likert scale from 1 to 4 with 1 indicating-‘not at all’ and 4- ‘much more than usual’. A validated Nepali Version was available and was used.
3. Beck’s Anxiety Inventory (BAI) and Beck’s Depression Inventory (BDI): Consisting of 21 items each. In BAI each item response is marked based on a likert scale from 1 to 4 with 1 indicating- ‘not at all’ and 4- ‘severely, I could barely stand it’. In BDI each item response is marked based on a four point likert scale from 1 to 4. Validated Nepali versions were available and were used.

Sample size calculation:
The sample size was calculated by using Bonnett’s Formula(Peker, 2011, a sample size of 133 subjects would be required. In order to allow a 10% missing data at least 146 subjects should be invited.

Clinical Sample
Adult patients with appearance problems were identified from hospital record comprising developmental or acquired disfigurement, these included craniofacial disfigurement (both developmental and acquired), post traumatic scarring, post burn scarring, and mastectomy patients reporting for secondary treatment due to appearance concern. We were able to retrieve records of 300 patients. All were invited for the study; of these two hundred twelve (70%) had concern for appearance and agreed to participate in the study. There were 111 females and 101 males aged between18-29 (Mean 23.08±1.69)

Non Clinical Sample
Similar numbers of young adults between 18-29 (Mean 23.13±2) years of age were recruited from a local University in Dharan municipality, Dharan City, Nepal who were not concerned about their appearance. There were 112 males and 100 females. In this way a total of 424 patients were asked to complete the questionnaire in the calm university hospital settings in the presence of one investigator who did not interfere with the privacy of the patient. Across the clinical and non-clinical samples, there were therefore 211 females and 213 males. Out of
total 50 patients were selected randomly (using random number tables against anonymous participant numbers) for test-retest analysis from each group.

**Statistical analysis:**
The data was entered in SPSS Version 19. Reliability of the scale was tested by Cronbach’s alpha coefficient and coefficient of correlation. The retest reliability was also tested using Spearman’s correlation coefficient between items and scale total score.

Discriminant validity was tested by assessing the differences between those who are not concerned about facial appearance and those who seek treatment for problems of appearance using Mann-Whitney test. Convergent validity was tested by assessing the correlation between DAS59 with GHQ12, BDI and BAI scales.

3. **Patient's expectations orthodontic treatment questionnaire**
Development of the translated version of a Questionnaire of Patients expectation of Orthodontic treatment: There were multiple steps as described previously in fig.1 that are involved in translation of final version of the questionnaire in Nepali language. The first step was to assess conceptual and item equivalence in the target settings, this was done by discussing the findings of the literature with subject experts and representatives from the target population. The second step was translation into the target language. Two English teachers in local, government Art College produced the initial translation independently. It was then synthesized into a final version by a third independent translator again an English teacher by profession. This version was then back translated again by two independent translators who were good in the original language and had sufficient knowledge of the target language. Similarly a final synthesized version was developed by a third independent translator. This was presented to the expert committee comprising of translators, orthodontist and representatives of the target population. The committee assessed that if words/sentences represent the similar idea in both original and translated version of questionnaire. The instrument was modified with the consensus of the committee members. This was followed by a pretest of the questionnaire on 50 participants. The participants were asked to rephrase individual item in their own words so as to identify that each item is understood. A
final semantic adjustment was made. The instrument was then tested for operational equivalence using literature and expert opinion. Again after due consensus the final version was developed.

**Sample size calculation:**
The sample size was calculated by using Bonnett’s Formula (Peker et al. 2011) a sample size of 353 subjects would be required. In order to allow a 10% missing data at least 388 subjects should be invited.

**Administration of the Nepali Questionnaire:**
This study was conducted in the department of Orthodontics, B.P.Koirala institute of Health sciences Dharan, Nepal from January 2011 to April 2012. A convenience sample of 390 subjects with an age group of 18-28 (mean 28.88±1.6) years (Male=172, Female=178) reporting for Orthodontic treatment were recruited for this study. The Questionnaires were administered by Author 1 who is well trained in the use of orthodontic indices and has good experience with questionnaire administration.

The questionnaire included demographic information followed by the items, all the items except two have responses to be marked in a Visual Analogue Scale (VAS) formed in a likert like response( extremely likely to extremely unlikely). The participants were asked to mark on a line which has ten equal intervals. One question had a middle mark also as it enquired participants about their reaction when wearing braces, the centre point coincides with no reaction. The 'likert' response format for all questions except two. The remaining two questions were regarding duration and frequency of treatment and had appropriate options out of which patients were asked to select one.

Construct validity was tested by means of a cognitive interview which was conducted among 100 participants. These subjects were asked to complete the questionnaire and were then interviewed by a researcher. The interview was performed using the standard question route considering the questionnaire's subject. The interviews were sound recorded. Based on the interview a second researcher filled a second identical questionnaire without knowledge of
the answer of the first questionnaire. Data of the subjects that participated in the construct validity were excluded from the test-retest reliability.

**Statistical analysis:**
The data was entered in Microsoft excel sheets and later transferred to SPSS Version 19 (Statistical Package for Social Science, IBM corporation, NY, USA) for statistical analysis. Reliability of the scale was tested by Cronbach’s alpha coefficient and coefficient of correlation. The retest reliability was also tested using correlation coefficient between items and scale. The construct validity was assessed by measurement of agreement (kappa) between the questionnaires as filed by subject and as filled by researcher based on cognitive interview with subject.

4. **Main Study on Adult Patients with congenital craniofacial anomalies reporting or referred to Orthodontic clinics:**
The study Design was Cross-sectional. The sampling frame was adult with congenital craniofacial anomalies visiting the department of orthodontics at BP Koirala Institute of health sciences, Dharan, Nepal. The inclusion and exclusion criteria for selection were

**Inclusion Criteria**
- Adult Patients with craniofacial anomalies of age group – 18 to 30 years.
- Patients reporting for the first time for orthodontic treatment.

**Exclusion Criteria**
- Mentally retarded patients
- Blind patients
- Patients having age less than 18 years or more than 30 years.
- Patients in which the diagnosis is not made.
- Patients with acquired or traumatic facial disfigurement.
- Patients who are not able to understand Nepali.
The study was conducted in the department of orthodontics from Feb 2011 to October 2012. Ethical clearance was obtained from institutional ethical review board and principles from declaration of Helsinki were followed. The study also included similar patients who were referred/or reported to the orthodontic OPD during 2005 – 2010 and did not undergo orthodontic treatment and patients from the waiting list for whom treatment had not started.

There were 112 patients satisfying the inclusion and exclusion criteria. All were invited to participate and 102 agreed to participate in the study. The breakup according to the type of anomaly is shown in table 1.

There were 52 males and 50 males with mean age of 24.78±2.5. A similar number of controls were selected conveniently from the university students and employees who have no acquired or congenital facial deformity. Subjects with severe malocclusion as assessed by an orthodontist were not included. The exclusion criteria were same as that of case groups.

The questionnaire pack consisted of

1. An introductory section with basic demographic information including age, sex, educational level in terms of schooling years and place of residence in terms of rural and urban.
2. Nepali version of DAS consisting of 59 items. Each item response is marked based on a likert scale from 1 to 4 with 1 indicating “almost never” and 4 indicate “almost always”.
3. Nepali version of PIDAQ consisting of 23 items arranged in four domains. Each item response is marked based on a likert scale from 0 to 4 with 0 indicating not at all and 4 indicates very strongly.
4. Nepali version of patient’s expectation from orthodontic treatment questionnaire consisting of 10 items. Each item response is marked on a visual analog scale with likert like responses.

These questionnaires were administered to the participants by Author 1 who is well trained in this procedure. The patients were seated in a separate room in the department of orthodontics and were asked to fill the questionnaire individually and were not disturbed by the administrator and were given full privacy. All of the travelling and other expenses were taken
care of and the appointments were given with due consideration of their engagements and commitments.

**Statistical Procedures:**
The data was entered in Microsoft excel sheets and later transferred to SPSS Version 19 (Statistical Package for Social Science, IBM corporation, NY, USA) for statistical analysis. Descriptive statistics were calculated for the demographic data. Independent “t test” was used to evaluate the differences between cases and controls for scores of DAS 59 and PIDAQ scales. Independent T test was used to assess the effect of gender and locality on PIDAQ and DAS59 scores in both cases and controls. Coefficient of Correlation was used to assess the effect of age and educational level on PIDAQ and DAS59 scores.

Coefficient of correlation was used to assess the relation between PIDAQ, DAS59 and objective, subjective assessment of severity. Paired t test was used to assess the relation between objective and subjective assessment of severity. Mann Whitney test was used to compare the expectation of cases and controls. Further analysis through interpretation of median scores was done to assess the difference.