Bedömning av gingival biotyp vid egna tänder

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Abstrakt

Bakgrund
Den gingivala biotypen utvärderas regelbundet kring egna tänder före och efter kirurgiska ingrepp (t.ex för behandlingsplanering och riskbedömning). Nyligen presenterade Colorvue® biotypprobe (CBP) en ny metod för bedömning av gingivala biotyper i syfte av att möjliggöra en mer detaljerad klassificering av gingivan. Studien syftade till att bedöma det nya sonderingsystemets reproducerbarhet, repeterbarhet och riktighet vid naturliga tänder.

Metoder
Denna tvärsnittsstudie omfattade 50 deltagare (3 tänder/deltagare) och gingival biotyp bedömdes med 3 metoder vid en centralincisiv, lateralincisiv och hörntand med: 1) med en standard periodontal sond (SPP), 2) med CBP-proberna (CBP1/2/3), och 3) genom visuell bedömning (VA). Den faktiska tjockleken bedömdes genom transgingival sondering med en endodontisk fil. Utvärderingen gjordes av 8 granskare och reproducerbarhet mellan granskare och repeterbarhet inom granskaren utvärderades.

Resultat
Fördelningen av gingivala tjockleken i studiepopulationen är uppdelad i *tunn* (18%), *mellan* (29%), *tjock* (29%) och *mycket tjock* (24%). Fördelningen av de fyra CBP-kategorierna är *tunn* (10%), *medium* (87%), *tjock* (2%) och *mycket tjock* (1%). Intervallet av gingivala biotypen bland de 8 granskarna enligt CBP: *tunn* (1% till 34%), *medium* (65% till 86%), *tjock* (0% till 4%) och *mycket tjock* (0% till 3%). Statistiskt signifikant skillnad i tjocklek av gingivan hittades i elva av fyrtio utvärderingar bland alla examinator och för alla metoder (VA, CBP och SPP). Fem av de signifikanta skillnaderna hittades bland CBP-sonderna, fyra för SPP och två för VA. Varken SPP eller CBP visade en tydlig tillförlitlighet i bedömning av gingivala tjockleken. SPP visade bäst resultat i både reproducerbarhet och repeterbarhet. Överensstämmelsen mellan granskarna med avseende på CBP varierade från *måttlig* till *stor* överensstämmelse. Reproducerbarhet bland granskaren varierade från *dålig* till *nästan perfekt* överenskommelse.

Slutsatser
Baserat på reproducerbarhet, repeterbarhet och exakthet, är SPP-sondernas förmåga att klassificera gingival biotyp i 4 kategorier av distinkt tjocklek bättre än CBP och VA.

Abstract

Background

The gingival biotype is regularly assessed around natural teeth before and after surgical procedures (e.g. for treatment planning and risk assessment). Recently, a new set of probes Colorvue® biotype probe (CBP) for gingival biotype assessment has been introduced, with the intention to facilitate a more detailed classification (i.e., 4 categories in total). The study aimed to evaluate the feasibility and reproducibility of this new probe system at natural teeth.

Methods

This cross-sectional study included 50 participants (3 teeth/participant), and gingival biotype was assessed by 3 methods at one maxillary central incisor, lateral incisor and canine with 1) with a standard periodontal probe, 2) with the CBP probes, and 3) by visual judgement. The actual thickness was assessed by transgingival sounding with an endodontic file. The judgements were done by 8 examiners, and inter-examiner reproducibility and intra-examiner repeatability were assessed.

Results

The distribution of the gingival thickness in the present study population is divided into *thin* (18%), *medium* (29%), *thick* (29%) and *very thick* (24%). The distribution of the 4 CBP categories are *thin* (10%), *medium* (87%), *thick* (2%) and *very thick* (1%). The range of gingival biotype among the 8 examinators: *thin* (1% to 34%), *medium* (65% to 86%), *thick* (0% to 4%) and *very thick* (0% to 3%). A statistically significant difference in gingival thickness was found in eleven out of forty evaluations among all evaluators and for all methods (VA, CBP, and SPP). Five of the significant differences were found among the CBP probes, four for the SPP, and two for the VA. When compared, neither the SPP nor the CBP was clearly more reliability than the other. SPP showed the best results in both inter-examiner reproducibility and intra-examiner repeatability. Inter-examiner reproducibility for the CBP ranged from *moderate* to *substantial agreement.* Intra-examiner repeatability varied from *poor* to *almost perfect agreement*.

Conclusions

Based on the reproducibility, repeatability and accuracy, the SPP method to classify the gingival biotype accurately into 4 categories of distinct thickness performed better than CBP and VA.

Introduction

The importance of the gingival biotype

The long-term success of aesthetic restorations, in regard to gingival recessions, depends on several factors like gingival morphology, gingival biotype, and architecture of the gingival tissue (1). A relevant prognostic parameter for the outcome of various clinical, including surgical, procedures around natural teeth is the gingival biotype (i.e., thin or thick gingival biotype) (1-3). Thick and thin gingival biotypes often respond differently to inflammation and trauma and therefore traumatic events may result in various types of periodontal defects and in turn can respond differently to various treatments (3). For example, a thin gingival biotype is often associated with a reduced rate of complete root coverage after recession treatment which can have an increased risk for an inferior aesthetic outcome (3). That is one of the reasons why the gingival biotype is regularly assessed around natural teeth, before and after surgical procedures for treatment planning and risk assessment (4).

Gingival biotype categories

Gingival biotypes, i.e. the cathegorization of gingival thickness, are previously classified into two or three groups. According to Ochsenbein and Ross (5), there are two gingival biotypes either ‘scalloped and thin’ or ‘flat and thick’. They suggested that the underlying bone depicts the contour of the gingival tissue above. Siebert and Lindhe (6) classified gingival biotypes also into two categories ‘thick – flat’ and ‘thin – scalloped’ which resembled a lot the classifications of Ochsenbein and Ross (5).A gingival thickness of ≥ 1.5 mm was considered as thick tissue biotype, and a gingival thickness of < 1.5 mm was regarded as thin tissue biotype (1, 3, 7-8). The measurements are often assessed by the transgingival probing method (8-10). The gingiva can be divided into three different biotypes: flat, scalloped and pronounced scalloped gingiva (11).

Gingival or periodontal diseases are more likely to occur in patients with a thin biotype, and the gingival thickness affects the treatment outcome possibly because of the difference in the amount of blood supply to the underlying bone and susceptibility to resorption (8). Therefore, a clinician’s knowledge in identifying gingival biotypes is important for achieving optimal treatment outcomes.

Methods to determine gingival thickness

There are several pre-treatment methods to determine the gingival biotype. Accurately, the gingival biotype and thickness can be determined for instance entirely visually (11-13), by a caliper (14-15), with ultrasonography (16-17), radiographically (16, 18), through transgingival puncturing (9, 16), or by the judgment of the transparency of a periodontal probe through the gingival margin (9, 11, 16).
De Rouck et al. (14), developed a simple visual inspection method for the classification of the gingival biotype based upon four clinical parameters: crown width/crown length ratio, gingival height, papilla height, and gingival thickness (11-13). Note that the classification

is only based on an assessment of maxillary teeth. One has to keep in mind that the visual inspection method is challenging and considered to be unreliable (13).

A study by Kan et al. (15) stated that gingival biotype assessment with the transparency method namely with periodontal probes had no significant difference compared to measurement with a tension-free caliper (14). Furthermore, the use of tension-free caliper can only be used at the time of the surgery and not for pre-treatment evaluation (14, 19). The spring modified caliper is not as accurate, especially when assessing thick biotype, where it tends to underestimate the true thickness (19).

The ultrasonography is a non-invasive method that produces images and/or values of the gingival thickness (20-21). The difficulty of the method is for the clinician to determine the correct position for attaining reproducible measurements, and unavailability of the method and the high cost of the device (17). 95% of repeated measurements were within more than 1 mm (22). Main drawbacks also include limited penetration into bone and gas-filled structures, less spatial resolution at deep tissues and lack of expertise (23).

The thickness of both hard and soft tissues can also be measured radiographically. It is reported that Cone Beam Computed Tomography (CBCT) measurements of both bone and labial soft tissue thickness are accurate (18, 24) although the method has a high cost and requires exposure to X-ray (18, 24).

Transgingival puncturing method also called the direct method, a periodontal/endodontic probe or a needle is used to measure the tissue thickness. If the gingival thickness is > 1.5 mm the tissue will be categorised as thick biotype and if < 1.5 mm then the tissue will be considered as thin (8, 10-11). The method has certain limitations, such as the precision of the probe, the angulation of the probe during the probing and distortion of tissue during puncturing (8, 10-11).

The most common method also called the transparency method which involves the placement of a standard periodontal probe (SPP) into the gingival sulcus at the midfacial aspect of the tooth of interest. If the periodontal probe is visible through the tissue at the gingival margin, the gingival biotype is considered as 'thin' while the gingival biotype is judged as 'thick' if the probe is not visible (9, 11). Recently, a color-coded periodontal probe Colorvue® biotype probe (CBP) for gingival biotype assessment has been introduced (25-26), with the retention to facilitate a more detailed classification. Four categories of gingival biotype can be assessed thanks to the different colors of the CBP: 'thin', 'medium', 'thick', and 'very thick'. CBP are non-invasive clinical instruments specially designed to objectively evaluate the gingival biotype.

Pigmentation, gender and smoking

The gingiva is the most frequently pigmented intraoral tissues as well as the most visible (27). The color of the healthy gingiva is assumed to vary from pale pink to coral pink/light

brown and to dark brown (28). The color variation is dependent on the amount of physiological melanin pigmentation in the epithelium, the vascularity, the degree of keratinisation and the fibrous nature of the underlying connective tissue (28). The thickness of the gingiva is paramount and plays a significant key role in the aesthetic and functional outcome of periodontal, restorative therapy (14). As previously mentioned, there is a correlation between gingival pigmentation and gingival biotype; specifically, the pigmented gingiva is thicker than non-pigmented gingiva, and it seems that the greater the pigmentation of the gingiva, the thicker is the gingival biotype (29). Furthermore, there are definite differences in the gingival biotype among different genders with a predominance of a thin gingival biotype with a reduced alveolar bone thickness in females as compared to males (30-31). However, there is no significant difference in the gingival biotype between the different age groups (32). Smokers seem to have thicker gingival biotype (31). One theory is that the gingival reaction to the heat from smoking increase in the keratinization of the gingival epithelium, which in turn increases the gingival thickness (33).

Aim

The aim of this study was to assess gingival biotype at natural teeth using three different methods, Colorvue® biotype probe (CBP), standard periodontal probe (SPP) and visual assessment (VA) and to compare the methods' reproducibility, repeatability and ability to accurately classify the gingival biotype.

Hypotheses

The CBP will show a significant difference in classification of gingival thickness between the four possible classifications, i.e. *thin*, *medium*, *thick*, and *very thick*, compared to the SPP.

Material & methods

Study population

The present study includes a convenience sample of 50 participants. Students and patients at the Faculty of Odontology (Malmö University) were invited to participate in the present study. The following exclusion criteria were applied:

1. Pregnancy
2. Teeth with fillings at the buccal gingival margin or crowns
3. Highly pigmented marginal gingiva
4. Less than 2 mm of keratinized gingiva
5. Intake of any medication affecting the soft tissues (e.g., Amlodipine, Cyclosporine A, Hydantoin)
6. Signs of gingival inflammation and/or probing pocket depths >4 mm.

Assessment of the gingival biotype

The gingival biotype was assessed by visual judgement and by the probe transparency test. For the latter two different types of probes were used:

1. Standard periodontal probe (CP-12, Hu-Friedy) (*figure 1)*
2. Colorvue® biotype probe (CBP, Hu-Friedy) (*figure 1)*

The transparency test is based on the observer's ability to detect a shine-through effect of any probe (whether SPP or CBP) through the gingiva, and in turn assess the probe as 'visible' or 'not visible'.
The visual assessment is a method where individual judgement of the observer regarding the gingival biotype, with no specific criteria. The observer decides whether the gingiva appears to be 'thick' or 'thin'.

The CBP consist of three different probes, which have either a white, green, or blue colored tip. For assessment of the gingival biotype each type of probe was placed into the sulcus at the midfacial aspect of the tooth of interest and a standardised digital photograph were taken. Specifically, the digital photograph was taken after drying the tooth and in a magnification ratio of 1/1, with a fixed distance of 12 cm and perpendicular to the buccal aspect of the tooth of interest. The photographs were taken at room light always with the same digital camera (Canon EOS 1000D), bearing a circular flash (MACRO RING LITE MR-14EX), and with a dental contrast of color black, but without direct light of the dental unit. The photographer ensured that the digital camera and the participant's Frankfort horizontal plane are both parallel to the ground. The digital photograph included the tooth of interest including approximately 4-5 mm of the marginal gingiva with the probe in situ. In total, five shots per tooth were recorded; i.e., one photo with only the tooth without any probes, one photograph with the standard periodontal probe and one photograph with each of the three different CBPs. The study-conductors made an individual assessment for each participant regarding which quadrant to photograph (either quadrant number 1 or 2). Central incisor, lateral incisor, and canine were the tooth of interest for this study. The gingival thickness was measured by using the transgingival puncturing method which will

act as the gold standard in this study. Firstly, the local anaesthesia gel (Emla® containing Lidocaine and Prilocaine) was applied topically, and an endodontic file (yellow S-file #20) was used for puncturing the buccal aspect of the gingiva at 1 mm apical to the gingival margin, until contact with the tooth surface as shown in *figure 2*. The insertion depth was then secured with a flowable composite (Ivoclar Vivadent Tetric EvoFlow). After removal of the endodontic file, a picture with a ruler was taken to allow measuring the insertion depth. Later the gingival thickness was analysed through calculating the pixel distance between the ruler and the endodontic file in the pictures and then the thickness was determined with an accuracy of three decimals using the software Java®ImageJ version 1.8. The tooth color was registered by visually comparing the pictures of the tooth and the VITA classical A1 - A4® shade guide. Prior to the comparison, the computer screen was professionally calibrated using the X-rite® i1 Display pro monitor calibration device.

Figure 1. Left to right: white tip CBP, green tip CBP, blue tip CBP, standard periodontal probe

Figure 2. Transgingival puncturing with endodontic file and flowable composite

Additional data collected:

1. Probing pocket depth (the distance between the gingival margin and the bottom of the pocket)
2. Gingival width (the distance between the gingival margin and the mucogingival junction)
3. The extension of gingival recessions (the distance between the cementoenamel junction and the gingival margin)
4. Smoking habits (Smoker, former smoker, or non-smoker)
5. Sex
6. Tooth color

Fifteen pictures per participant were used; 5 pictures of each incisor and canine including one picture with each of the 4 probes and one without any probes. The photos were cropped and masked using Adobe®Lightroom Classic 8.1. The probes and 0.5mm of the marginal gingiva were masked in the pictures of probed teeth (figure 3), and the pictures without probes included both adjacent papillae (figure 4). An addition of 50 randomised unprobed pictures was masked in the same manner as the probed pictures (figure 5) and added to the total amount of photos. This is done to ensure the reliability of a positive answer when an actual probe is put in the sulcus. The total amount of pictures was 800 (750 of all participants and 50 randomised masked but unprobed pictures). The conversion of the pictures from the format .TIFF to .JPG using Adobe®Photoshop CC+ 19.0.0.
The standard periodontal probe allows classification into two categories.

- Thin - When the periodontal probe is visible through the gingival margin.
- Thick - When the periodontal probe is not visible through the gingival margin.

The CBP allow classification into four categories.

- Thin - The probe with the white tip is visible through the gingival margin.
- Medium - The probe with the white tip is not visible through the gingival margin, but the probe with the green tip is visible.
- Thick - The probe with the white and green tip is not visible through the gingival margin, but the probe with the blue tip is visible.
- Very thick - None of the probes is visible through the gingival margin.

The visual assessment (VA) are classified into two categories:

- Thick - the gingival biotype is assessed as thick only using visual judgement
- Thin - the gingival biotype is assessed as thin with only using visual judgement

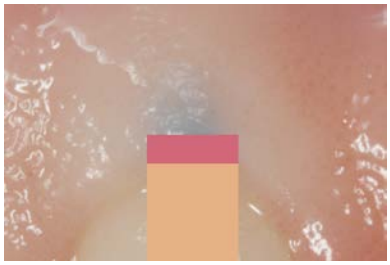

Figure 3. Probed latera incisor with masking

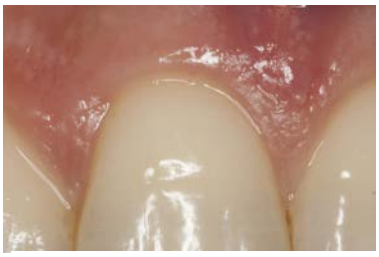

Figure 4. Unprobed central incisor including adjacent papillae, without masking

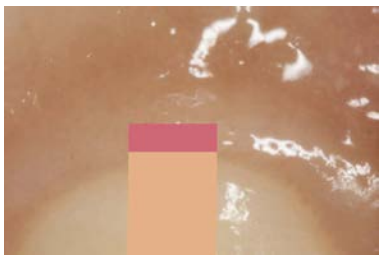

Figure 5. Unprobed canine with masking

Two surveys were created using the online service Swedish University computer Network (SUNET) and were presented in a randomised order to 8 evaluators (two specialists in prosthodontics, two specialists in periodontics, two general practitioners, two dental students, as shown in *table 1*). The first survey consisted of 800 randomized pictures and the second included the first 400 pictures of the first survey and was answered by four evaluators (one from each pair) two weeks after the first survey. The evaluators had access to the survey using an iPad

(model A1701) with the same screen settings (including highest brightness, deactivation of True-tone), at all times and were restricted to the survey page.

The protocol for this study was approved by ‘The Regional Ethical Review Board in Lund‘ (see *‘attachments’*). Oral and written information about the background, aim, and procedures of this project were provided before any intervention. Verbal information was provided chair-side and participants could discuss and receive the necessary additional information. The participants could present with an accompanying person throughout the information process. Participants could take as much time as they needed to decide. Before the final enrolment and any intervention, participants signed informed consent (see *‘attachments’*). Participants were also informed on the possibility to withdraw from the project at any stage and without any consequences and reasons for their further treatment at the clinic.

Table 1. The titles of all evaluators

Identity	Title
Evaluator 1	Specialist in periodontics
Evaluator 2	Specialist in periodontics
Evaluator 3	Dental student
Evaluator 4	Dental student
Evaluator 5	General practitioner
Evaluator 6	Specialist in prosthodontics
Evaluator 7	General practitioner
Evaluator 8	Specialist in prosthodontics

Statistical analysis

Study aim: Inter-examiner reproducibility and intra-examiner repeatability of gingival biotype evaluation were tested with the intra-class correlation coefficient (ICC 3.1), calculated for both probe types separately, and with kappa values by a generalisation of Kappa for multiple evaluators. The 95% confidence intervals for Kappa and ICC values were adjusted percentile intervals based on 100 000 bootstrap replications.
The level of agreement for the intra-observer values and inter-observer values was assessed according to a six-level ranking (34):

- poor agreement:<0.00
- slight agreement: 0.00–0.20
- fair agreement: 0.21–0.40
- moderate agreement: 0.41–0.60
- substantial agreement: 0.61–0.80
- almost perfect agreement: 0.81–1.00

Statistical analysis was performed with SPSS version 19.0 (SPSS, Chicago, IL, USA)
The null hypothesis is ‘there is no difference in gingival thickness between ‘thick/thin’ gingiva’ or ‘there is no difference in gingival thickness between ‘visible/not visible’ probes’. This hypothesis is rejected when the probability value was less than 5% (i.e. 0.05). The statistically significant values are marked in bold.

Results

Study population

The study population consisted of 26 men and 24 women. One quadrant was examined per participant, 43 second-quadrants and seven first-quadrants were examined in total. Data about gingival thickness is based on the gingival puncturing method, and gingival width, recession and probing depth are measured using a SPP. *Table 2* presents the mean values in mm regarding gingival thickness (GT), gingival width (GW), probing depth (PD), and gingival recession (GR) for each type of tooth (central incisor, lateral incisor, and canine). *Table 2* also includes the average gingival thickness for each type of tooth among females and males.

Table 2. Mean gingival width, recession, thickness and probing depth among all participants

	Mean GW ± SD	**Mean PD ± SD**	**Mean GR ± SD**	**Mean GT ± SD**
Central incisor	5.3±0.9	1.9±0.4	0.1±0.3	1.4±0.3
Lateral incisor	5.8±1.1	1.9±0.4	0.02±0.1	1.3±0.3
Canine	5.9±1.4	1.8±0.4	0.1±0.3	1.2±0.3

Table 3. Tooth color of all evaluated teeth, according to the Vita®

	A1	***A2***	***A3***	***A4***
Central incisor	*78%*	*20%*	*2%*	-
Lateral incisor	*66%*	*26%*	*8%*	-
Canine	*6%*	*32%*	*58%*	*4%*

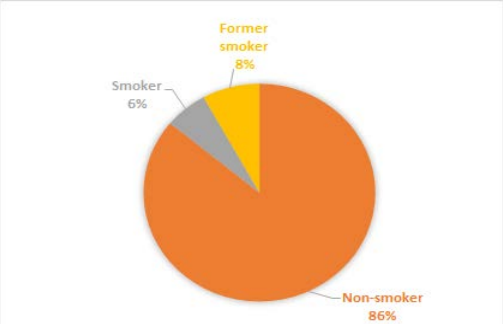

Chart 1. Smoking habits among all participants

The tooth color according to the Vita® Scale A1-A4 is presented for each tooth in *table 3*. *Chart 1* presents the smoking habits of the participants. The gingival thickness according to the 'transgingival puncturing method of all assessed teeth is classified into four groups, as shown in *table 4*. The number of observations is almost equal in each of the groups. 58% (n=87) of all biotypes are in the range of ≥ 1 to < 1,5 mm.

Table 4. Gingival thickness of all evaluated teeth

Gingival thickness	***n***	***%***
< 1 mm	*27*	*18%*
≥ 1 to < 1.25 mm	*44*	*29%*
≥ 1.25 to < 1.5 mm	*43*	*29%*
≥1.5 mm	*36*	*24%*

Judgement of the gingival biotype

398 of the 400 evaluations of the masked teeth without probes are assessed as 'not visible', only 2 evaluators marked an unprobed picture as 'visible' each as shown in *chart 3*.

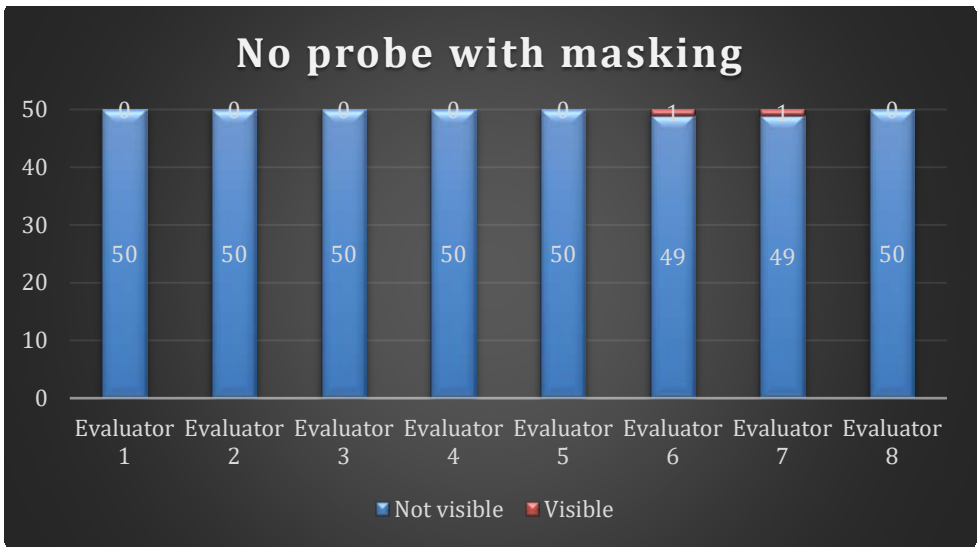

Chart 2. 50 masked but unprobed teeth per evaluators were assessed

The assessments of all evaluators the gingival biotype and probe visibility through the gingiva are summarized in the table in the *'attachments'*. The table includes the average gingival thickness 'mean± standard deviation', number of teeth that are assessed 'n', and probability value 'p-value'. The table shows statistically significant differences in gingival thickness among evaluators is most frequent when using an SPP, where four out of all evaluators had significant differences in thickness. Least frequent significance was found when using the CBP 3 (blue tip) where only one where only one evaluator had significant

variations in thickness. The gingival thickness was similar for CBP 2 and CBP 3 when the evaluators marked the probes as ‘visible’.

A summary of the results from one of the evaluators are shown in *chart 2*. The chart shows the percentage of ‘visible’/’not visible’ or ‘thin’/’thick’ that was chosen by the evaluator. The CBP 2 and CBP 3 were rated similarly regardless of the gingival thickness that was assessed by the evaluator. The evaluator classed 93% of all gingival thicknesses <1 mm as ‘not visible’ when using CBP 1, the results are similar when the gingival biotype is 1mm<->1.5mm when using the same probe. The probe visibility of the SPP is decreased when the gingival thickness increases, although the visibility of the SPP is equal for the two middle categories (1-<1,25mm and 1,25-<1,5mm). The results of the other evaluators can be interpreted from the values in the table in *‘attachments’*.

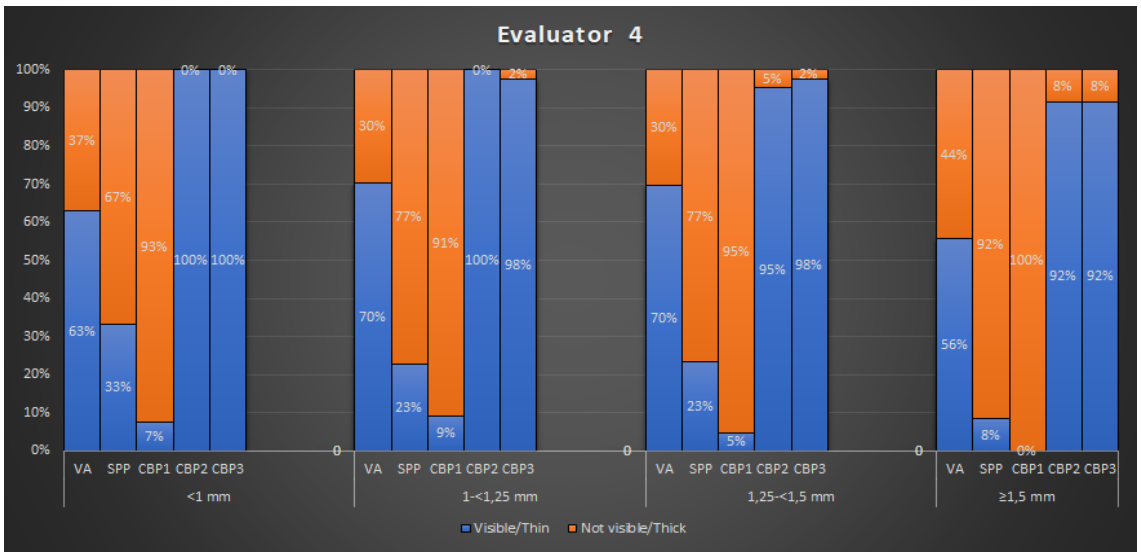

Chart 3. The visual assessment and probe visibility of Evaluator 4, divided into the four groups of gingival thickness

Classification of the gingival biotype using CBP

The classification according to CBP among the evaluators is presented in *chart 4*. The statistical significance between the different probes is marked using arrows (↔) to connect the probes. The most common biotype using CBP is 'medium' among all evaluators. Two out of all eight evaluators showed statistical significance in biotype thickness using the CBP method as shown by the marked arrows in *chart 4*.

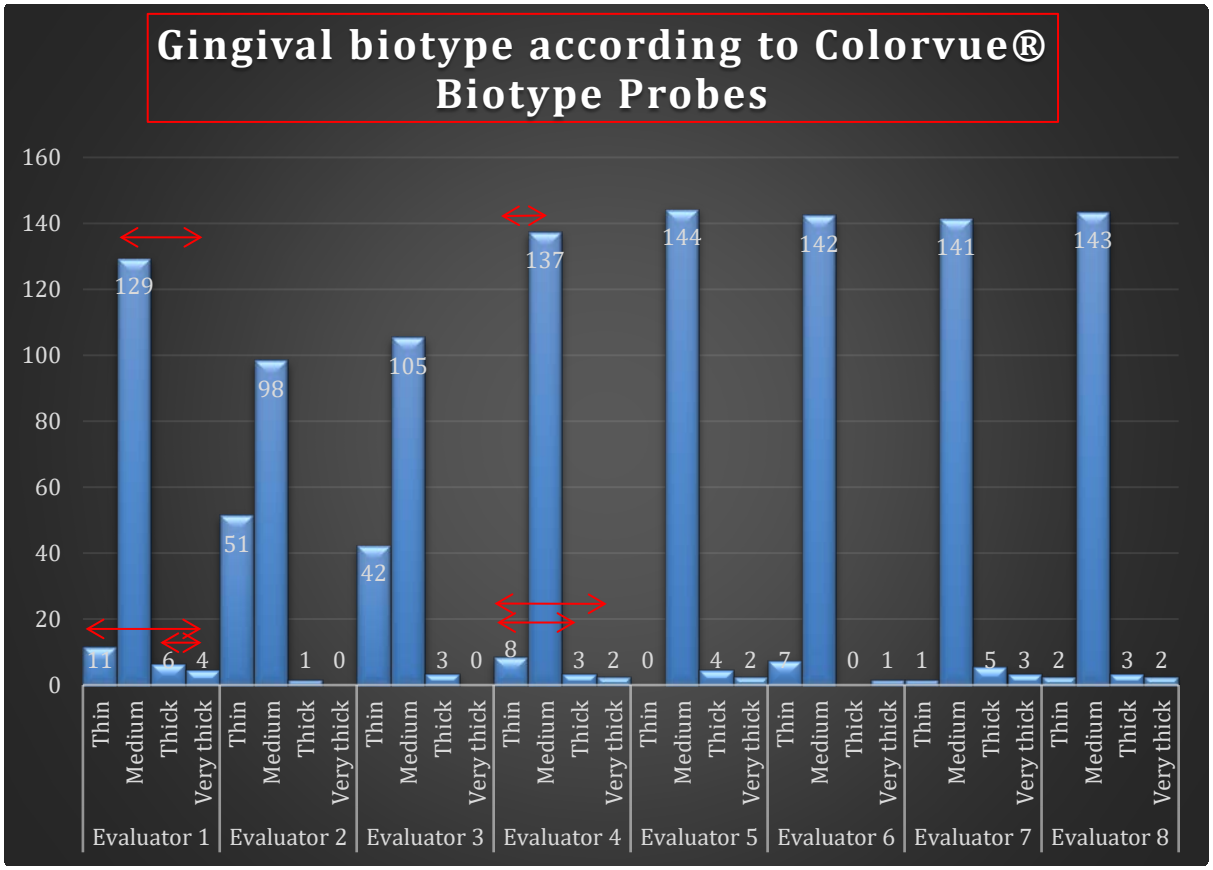

Chart 4. Gingival biotypes according to CBP, the arrows mark the significant gingival thickness between CBP-probe

Reproducibility of each method

The agreeability between evaluators and repeatability of four evaluators is presented in *table 6.1*, and the different colors follow the classification in *table 6.2*. The numbers in brackets on *table 6.1.* show the range of the lowest to highest ICC value (lowest-highest). The level of agreement among all evaluators using the CBP varied from *moderate* to *substantial* where SPP was scoring the highest and CBP1 scoring the lowest. The repeatability of each evaluator varied from *poor* to *almost perfect* agreement, the lowest repeatability is found for the CBP 1 (white probe).

Table 6.1. ICC values for agreement between evaluators and repeatability for each evaluator, and range of values in brackets

	VA	SPP	CBP1	CBP2	CBP3
Among all evaluators	0.70 (0.61-0.77)	0.86 (0.82-0.90)	0.48 (0.34-0.59)	0.76 (0.70-0.82)	0.80 (0.75-0.85)
Evaluator 1 run 1 vs run 2	0.49 (0.25-0.67)	0.23 (0.03-0.42)	0.32 (0.11-0.50)	0.34 (0.13-0.52)	0.00 (-0.20-0.21)
Evaluator 4 run 1 vs run 2	0.26 (0.04-0.46)	0.68 (0.54-0.78)	0.42 (0.21-0.58)	0.58 (0.40-0.71)	0.31 (0.08-0.50)
Evaluator 7 run 1 vs run 2	0.46 (0.25-0.62)	0.42 (0.20-0.59)	-0.02 (-0.24-0.20)	0.38 (0.17-0.56)	0.66 (0.51-0.77)
Evaluator 8 run 1 vs run 2	0.42 (0.20-0.59)	0.54 (0.36-0.68)	-0.01 (-0.24-0.21)	0.66 (0.51-0.77)	1.000

Table 6.2. The colors of the different values vary according to the level of agreement in the scale

Poor agreement: <0.00
Slight agreement: 0.00-0.20
Fair agreement: 0.21-0.40
Moderate agreement: 0.41-0.60
Substantial agreement: 0.61-0.0
Almost perfect agreement: 0.81-1.00

Discussion

According to the present study results, the difference in thickness between the green tip and the blue tip CBP are slight. An overrepresentation of 'medium' gingival biotype is shown according to the CBP. The subdivision of the gingival biotype using CBP is therefore not clinically practical.

Thicker gingiva has a better ability to withstand trauma and generate a better aesthetic outcome. (1, 2, 3, 35, 36) The findings of the importance of the gingiva thickness seem to be universal and standard. However, there seems to be no universal or golden standard to assess the gingival biotype in the current state. The challenge is to find a reliable, non-invasive method to measure the gingival biotype objectively. It is important to point out when measuring the gingival thickness, even the slightest differences in the result may prevent an accurate classification of the different gingival biotypes. This may lead to underestimating gingival thickness, which could result in unexpected gingival retraction after implant installation.

The most non-invasive method is ultrasonography and has limited clinical practicality considering its' commercial unavailability (37). Cone Beam Computerized Tomography (CBCT) is superior and can obtain detailed information. However, the method is technical, expensive, and require strict indications because of radiation exposure (18, 30). Assessing the gingival thickness only visually is not equally reliable nor objective when compared to gingival puncturing and the transparency method (14). The transparency method of CBP in the present study was chosen because the method aims to be reliable, objective, economical and minimally invasive. The ability of the gingival tissue to conceal the underlying material is influential. In dental implants, the subgingival alloy is presented extensively. Therefore, it is logical to use the transparency method (15). The present study reveals few evaluators with a statistically significant difference in gingival thickness when assessing the visibility of the CBP probes. The visibility or non-visibility of the CBP probes does therefore not reflect on the actual thickness of the gingiva. Whereas four out of eight evaluators showed statistical significance in gingival thickness when using an SPP. Most green and blue tip probes of the CBP were marked as 'visible', while most white tip probes were marked as 'not visible', among all evaluators. One can, therefore, conclude that the CBP can reveal the gingival thicknesses of the far thin and far thick biotypes, but it is unable to identify more subtle differences in thickness. The visual assessment had a slight difference in gingival thickness between the two options 'thin' and 'thick'. Only two evaluators showed statistical significance, but the agreeability among all evaluators was substantial (ICC 0.696, table 6.1).

Study result also presents inter-examiner agreement is not increased with the new CBP compared to the SPP. On the contrary, the SPP showed the highest inter-examiner agreeability. It also appears to be that inter-examiner agreement is increase when the CBP is darker, as shown in table 5 whereas the intra-examiner repeatability scores seem to be random and differ individually within different examiners as shown in table 5. CBP is not widely commercialised in daily clinical practice, and there are still a few studies present. Further research on CBP is still needed.

For this study, the evaluators assessed 800 pictures each, and four of the evaluators repeated the assessment of 400 pictures. The transgingival puncturing with an endodontic file was determined to be the golden standard for the measurement of gingival thickness in the current study. This method tends to overestimate the gingival thickness (38) but has a sufficient reproducibility (37), which is key in creating a baseline to proceed from. The aim was to

assess whether the ‘shine through’ effect of each probe was visible or not. A flaw in this method is that the gingiva tends to crease due to the probe-circumference underneath, which in turn can give away the presence of the probe shown in figure 6. This may also be the reason for the positive results of the ‘unprobed but masked’. The degree of the ‘shine through’ effect may also be different, where a green probe could is clearly visible in one picture, and barely visible in another. The evaluator has only the option ‘visible’ or ‘not visible’ to choose from, which could mean that two gingival biotypes with different ‘shine through’ effect are assessed the same. The low and varying results in ICC scores for repeatability of the CBP probes lead to rejection of the hypothesis.

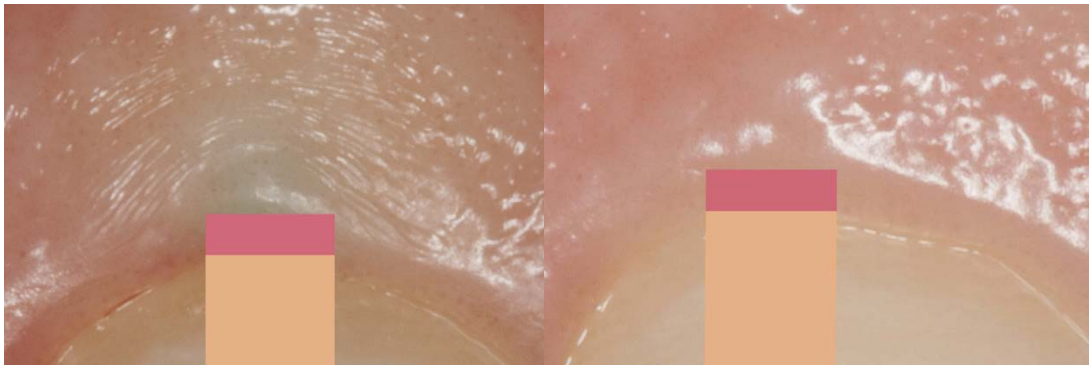

Figure 6. Crease formation of the gingival tissue during probing in the left picture compared to the absence of the probe in the right picture. The same tooth is in both pictures.

Again, it needs to be pointed out that there is no golden standard method to classify the gingival biotype. In the contrary there are various method to determine the gingival biotype, each method has its advantages and disadvantages. Clinicians can choose individually appropriate method to evaluate the gingival biotype. The transgingival puncturing method was elected to be the golden standard for the present study, it is a direct method who are relatively simple and common. However, the method has its limits as mentioned in the introduction and therefore may have affected the present study outcome.

Conclusions

Based on the results of the present study differences among the methods was displayed, as far as accuracy and reproducibility are concerned. Based on the reproducibility, repeatability and accuracy, the SPP method to classify the gingival biotype accurately into 4 categories of distinct thickness performed better than CBP and VA. Additionally with CBP most of the cases the gingival biotype was judged as *medium* class (87%), and the *thin*, *thick* and *very thick* category appeared only in a minor percentage with the *thick* and *very thick* category displaying no difference.

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Attachments

The table below shows gingival thickness of all assessments and probability value for each evaluator and method.

		Evaluator 1		Evaluator 2		Evaluator 3		Evaluator 4		Evaluator 5		Evaluator 6		Evaluator 7		Evaluator 8	
		n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD
VA	Thin	74	1.24± 0.31	82	1.28± 0.31	57	1.23± 0.33	98	1.28± 0.27	66	1.31± 0.33	94	1.27± 0.32	46	1.27± 0.32	119	1.30± 0.31
	Thick	76	1.40± 0.29	68	1.33± 0.31	93	1.35± 0.28	52	1.35± 0.36	84	1.30± 0.29	56	1.36± 0.28	104	1.32± 0.30	31	1.30± 0.32
	p-value	**0.019**		0.342		**0.025**		0.221		0.940		0.098		0.319		0.987	
SPP	Visible	13	1.18± 0.37	57	1.23± 0.30	47	1.22± 0.29	32	1.22± 0.28	23	1.15± 0.28	69	1.25± 0.30	21	1.26± 0.29	38	1.21± 0.29
	Not visible	137	1.32± 0.30	91	1.35± 0.31	103	1.34± 0.31	118	1.32± 0.31	127	1.33± 0.31	81	1.35± 0.31	129	1.31± 0.31	112	1.34± 0.31
	p-value	0.116		**0.022**		**0.020**		0.078		**0.011**		0.067		0.452		**0.027**	
CBP 1	Visible	11	1.26± 0.26	51	1.22± 0.28	42	1.30± 0.34	8	1.09± 0.25	0	-	7	1.35± 0.21	1	0.95	2	1.43± 0.10
	Not visible	139	1.31± 0.31	99	1.35± 0.31	108	1.31± 0.30	142	1.32± 0.31	150	1.30± 0.31	143	1.30± 0.31	149	1.31± 0.31	148	1.30± 0.31
	p-value	0.605		**0.013**		0.900		**0.040**		-		0.714		0.253		0.573	
CBP 2	Visible	140	1.29± 0.30	149	1.30± 0.31	147	1.30± 0.31	145	1.29± 0.31	144	1.30± 0.31	149	1.30± 0.31	142	1.30± 0.31	145	1.30± 0.31
	Not visible	10	1.52± 0.28	1	1.58	3	1.54± 0.23	5	1.56± 0.20	6	1.43± 0.10	1	1.41	8	1.37± 0.12	5	1.37± 0.10
	p-value	**0.023**		0.376		0.179		0.062		**0.020**		0.714		0.168		0.209	
CBP 3	Visible	139	1.28± 0.30	149	1.30± 0.31	147	1.30± 0.31	145	1.30± 0.30	145	1.29± 0.31	149	1.30± 0.31	146	1.30± 0.31	146	1.30± 0.31
	Not visible	11	1.57± 0.23	1	1.42	3	1.62± 0.10	5	1.54± 0.32	5	1.56± 0.19	1	1.42	4	1.47±0.11	4	1.50± 0.09
	p-value	**0.003**		0.714		0.069		0.076		0.060		0.714		0.280		0.185	

Avdelning 2

PROTOKOLL 2017/9
Sammanträde 2017-09-26 kl 13.00 – 16.30
Sammanträdesrummet, Sandgatan 1, Lund

Närvarande

Ledamöter

Ordförande
Karoline Fridolf

Ledamöter med vetenskaplig kompetens
Margareta Reis, vetenskaplig sekreterare
Dag Wide Svensson, vetenskaplig sekreterare (deltar ej i § 4 punkten 4.2 pga. jäv)
Annelie Carlsson
Per Kahrman
Karin Leanderson
Bodil Ohlsson
Anna Rignell-Hydbom
Ellen Tufvesson
Eva Tuninger
Malin Wennström (deltar ej i § 4 punkten 4.3 pga. jäv)

Företrädare för allmänna intressen
Lars Fagerström
Donúl Gaynor (deltar ej i § 2 punkten 2.9 pga. jäv)
Amela A Hodzic (deltar ej i § 2 punkten 2.9 samt §§ 3, 4 och 5)
Ingrid Karlsson
Gunilla Lundström

Övriga närvarande

Irène Barsegård, Administrativ sekreterare

----------**utdrag ur protokoll**----------

§ 2

Ansökningar om godkännande av nya forskningsprojekt

2.3

Dnr 2017/679
Föredragande
Eva Tuninger

Forskningshuvudman
Malmö högskola

Forskare som genomför projektet (kontaktperson)
Andreas Stavropoulos

Projekttitel
Bedömning av gingival och mukosal biotyp vid egna tänder och tandimplantat. Version nummer: 1.0.

Beslut
Ansökan godkänns med följande villkor

Postadress	Bankgironr	Organisationsnr	Besöksadress	Telefon	E-post	Hemsida
Box 133	293-9861	202100-1560	Sandgatan 1	046-2224180	eva.e.vastrand@epn.lu.se	www.epn.se
221 00 LUND			Lund	046-222-3312	irene.barsegard@epn.lu.se	
Växelnr 22				046 2224516	ann-marie.kollmer@epn.lu.se	

Avdelning 2

PROTOKOLL 2017/9
Sammanträde 2017-09-26 kl 13.00 – 16.30
Sammanträdesrummet, Sandgatan 1, Lund

1. Patientinformationen ska inledas med förfrågan om deltagande och du tilltrågas inte. Ordet inbjudan och inbjuder dig ska strykas.
2. Patientinformationen ska kompletteras med fullständiga uppgifter om forskningspersonens rättigheter enligt personuppgiftslagen. Forskningspersonen har rätt att ansöka om information från personuppgiftsbehandling enligt PuL § 26 och detta gör man genom att skriva till personuppgiftsombudet. Sådan ansökan måste vara egenhändigt undertecknad. Man har också rätt att få eventuella felaktiga personuppgifter rättade. Uppgift om att i studien ingående information hanteras enligt gällande sekretessbestämmelser ska också framgå samt att svar och resultat kommer att behandlas så att inte obehöriga kan ta del av dem.
3. Information om vilka uppgifter som kodas och vad en kodnyckel är och innebär ska framgå i patientinformationen.
4. Under rubriken "Risker att medverka" i patientinformationen läggs information som redan tagits upp under rubriken "Studiens genomförande". Se över dessa stycken språkligt.
5. Under rubriken studiens genomförande i patientinformationen ska sista meningen "Detta innebär inga obehag för dig" strykas.

Beträffande hur man överklagar, se bilaga.

Att utdraget överensstämmer med originalet intygar:

Iréne Barsegård
administrativ sekreterare,
tfn 046-222 43 12

Exp till:
Gunilla Klingberg
Andreas Stavropoulos

Postadress	Bankgironr	Organisationsnr	Besöksadress	Telefon	E-post	Hemsida
Box 133	792-6161	202100-1360	Sandgatan 1	046 2224180	eva.elvstrand@epn.lu.se	www.epn.se
221 00 LUND			Lund	046-2224012	irene.barsegard@epn.lu.se	
Hantverket 12				046-2224616	ann-marie.kellner@epn.lu.se	

Bedömning av gingival och mukosal biotyp vid egna tänder och tandimplantat

Medgivande:

Namn: ....

Födelsedatum: ..... **Kod:** ....

Jag deltar frivilligt i den kliniska prövningen "Bedömning av gingival och mukosal biotyp vid egna tänder och tandimplantat".

Bakgrund, syfte, innehåll och eventuella risker för den aktuella studien förklarades i detalj och på ett begripligt sätt för mig. Jag har läst texten i denna patientinformation, vilken omfattar totalt 3 sidor, och samtycker till att delta. Eventuella frågor besvarades av tandläkaren. Jag hade gott om tid att bestämma mig och jag har för närvarande inga fler frågor.

Jag kommer att åhöra tandläkarens påbud, vilka är nödvändiga under deltagandet i studien, men jag förbehåller mig rätten att avsluta mitt frivilliga deltagande när som helst utan att det ska innebära några nackdelar för mig och min fortsatta behandling. Jag samtycker även till att mina personuppgifter kommer att insamlas i detta kliniska försök.

Jag har fått en kopia av patientinformationen och samtyckesblanketten. Originalet förblir hos provförrättaren.

.....	.....
(Datum och underskrift av patienten)	**(Datum, namn och underskrift av ansvarig provförättare)**

Patientinformation

Bedömning av gingival och mukosal biotyp vid egna tänder och tandimplantat

Inbjudan

Vi inbjuder dig att delta i en undersökning för bedömning av gingival och mukosal biotyp (tandköttstyp) vid egna tänder och tandimplantat, som utförs vid Avdelningen för Parodontologi på Malmö Högskola, Odontologiska fakulteten.

Bakgrund och syfte

Biotypen av ditt tandkött (dvs. om du har tunn eller tjock mjukvävnad) betraktas som en viktig egenskap för resultatet av olika kliniska, inklusive kirurgiska, åtgärder av vävnaden kring egna tänder och tandimplantat. Det finns olika metoder för att bedöma biotypen av ditt tandkött och nyligen har ett nytt hjälpmedel (dvs. en specifik typ av sond) utvecklats. Hittills finns det ingen data tillgänglig för denna sond, och om olika utvärderare uppnår samma resultat vid användning av sonden och om den kan användas kring tänder och implantat på samma sätt.

Syftet med denna studie är att testa en metod för att bedöma typen av tandkött runt tänder och implantat.

Studiens genomförande

Om du bestämmer dig för att delta i den aktuella studien, kommer studien att utföras i slutet av en av dina ordinarie klinikbesök, vilket i så fall tar cirka 15 minuter längre. Vid denna tidpunkt kommer vi att utvärdera ditt tandkötts biotyp på fyra olika sätt; Dvs. med två olika typer av sonder, med ett litet skjutmått (krumcirkelmått) och med en liten nål. Vid bedömning av ditt tandkötts biotyp kommer flera foton att tas, vilka kommer att utvärderas senare, men dessa foton visar bara dina tänder och inte ditt ansikte (det är inte möjligt att känna igen dig från dessa bilder). Alla metoder används regelbundet under den dagliga klinisk verksamheten och/eller forskningsprojekt och de innebär ingen risk för dig. Endast en av de fyra metoderna kräver applicering av lite bedövningsgel, eftersom vi behöver sticka lätt i tandköttet en gång med en tunn nål. Detta är jämförbart med sticket när man får lokalbedövning och tar bara några sekunder. Dessutom kommer några få standardundersökningar (t.ex. fickdjup), som ingår vid vanlig undersökning, att användas; Detta innebär inga obehag för dig.

Risker med att medverka

Som nämnts ovan innebär bedömningen av ditt tandkötts biotyp inte någon risk för dig. Endast en av de fyra metoderna kommer att kräva applicering av lite bedövningsgel,

eftersom vi behöver sticka lätt i tandköttet en gång med en mycket tunn nål. Detta är jämförbart med sticket när man får lokalbedövning och tar bara några sekunder. Eftersom vi använder en mycket tunn nål känner du ingen smärta efteråt.

Fördelar med att medverka
Den här studien testar en metod för att bedöma typen av tandkött runt tänder och implantat, men det finns ingen direkt fördel för dig.

Hantering av data & sekretess
Ansvarig för dina personuppgifter är Malmö Högskola. Dina personliga data kommer handläggas enligt vad som föreskrivs i Personuppgiftslagen (PuL) (1998:204). Information gällande PuL kan inhämtas på webbsidan http://www.notisum.se/rnp/sls/lag/19980204.HTM och information om Region Skånes informationspolicy, vilken studien kommer åtfölja på webbsidan www.skane.se/informationssakerhet. Studien anmälas enligt PuL till personuppgiftsombud vid MAH, Hans Jonsson, Gemensam förvaltning, 205 06 Malmö, tel: 0708-655289

Dina resultat och data kommer att behandlas på ett sådant sätt att ingen obehörig får tillgång till dem. Endast de ansvariga personerna i denna studie kommer att kunna nå information om ditt namn och ditt namn kommer inte att ingå i någon publicering av resultaten från studien. Efter studiens avslutande kommer all personlig data som kan anknytas till dig att förstöras. All övrig individuell data förstörs på begäran av dig.

Studiens resultat
Om du så önskar kan du ta del av dina egna resultat. Vid en eventuell publicering har du även möjlighet att få information om i vilken tidskrift och vilket nr studien publiceras.

Försäkring – Ersättning
Du är täckt av samma försäkringsregler som gäller för alla patienter som får behandling vid Odontologiska fakulteten.
Ingen ekonomisk ersättning kommer att delas ut för ditt deltagande i denna studie.

Frivillighet
Du medverkar helt frivilligt i denna studie och kan när som helst välja att avbryta ditt deltagande - ingen förklaring krävs av dig. Du kan be att få all din data förstörd. För att återta samtycket att deltag i studien, skall du kontakta studiens ansvarig. Ditt eventuella beslut att avsluta deltagandet kommer inte att påverka din övriga planerade behandling.

Patientinformation

Ansvar
Prof. Andreas Stavropoulos
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