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DEPARTMENT OF ORTHODONTICS

EVALUATION OF PATIENTS' PREFERENCES OF IMPRESSION TECHNIQUES AMONG DIFFERENT AGE GROUPS

DOCTOR OF PHILOSOPHY THESIS

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DECLARATION

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LIST OF ABBREVIATIONS AND SYMBOLS

°C	: Degree Celcius
µm	: micrometer
2D	: Two Dimensional
3D	: Three Dimensional
ANSI	: American National Standards Institute
AWS	: Active Wavefront Sampling
CAD-CAM	: Computer Aided Design and Computer Aided Manufacturing
CBCT	: Cone Beam Computer Tomography
CLSM	: Confocal Laser Scanning Microscopy
COS	: Chairside Oral Scanner
IEC	: International Electrotechnic Commission
IOC	: Orthodontic Scanner and Software System
NCSS	: Number Cruncher Statistical System
OCT	: Optical Coherence Tomography
PVS	: Polyvinyl Siloxane
STAI	: State-Trait Anxiety Inventory
STL	: Stereolithography
mm	: Milimeter
VAS	: Visual Analogue Scale
WBS	: Wong-Baker FACES® Pain Rating Scale

ABSTRACT

Nizam, MB. (2023). Evaluation of Patients' Preferences of Impression Techniques Among Different Age Groups. Yeditepe University, Institute of Health Science, Department of Orthodontics, PhD Thesis, İstanbul.

The aim of this prospective study was to evaluate and compare chairside time, perception and preference of patients receiving conventional and digital impressions in different age groups. Within the scope of this study, 63 patients who applied for orthodontic treatment and met the inclusion criteria were enrolled in the study groups. The patients were grouped according to the age (Group 1: 8–12 years old, Group 2: 13–17 years old, Group 3: 18 years old and above). Each group consisted of 21 patients. Each patient's anxiety level was evaluated by state anxiety measurement test (STAI) prior to the intervention. After an anxiety test, patients' dental records were taken with alginate impression (Kromopan® Lascod, Florence, Italy) and intraoral scanning (iTero Element 2, Align Technologies, San Jose, Calif.) and the chairside time was recorded. Each patient filled out a perception and preference questionnaire. Statistical analysis were performed. The duration of digital impression was shorter than that of the conventional impression in all groups ($p<0.001$). The chairside time of digital impression method in the 8–12 age group was statistically shorter than that of the 13–17 age group and ≥18 age group ($p<0.001$). Chairside time of digital impression method in the 13–17 age group was statistically shorter than that of the ≥ 18 age group ($p<0.05$). For the conventional impression method, there was no statistically significant differences in perceptions of the patients in different age groups ($p>0.05$). For the digital method, the overall VAS scores of perception of the 13-17 age group was statistically lower compared to other groups ($p<0.05$). In each age group, digital impression method was mostly preferred over conventional impression method although there was no statistically significant difference among age groups in terms of impression method preferences ($p>0.05$). As a conclusion, intraoral scanning took less time in children aged 8–12 compared to older patients. All age groups perceived digital scanning more positively compared to the conventional method. The patient's perception of digital impressions differed between different age groups. 13–17-year-old patients had a more positive overall perception of the digital method. The majority of patients preferred digital impressions; however, the age of the patients did not play a role in their preference.

Keywords: Conventional impression method, Digital impression method, Age groups

ÖZET

Nizam, MB. (2023). Farklı Yaş Gruplarında Hastaların Ölçü Tekniği Tercihlerinin Değerlendirilmesi. Yeditepe Üniversitesi, Sağlık Bilimleri Enstitüsü, Ortodonti ABD., Doktora Tezi, İstanbul.

Bu prospektif çalışmanın amacı, farklı yaş gruplarında konvansiyonel ve dijital ölçü alınan hastaların işlem süresini, algısını ve tercihini değerlendirmek ve karşılaştırmaktı. Bu çalışma kapsamında ortodontik tedavi için başvuran ve dahil edilme kriterlerini karşılayan 63 hasta çalışma gruplarına dahil edilmiştir. Hastalar yaşlarına göre gruplandırıldı (Grup 1: 8–12 yaş, Grup 2: 13–17 yaş, Grup 3: 18 yaş ve üzeri). Her grup 21 hastadan oluşuyordu. İşlem öncesinde her hastanın kaygı düzeyi durumluk kaygı ölçüm testi (STAI) ile değerlendirildi. Anksiyete testinin ardından hastaların ağıziçi kayıtları aljinat ölçü (Kromopan® Lascod, Florence, İtalya) ve intraoral tarama (iTero Element 2, Align Technologies, San Jose, CA) ile alındı ve işlem süreleri kaydedildi. Her hasta bir algı ve tercih anketi doldurdu. İstatistiksel analiz yapıldı. Dijital ölçü süresi tüm gruplarda konvansiyonel ölçü süresinden daha kısaydı ($p<0.001$). 8-12 yaş grubunda dijital ölçü yönteminin işlem süresi, 13-17 yaş ve ≥18 yaş grubuna göre istatistiksel olarak daha kısaydı ($p<0,001$). 13-17 yaş grubunda dijital ölçü yönteminin işlem süresi ≥ 18 yaş grubuna göre istatistiksel olarak daha kısaydı ($p<0,05$). Konvansiyonel ölçü yöntemi için farklı yaş gruplarındaki hastaların algılarında istatistiksel olarak anlamlı fark yoktu ($p>0,05$). Dijital yöntem için 13-17 yaş grubunun genel VAS algı puanları diğer gruplara göre istatistiksel olarak daha düşüktü ($p<0,05$). Her yaş grubunda ölçü yöntemi tercihleri açısından yaş grupları arasında istatistiksel olarak anlamlı bir fark bulunmamakla birlikte, geleneksel ölçü yöntemine göre en çok dijital ölçü yöntemi tercih edildi ($p>0,05$). Sonuç olarak ağız içi tarama 8-12 yaş arası çocuklarda daha büyük hastalara göre daha kısa sürmüştür. Tüm yaş grupları dijital taramayı geleneksel yönteme göre daha olumlu algılamaktadır. Hastanın dijital ölçü algısı farklı yaş grupları arasında farklılık gösteriyordu. 13-17 yaşındaki hastalar, dijital yöntemle ilgili genel olarak daha olumlu bir algıya sahipti. Hastaların çoğu dijital ölçüleri tercih etti; ancak hastaların yaşı tercihlerinde rol oynamadı.

Anahtar kelimeler: Konvansiyonel ölçü yöntemi, Dijital ölçü yöntemi, Yaş grupları

1. INTRODUCTION AND PURPOSE

For the identification of abnormalities and case-specific treatment planning and eradication of malocclusion, orthodontic study models, intraoral and extraoral images of the case, and clinical and radiographic evaluation techniques are utilized (1). The study models made from the patient's impressions are a three-dimensional reflection of the case's intraoral image, which may be thoroughly examined. Analyses based on study models are essential in clinical practice and in the extensive examination of malocclusion.

Regarding orthodontic diagnosis and treatment planning, dentition and occlusion are frequently assessed with dental models (2). The traditional way of creating dental models is taking intraoral impressions, which has been successfully used for years. On the other hand, alginate impression is often seen as uncomfortable by the patients (3). Patients may experience discomfort including gag reflex, smell, taste, temperature change, difficulty in breathing, etc. Particularly for individuals with hypersensitive gag reflex, it has been demonstrated that the patient's experience at the initiation of an orthodontic treatment has a significant impact on adherence and treatment success (4). Moreover, while taking a conventional alginate impression, there is a possibility of dimentional distortion due to moisture absorbtion or loss from the impression substance. Furthermore, when there are deep undercuts, such as with orthodontic brackets on the teeth, irreversible distortion of the imprint material might develop. To get around these problems and avoid having to digitize the plaster study models and alginate impressions, it would be better to digitize the teeth directly.

Digital medical technology is becoming an increasingly important aspect of contemporary orthodontic treatment. With the intraoral scanners used in dentistry, patient data can be easily archived, accessible, transferred, designed, and produced. Moreover, the intraoral scanners have voice and motion control features, are portable, and make it possible to create digital measurement data easily and quickly. Furthermore, using the system's built-in software, the digital models may be utilized to accurately quantify essential treatment parameters include overjet, overbite, and length of the arch.(5). Also, If a physical representation of the dentition is required for the fabrication of orthodontic equipment, digital 3D models may be manufactured using rapid prototyping technology. (6). Another advantage of intraoral scanning was proposed by the manufacturers as a better patient experience and improved patient satisfaction. Several studies have been conducted on the preferences of patients regarding impression technique leading to contradictory findings (7,8). Some authors have reported less acceptance of intraoral scans over traditional impression method with respect to chair time and patient acceptance (7). Whereas some authors have shown better patient experience during intraoral scanning (8–10). The patients experience and perception may be impacted by many circumstances, including the patient's age and level of anxiety (10–13), feeling of being in control (4) or duration of the procedure (7).

When compared to standard alginate imprints, the time needed for intraoral full-arch scans also varies in the literature which reports no difference between impression methods, or significantly shorter chairside for intraoral scanning or for alginate impression (7,8,10,13,14).

The age of the patient may play a role in the experience and the preference of impression technique (13). Therefore, the orthodontist might need to adopt different methods for different age groups. There is no study comparing the perception and preference of children, teenagers and adults regarding impression techniques.

In the light of the conflicting findings and lack of information in the orthodontic literature, we aimed to evaluate and compare chairside time, perception and preference of different age groups receiving intraoral scan and conventional alginate impression.

2. LITERATURE REVIEW

2.1. Orthodontic Dental Models

Dental models are essential parts of orthodontics treatment regarding diagnosis and treatment planning, fabrication of the orthodontic appliances and outcome evaluation. Orthodontic dental models are plaster reproductions of both maxillary and mandibular teeth and soft tissue around them that offer a good representation of the patient's occlusion. The diagnostic model, along with an extensive exploration and medical history, forms the basis for an assessment and treatment plan that includes choices and is the standard of orthodontic treatment. Preprocessing unchanged diagnostic records for comprehensive orthodontic care should include dental models (or virtual models) to evaluate the inter arch and intra-arch relations of teeth, assist in determining arch length and depth needs, and evaluate arch symmetry. Diagnostic records also help to evaluate the occlusion and dentition from all three dimensions (sagittal, transversal, and vertical planes), which is very important for proper treatment planning.

The American Orthodontic Society stated in 2003 that orthodontic records should be collected before and after treatment. The recording materials comprise dental models, extraoral and intraoral photos, cephalometric radiographs, panoramic radiographs, and, if required, further recordings (15).

Hou et al. reported that arch form and arch symmetry, Spee and Wilson curves, and Bolton, Peck & Peck, tooth width, and arch length may be examined using orthodontic models (16).

In their research, Han et al. (17) examined the impact of information collected from various kinds of diagnostic records on treatment choices. They observed that in 55% of instances, treatment planning using simply the orthodontic model did not differ substantially from treatment planning utilizing additional diagnostic methods like facial pictures, panoramic radiography, lateral cephalometry, and cephalometric drawing. They claimed that, in many circumstances, plaster models alone may be adequate for treatment planning, emphasizing the importance of obtaining diagnostic models prior to orthodontic treatment.

Initial circumstances, treatment progress, and overall treatment results are all recorded in orthodontic models. Orthodontists also utilize these models to educate, evaluate, and study their patients and colleagues on their treatment outcomes. (17).

2.2. History of the Orthodontic Dental Models

Taking intra-oral impressions and then obtaining a plaster model is method which has been used since 1700s. It was first created by Philipp Pfaff in order to achieve a study model from the patient by using a substance based on wax with heating, and it has been reported that plaster of Paris was used to create the model. In 1839, Chapin A. Harris took a wax-based impression from his patient, and he advocated the use of a material in the structure of lime. In the middle of the 19th century, the use of gutta-percha, plaster of Paris, and various materials became more common as impression materials (18).

At the beginning of the 1900s, new materials were produced that showed fewer dimensional changes, were less costly, and were easier to apply. Today, we use an irreversible hydrocolloid (alginate), polyvinylsiloxane, in the structure of elastic polyether, which is the basis of impression materials. Currently, in orthodontic clinics, alginate is used as the intraoral impression material, and type II plaster is most often used to create study models (15).

Recent years, instead of creating a plaster model after taking intraoral records, the patient's intraoral impressions are sent to digital model companies. Computer Aided Design and Computer Aided Manufacturing (CAD-CAM) technology is used in businesses. Patient's dental arches are transformed into a three-dimensional visual image. These data can be downloaded to any computer digitally through various computer programs. Then models to be taken at the beginning and at the end of treatment, can be viewed in detail to be taken at the beginning of treatment and at the end of treatment.

The development of digital technology in dentistry started a new era in orthodontics by directly scanning the maxillary and mandibular dental arches and generating 3D digital models.

Dr. Werner Mörmann, a Swiss dentist, and Marco Brandestini, an Italian electrical engineer, created the first computerized intraoral scaning device for restorative dentistry in the

1980s. In 1984, Dr. Francois Duret invented and patented a CAD/CAM device. The developed process was shown at the Chicago Midwinter Meeting in 1989 by generating a dental crown in 4 hours (12). Cadent created the intraoral scanning-capable in-office iTero digital printing system in 2006, and this technology became capable of doing intraoral scanning of the complete arch in 2008. Cadent introduced the IOC (orthodontic scanner and software system) system for iTero subscribers towards the end of 2009. In 2011, Align Technology bought Cadent, allowing doctors using the IOC to begin submitting 3D digital scans rather than physical impressions for the fabrication of the Invisalign device (19).

2.3. Conventional Method

Most intraoral records are still carried out with the use of conventional techniques that a perforated metal tray or plastic tray and diagnostic model casting materials. According to the traditional method, the most preferred material in the construction of the diagnostic model is plaster. An intraoral impression is taken with the correct technique, covering the teeth and the tissues that surround them. The model is obtained by applying the correct plaster pouring procedure.

Although orthodontic models made of hard gypsum have been the most preferred material for years, it can be difficult to maintain their initial state. Making many measurements on the study model causes abrasions on the plaster over time, and the details in the model become blurred. The space requirement for the storage of these models and their long-term retention cause time problems. Protective boxes are preferred so that the models are not damaged. In orthodontic clinics with high patient density, a room should be reserved for models only. In addition, each model differs from country to country for possible legal review, which must be stored for a period of time (5 to 15 years) (15,20).

Another issue is portability. Even traveling with a few breakable diagnostic models is a daunting task. Orthodontist may have to duplicate models. Communication with other dentists and specialists can be an expensive and time-consuming process.

2.4. Conventional Impression Materials and Properties

2.4.1. Properties of Impression Materials

Impression materials are always getting better, but it's important to understand how they differ in order to know which one is best for a given clinical situation.

1. Wetting, Hydrophilicity, and Contact Angles

The degree of hydrophilicity of impression materials distinguishes them. They might be hydrophilic, hydrophobic, or hydroactive. The contact angle may be used to quantify surface wetting, which represents a liquid's relative affinity for a solid. A zero contact angle indicates a low angle suggests whole surface moisture, while a high angle indicates less wetness. Moisture compatibility has a substantial influence on the material's capacity to capture surface information properly inside the oral tissues.

Hydrophilic substances have a great affinity for water (a low contact angle), superior surface wetting, and a high degree of surface detail. Hydrophobic impression materials have a low affinity for water (high contact angle), poor surface wetting, and little surface detail. By adding surfactants to hydrophobic impression materials, hydroactive impression materials become hydrophilic. These materials have a high degree of surface detail as well as great surface wetting (low contact angle). When considering the wetting power of impression materials, it is vital to evaluate the materials' wetting ability for soft and hard tissues, as well as for gypsum slurry (21).

2. Categorization Based on Viscosity

The flow properties of an unset imprinted substance are described by the word "viscosity." The percentage of filler present enhances the viscosity of the substance. When the viscosity of the impression material falls in response to considerable shear stress, shear thinning occurs. As a consequence, the impression material's viscosity will vary in reaction to shear stress. Sometimes, low-viscosity substances are referred to as "light body," "syringe," or "wash substance." These polymers with a reduced viscosity may easily flow into and capture minute details, however they are seldom used alone. They collaborate with a second, more viscous substance to hydraulically push and support the lower-viscosity material. (21).

3. Time Setting and Work

The period from the beginning of mixing until the impression material can be withdrawn from the mouth cavity without distortion is the impression material's setting time. The working time is determined from the moment the mix starts to the point at which the material can no longer be altered without creating distortion or inaccuracy in the final impression. Before the end of the working time, the impression material must be well combined and positioned. The working time of elastomeric impression materials is around two minutes, and the setting time ranges from two to six minutes. In general, working time and setting time are correlated. Therefore, a fast-setting material has a brief working time, while a slow-setting substance has a long working time. The setting time of all elastomeric impression materials is affected by temperature. One method for extending the working time by up to 90 seconds is to refrigerate the components prior to mixing. In addition, lowering the material temperature below 65 °C will affect the pastes' flow and result in variable ratios of base to catalyst. Humidity, the base-to-catalyst ratio, and the manner in which the material was combined are all factors that may influence the setting and working time of a substance. (21).

4. Elastic Recovery and Tear Resistance

The strength of impression materials must permit removal without damaging. A material with increased tear energy provides resistance to tearing for an imprint. The material's elasticity allows it to resist ripping and recover to its natural, pre-stressed condition. The degree to which this occurs indicates the material's elastic recovery. When the polymer is stretched beyond the point where elastic recovery is possible, irreversible deformation may occur. These two physical characteristics (elastic recovery and tear resistance) are crucial for preserving imprint accuracy during intraoral removal and after cast separation. Materials having enough tear resistance and elastic rebound may withstand many pours, resulting in a number of castings with high precision. (21).

5. Dimensional Stability

The ability of an impression to accurately reproduce intraoral characteristics is contingent on its dimensional stability. The following factors contribute to dimensional changes in elastomeric impression materials: contraction due to reduction in spatial volume following polymerization; reduction in set volume due to release of by-product or accelerator components; water absorption from wet or variable humidity environments; and temperature variations. Materials with enough dimensional stability may remain stable for a fair period of time (seven days) and tolerate temperature variations during transportation while still producing multiple castings with precise dimensions. (21).

6. Surface Detail

Surface detail relates to the ability of an impression material to correctly reproduce the surface of an object and is related to the thickness of the substance used to form the impression. Detail is enhanced by low viscosity. High-viscosity putty materials reproduce detail less well. All-impression materials and die stones replicate smooth, rounded preparations better. The sulcus should be thoroughly cleansed before generating a PVS (Polyvinil Syloksan) impression to remove any remains of the hemostatic material used during retraction. (21).

2.4.2. Classification of Impression Materials

There are a variety of materials available for creating precise negative molds of soft and hard tissue. Each substance has its advantages and disadvantages, and none is without imperfections. Types of impression materials include:

1. The non-elastic impression compounds

a. Imprint plaster

b. Imprint compound

c. Eugenol

2. The elastic impression substances

a. The hydrocolloids: Agar and alginate

b. The synthetic elastomers: Polysulfide, silicone, and polyether

2.4.2.1. Alginate as a Dental Impression Material

Dental irreversible hydrocolloid (alginate) is a common impression substance used in a number of medical procedures around the world. Alginate, on the other hand, is dimensionally unstable and changes dimensions "distortion" after being removed from the mouth. After more than ten minutes of storage, alginate starts to deform, and after one to three hours (depending on the product and storage circumstances), it is no longer suitable for many clinical applications, specifically fixed prosthodontics like tooth crowns and bridges. This lack of precision is seen as a shift in the form of the poured stone over time due to dimensional instability (22).

2.5. Digital Model Acquisition Strategies

As a result of studies on the digitization of orthodontic models, many methods have been developed. Since the end of the 1990s, the developments in obtaining digital models have accelerated, and the techniques we use today have been developed (23).

Photocopy:

A digital scan permits the picture to be moved to the desktop monitor for computerized examination. This strategy depends on putting a plaster model or a made-up copy on a scanner machine and acquiring a picture of the occlusal surface of the checked model. Computer programming is additionally utilized for distance estimation and examination of the model picture made after these cycles. In many examinations, two-layered strategies and particularly plaster model copying have been utilized to make measurements (24).

According to a study conducted in 1992, a comparison was made between the measurements made by taking plaster models with a photocopy machine and the measurements made by hand on plaster models. It was concluded that manual measurements calibrated on the photocopy are accurate, repeatable, and reliable. The disadvantage of this method is that a traditional plaster model is still needed, and a 2D image of a 3D object is created (25).

Schirmer et al. (26) placed a ruler next to the plaster models as a scale, photocopied them, and transferred the images to the computer. It has been reported that when a three-dimensional structure is reduced to two dimensions, the teeth's convex structure, tooth inclinations, Spee of curve, and tooth positions cannot be reflected correctly, so the photocopy method is insufficient for digitization.

Paredes et al. (27) who compared the Bolton analyses measurements using the photocopy technique with the conventional approach, determined that the photocopy method is as sensitive and accurate as the traditional method.

Nollet et al. (28) explored the dependability of evaluating dental arch relationships using pictures rather than working models. The research comprised the records of 49 children with cleft lip and palate; photographs of the models were taken from the front, right, left, and occlusal orientations. The images were rated using the Goslon Yardstick index, and the results were in the same range as the scores obtained from the dental models, indicating that the photographs may be a credible substitute for the models. Despite the fact that the photographic approach has been demonstrated to be reliable, observers during the assessments reported that they had difficulty analyzing the overjet.

Holography:

Holography, with modifications to the wavefront microscope, was first introduced in 1948 as a new method (29). Leith and Upatnieks made a great contribution to this method by enabling the use of a laser beam in the holography method. It has been reported that measurements can be made in three dimensions with high precision with the holography method (30).

Holograms are costly and hard to deliver. Additionally, although the picture captured with holography is three-dimensional, it is stored in a static structure and can't be moved like a study model. The most serious issue with this procedure is the subtleties of the study models and the inferior quality of the recording, particularly in the incisor region. Notwithstanding the benefits of holographic records being put away with clinical records and being a high-level advance in traditional working models, it doesn't appear to be feasible to totally supplant the original models (31).

Martensson and Ryden studied the sensitivity of three-dimensional measurements of holographic pictures. The ‘’holodent’’ technology enabled not only model-hologram registration but also hologram-hologram registration. A sharp metal instrument was used to create holograms of a plaster model of the upper jaw, and measurements were taken on the overlapping holograms.

It has been discovered that the measurements of metal test items with sharp edges are sensitive between 0.02 and 0.11mm for the x, y, and z coordinates. Using plaster models with less obvious outlines lowered the sensitivity to between 0.03 and 0.53 millimeters. Researchers suggested that holograms may be appropriate for retaining working models and assessing the positional changes of teeth throughout the course of extended investigations (32).

Photostereometric Technique:

In this method, two stereo video cameras are connected to a computer, and plaster models are digitally stored with specially colored lighting. The recorded data can be converted into stereolithographic format for reconstructing the working model. With this device, surgical planning and maxillofacial evaluation can be performed by taking an image of the face (33).

2.6. Optical Scanning Technologies

Scanner devices with different optical components and different technologies according to the various light sources they reflect are currently used in orthodontics.

Class I medical electrical devices, such as digital intraoral scanners, are developed and built in line with ANSI (American National Standards Institute) and IEC (International Electrotechnic Commission) 60601-1 standards. Each browser is comprised of three key components: a wireless mobile data input workstation; a computer display for writing prescriptions, verifying scans, and analyzing digital documents; and a cam for gathering scan data from the patient. Energy from either laser light or white light is transmitted onto the item through the use of the scanner to gather surface data points, and this energy is reflected back to the sensor or camera within the scanner. Tens or hundreds of thousands of measurements per inch are gathered using the algorithms, resulting in a three dimensional representations of the object's form. The technology used to acquire surface data inside the scanner affects the measuring resolution, speed, and accuracy of the scanner. Today, four kinds of imaging technologies are used (19).

1) Confocal Laser Scanner Microscopy (CLSM):

Confocal laser scanning microscopy (CLSM or LSCM) is a method for obtaining high-definition pictures with depth selectivity. Instead of being collected via an eyepiece, Images are projected one dot, one line at a time or from several points at the same time, and are computer-generated and three-dimensional. Confocal microscopy is distinguished by its capacity to generate optical slices of objects at varied depths with great resolution and contrast in x, y, and z dimensions. Spatial filtering is used to reduce out-of-focus glare and background light. Changing the scan sample duration allows you to change the picture magnification and spatial resolution, known as the zoom factor. (34).

2) Optical Triangulation:

Optical triangulation calculates distances to objects without contacting them with exactness from a couple of millimeters to a couple of microns. Triangulation sensors are especially helpful in gaining rapid information when examining sensitive, delicate, or wet materials where contacts are not desired. The framework utilizes a focal point, a laser light source, and a straight light touch sensor. The laser illuminates a point on an example, framing a light spot picture on the sensor surface. The separation from the sensor to the surface is then determined by deciding the place of the imaged spot and the gauge points and length included. The standard of triangulation has been utilized for quite a long time yet pragmatic sensors opened up for modern applications in 1971. Triangulation sensors are normally utilized for observing vibrations, tire aspects while turning at high velocity, and as a security instrument in programmed entryways (35).

3) Optical Coherence Tomography (OCT):

Optical coherence tomography (OCT) is an interferometric technique for studying the internal architecture of natural materials and tissues in cross-section. It is similar to ultrasound imaging, except unlike ultrasound, it uses light rather than sound. Micron-scale estimates of distance and microstructure are obtained gradually and in vivo from backscattered or back-reflected light waves. Despite the fact that OCT imaging profundities are not quite as profound similarly as with ultrasound, goal of 1 to 15 μm can be accomplished, 10 to multiple times higher than standard clinical ultrasound. The generally long-wavelength light can infiltrate into the dispersing medium up to 2-3 mm somewhere down in many tissues. OCT has turned into a grounded clinical analytic strategy since it was first exhibited in 1991 (36).

4) Active Wavefront Sampling (AWS):

Active wavefront sampling (AWS) utilizes a 3D surface imaging strategy, which requires just a single optical path of an AWS module and a single camera to get depth data. The optical wavefront crossing a focal point is examined in at least two off-axis areas, and a solitary picture is recorded and estimated at each position. Targeting techniques include picture pivot, which can be utilized to compute the component's distance to the camera. The opening examination can be carried out precisely or electronically, and various parts can be altered for better execution. Opening size, target brightening, and examining plane position can be upgraded to boost the captured picture quality. AWS diminishes framework cost by taking out the requirement for costly laser based objective illuminators and various cameras to gain 3D pictures (36).

2.6.1. Digital Scanners that Work with Different Scanning Principles

There is no question about the conceivable outcomes and capability of taking computerized records with the assistance of intraoral optical frameworks today, and throughout the course of recent years there has been a critical expansion in the scope of intraoral scanners regarding accessibility and availability. With the strength of various advancements in orthodontics and a more extensive scope of signs, intraoral examining frameworks appear to be an extremely encouraging improvement for what's to come (37).

Nearly 42 years ago, 3D scanning of the dental arch was presented for use with computer-aided design and computer-aided manufacturing (CAD/CAM) technology to make dental restorations. Its use in dentistry has risen significantly throughout this period, particularly in orthodontics. From existing plaster models or impressions, desktop scanners may now provide a digital 3D imaging of the maxillary and mandibular arches, both within and outside the occlusion. (38).

The application of the concept of intraoral scan for dental treatment was introduced in 1973 by Duret. Several years later, with a scanning (CEREC) commercially manufactured by Sirona Dental Systems, CAD/CAM technology was available (39).

Some of the major current intraoral digital impression systems on the market include CEREC (Sirona, Bensheim, Germany), E4D (Richardson, TX), TRIOS (Copenhagen, Denmark), the Lava C.O.S. system (Lava Chairside Oral Scanner; 3M ESPE, Seefeld, Germany), and iTero (Align Technologies, San Jose, Calif). They have different characteristics such as necessity of powder coating application, working principle, light source, output file format, and scanning process (40).

The CEREC system (Sirona, Bensheim, Germany) was introduced in 1987 with the Duret system. It is the world's first intraoral digital imprint and CAD/CAM system (41). This scanner is based on the "light triangulation" principle, which focuses on the intersection of three linear light beams at a given place in 3D space (39). Scan accuracy is reduced on surfaces with uneven light dispersion. Then, to increase scanning accuracy and generate uniform light dispersion, an opaque powder coating of titanium dioxide is required. (40).

D4D Technologies created the E4D technology using optical coherence tomography and confocal microscopy concepts. It makes use of a red laser as a light source and a micromirror that vibrates at 20,000 times per second. The high-speed laser used by E4D produces digital imprints of prepped and proximal teeth in order to generate dynamic 3D pictures (42).

The Lava Chairside Oral Scanner (Lava Chairside Oral Scanner; 3M ESPE, Seefeld, Germany) is an intraoral digital scanning equipment that was designed in 2006 and introduced in 2008. It operates on the "active wavefront sampling" idea. (43).

This idea applies to the capture of three-dimensional data from a single-lens imaging system. Three sensors may take clinical pictures from various angles at the same time and utilize unique image processing techniques to build surface patches with in-focus and out-of-focus data. (44).

TRIOS is an intraoral digital impression system introduced by 3Shape in 2011. This technology is based on ultra-fast optical sectioning and confocal microscopy concepts. While keeping a stable spatial connection between the scanner and the scanned item, the system identifies alterations in the focal plane of the model over a variety of focal plane locations (42).

Cadent Inc. (Carstadt, NJ) introduced iTero in 2007. The device was redesigned by Align Technology and launched in 2013. The scanner is of two types: a roll-stand and a table-top version, both equipped with touch screens. The iTero® Element's scan head is about 40% smaller than the previous model (37). One of the differences is that the iTero's camera needs a shading wheel joined to the obtaining unit, which brings about a huge and cumbersome scanner's tip in contrast with other frameworks (36).

This technology operates on the concepts of ultra-fast optical sectioning and confocal microscopy. The system identifies alterations in the focal plane of the model over a variety of focal plane locations while keeping a stable spatial connection between the scanner and the scanned item. (45). The iTero device uses parallel confocal scanning to capture all structures and materials in the mouth without using scanning powder on the teeth. (46). This system includes a host computer, keyboard, monitor, mouse, and scanner, as well as a red laser as a light source. (47).

The iTero system also makes use of a telecentric system to maintain a continuous field of vision of the region being scanned regardless of distance from the item being photographed. As a consequence, the scanner no longer has to be hovered over the item being scanned, and the scanning probe may be put right on the surface of the tooth being scanned. Furthermore, no reflective coating powder is used in the mouth cavity (48).

Flügge et al. (49) analyzed the sensitivity of intraoral and extraoral scans using iTero and a different model extraoral scanner. A patient's intraoral scans were performed ten times using iTero and polyether (Impregum Penta; 3M ESPE, Seefeld, Germany) in the standard size. The plaster model was scanned ten times using an extraoral scanner (D250; 3Shape, Copenhagen, Denmark) and iTero, producing digital models. The study revealed that, although the sensitivity was best in the group whose model was scanned with 3Shape, the sensitivity of the intraoral screening group was lowest. The researchers concluded that saliva and a lack of space in the mouth made the scan less sensitive.

Chun et al. (50) studied the accuracy of intraoral scanner devices in the presence of a mandibular anterior diastema. Four mandibular arch models with similar diastemas between the incisors and canine-canine distances of 0 mm, 1 mm, 3 mm, and 5 mm were employed in the research. According to the producers' directions, all arcs of each model were scanned 10 times with iTero and Trios. Using the Geomagic Verify program, the photos were appropriately matched with the images of the reference scanner (Sensable S3). The differences in picture accuracy were statistically significant for both intraoral scanners, with higher deviation rates seen as the anterior interdental gap increased. Trios was shown to be more sensitive than iTero in all models and over the whole arc. On the other hand, the mean deviation levels showed that both iTero and Trios could be used in clinical settings.

2.6.2. Digital Impression with the iTero® Intraoral Scanner

Workflow becomes more ergonomic as operator expertise grows, with the possibility of reducing patient session times with digital technology. More research is needed in the field of orthodontics; However, manufacturers often emphasize that intraoral scanning duration is determined by operator skill and expertise. (38).

When the rinsing, air drying, hemostasis, and retraction processes are finished before the scanning process, the operator puts the scanner in the occlusal area of the tooth and starts the scanning process. The scanning of teeth progresses by including lingual, buccal, occlusal, and proximal contacts of adjacent teeth. If any shaking is detected, the system will require a rescan. The vestibular and palatal surfaces of the teeth are scanned by holding the camera at an angle of 45° to the occlusal surface. Finally, a vestibular scan of the patient's centric occlusion is performed. The system will instantly record a virtual bite (51).

The intraoral scanner highlights ceaseless and snap to catch scan mode; delivering in customary stone tone and real nature models; and discretionary voice direction and visual orders. Computerized pictures for orthodontic treatment are captured by continuing through the upper and lower quadrants. (52)

In average, full mouth scanning and a bite enrollment can take around 10 - 15 minutes. In a two years study including 328 records, it has been accounted for that the quickest intraoral output can require 6 minutes and 22 seconds and the longest right around 18 minutes.(53)

Birnbaum and colleagues. state that after the digital scan is complete, the dentist may choose from a variety of diagnostic instruments to analyze and finalize the impression. To assist in displaying the clearly defined margin, a margin line tool is offered. Following the clinician's thorough evaluation of all parts of the digital model, any required alterations are made, and several are reconfigured with further scanning. The modifications are saved by the system. (54).

Cadent receives the final digital scan over a HIPAA-compliant wireless system. Cadent sends digital information to a model after laboratory inspection. The model is ground from a mixed resin and fixed, cut, and spliced depending on the dentist's computer model. Cadent industrial 5-axis milling machines ensure the accuracy of milled objects. (54).

Toward the end of the scanning period, a line of indicative apparatuses is accessible to evaluate and conclude the impression. Extra outputs can be added to any areas of incomplete data. The last 3D models are put away in the web-based MyAligntech data set under the specialist's profile and are accessible for sending out in the STL open document design (36).

The STL open data format is interoperable with other restorative or orthodontic software systems, and iTero® stores data on the cloud. These iTero® scanners are intended for use with the OrthoCad and Invisalign ClinCheck software packages. While employing Invisalign technology, physicians may analyze and alter prescription malocclusion treatment programs. In addition, the company has designed the Invisalign Outcome Simulator software program to allow clinicians to use Invisalign appliances to simulate malocclusion and treatment outcomes for patient education. This scanner is also compatible with Incognito Appliance Systems (38).

iTero® is a system that can be used for the treatment of implants, retainers, aligners, crowns, and veneers. Outputs digital image files in stereolithography (STL) format, which may be shared with any other lab that has a CAD/CAM system (55).

2.7. Digital Model Creation

Digital models are compatible with many imaging systems today. A computer with internet access is the first requirement to be able to use the digital models. Internet access can be DSL or cable connection. It should be noted that DSL and cable internet access make it simpler to download 3D models faster from the company system. Second, there must be a folder created on the computer to save the 3D models, and finally, there must be a software program used to view the models (56).

OrthoCADTM was the first company to commercially show computerized models in 1999. (Cadent, Carlstadt, NJ). The findings of a research performed by the Journal of Clinical Orthodontics revealed a significant increase in the use of sophisticated models for pre-treatment diagnosis and therapy, from 6.6% in 2002 to 18% in 2008.(57).

Today, numerous orthodontists get advanced models using restrictive administrations. Conventional impressions, plaster models, or oral records are submitted to the chosen organization with the goal that they can produce the advanced models and make them accessible for download in exclusive or stereolithography (STL) document design. STL is an open, industry-standard document design that is upheld by most intraoral scanning devices and generally utilized for quick prototyping, PC-aided fabrication, and across various 3D-demonstrating connection points. Another open record design is Utilize, polygon document design (otherwise called Stanford triangle design), which is utilized when tone and additionally straightforwardness data is required (36).

Digital models may be obtained directly or indirectly. (49). Direct approaches eliminate the need for dental impressions by taking data directly in the patient's mouth using an intraoral scanner. Indirect approaches include 3D scanning, imaging, and printing orthodontic alginate impressions and plaster casts using a desktop scanner, intraoral scanner, or computed tomography imaging scan. There is no common definition of model correctness. In orthodontics, however, it is widely considered that a measurement accuracy of up to 0.1 mm is adequate for clinical reasons and does not jeopardize the model's diagnostic usefulness. Many investigations have been conducted to assess the dependability of stereolithographic models acquired indirectly by comparing the measurement consistency of plaster and digital models. (58,59).

2.8. Advantages of Digital Scans Over the Conventional Method

Digital models are not physically harmed and leave no dust or other trace behind. They do not need extra storage space. Digital information may be saved on the hard drive of a clinic computer, on portable storage devices such as CDs or memory cards, or on a central server in each instance. A lot of orthodontic working models include digital information that is less than 1 megabyte in size. The software applications needed to view these digital models range in size from 8 to 12 megabytes. Because models are kept by patient name and number, access is rapid and efficient. (60).

Simultaneous viewing of digital models on computers in different locations is possible. Thus, both the orthodontist and the patient, as well as another dentist, can examine the model at any time and share ideas (61).

Compared to the traditional method, taking impressions directly from the mouth with a digital device has the following benefits (37):

- With traditional impression taking, important fine details only become apparent during the plaster model phase. Early quality analysis on the computer monitor of the digital model can be performed during the scanning procedure.
- • If the findings are unsatisfactory, the scanning operation may be easily and quickly repeated. By repeating this procedure, there is no need to prepare an impression tray or mix the impression substance.
- If there is an area that does not come out properly in the model obtained with the traditional impression, it may be necessary to take an impression from the patient again, but when there is an area with an incorrect scan, it can be selectively limited to only the affected area. For this purpose, the affected area is simply digitally excised and rescanned.
- Intraoral scanners can be handily sanitized and utilized scanner tips can once in a while be autoclaved. Expendable plastic protective sleeves are not generally needed after finish of the scanning method. This wipes out the tedious work step of cleaning and sanitizing impression plate.

- With digital models, important preparation parameters such as the insertion path or the distance to the relevant antagonist tooth can be viewed directly on the computer screen. Likewise, restoration parameters can be controlled via the digital model.
- When checking the fit of the restoration to a model, a loss of substance may occur in the restoration. A digital model is always of the same, original quality.
- Digital data transfer via cloud-based systems saves on transportation costs. and this transfer process can be performed without a great waste of time.
- Digital impression taking evades byproducts and is along these lines favorable as far as maintainability and preservation of assets.
- Unlike conventional models, Numerous intraoral alterations, such as tooth tipping, tooth migration, tooth rotation, and recession, may be shown using computerized models. It is necessary to use a particular software program to do a three-dimensional comparison of the first clinical results and subsequent intraoral scans. Intraoral scanning devices presently produce naturally colored models, allowing the detection and nitty-gritty assessment of things like tooth structures and gingival tissue. This allows the analysis of color changes in the teeth and gingiva, which is not possible with a plaster model. In some scanners, color selection can be made for restorations as an additional feature.
- A digital file can be matched with a face scan or other data files such as 3D radiographs or CBCT. This provides a more comprehensive analysis and more possibilities for diagnosis and treatment.

2.9. Reliability of Digital Records

The main element of the intraoral scanner device ought to have the option to record the scanned region with the closest exactness to reality. Preferably, an intraoral scanner ought to have high reliability; therefore, an intraoral scanner ought to be just about as exact as could be expected. It ought to have the option to recognize any intraoral impression subtleties and permit generating a virtual 3d model that is pretty much as comparative as conceivable to the genuine model and veers off hardly anything from the reality. Sensitivity can be calculated more easily by superimposing the models created with different intraoral scans taken at different times with the same intraoral scanner and evaluating the differences again at the micrometric level. Technically, an intraoral scanner can have high accuracy but low sensitivity, and vice versa. In either case, optical impressions will be insufficient (12). In any case, the most recent age scanners are described by exceptionally low blunders in full-mouth impression (62).

Criteria such as repeatability, validity, and reproducibility are used to qualify the accuracy and reliability of a measurement.

2.10. Studies Comparing Digital and Conventional Impression Methods

In a 2014 study with 24 adult patients, Yuzbasioglu et al.(10) compared the digital scanner CAD-CAM system (Cerec OMNICAM, Sirona Dental GmBH, Wals Bei Salzburg, Austria) device with the traditional technique for regarding patient perception, comfort, and efficacy. They discovered that there were significant differences in total working time across groups. Digital scans were reported to be more pleasant for patients than traditional techniques. Digital impressions resulted in a faster procedure than the traditional impression process.

In the same year, Grunheid et al. (7) conducted a study with 15 patients with a wide age range. They used Lava COS (3M ESPE, St. Paul) from digital scanner devices, and They claimed that the fact that traditional impressions obtained with alginate result in less chairside time than the digital imprint approach influences the patient's decision. They attributed the patients' preference for the traditional imprint approach in their research to the fact that it is simpler and quicker.

In another study conducted with 50 adult patients in 2015, the Cerec Omnicam scanner device was used, and all the participants— Over 80% of participants favored the digital approach over the analog procedure. The average time it took to make a digital imprint was 6 minutes and 39 seconds (SD=1:51), compared to 12 minutes and 13 seconds (SD=1:24) for an analog impression. Participants preferred the digital scan because it caused less discomfort, shortness of breath, dread of repeating the sensation, and feelings of powerlessness throughout the operation. (63).

In another study conducted with 38 patients aged 10–17 years, 2 scanners were used (Omnicam, Sirona, and Lava COS, 3M), and There were no perceptual differences between alginate imprints and the Lava COS, nor between the two scanners. The chairside durations for alginate impressions (9.7 1.8 minutes) and the Omnicam (10. Young orthodontic patients preferred digital impression methods over alginate impressions, the researchers discovered. Despite the fact that alginate impressions needed the least amount of chairside time. (13).

In 2017, Mangano et al. (12) evaluated comfort, stress, and acceptability in 30 patients aged 7–16 years using the CS3600 (Carestream, Rochester, NY) digital scanning device and applying the conventional measurement method. In terms of time, the conventional impression procedure was considerably quicker. Patients favored the digital impression method, which was favoured by all individuals.

In a study by Burzynski et al. (14) in 2018, the iTero Element (Align Technologies, San Jose, Calif.) and the TRIOS Color (3Shape, Copenhagen, Denmark) digital scanners were used, and alginate impressions were obtained in a total of 180 patients. Subjects reported much greater comfort and less discomfort with the iTero scanner than with the TRIOS scanner with alginate impressions, according to the satisfaction questionnaire. In addition, the iTero participants experienced considerably reduced dry mouth as a result of the impressions.

In another study conducted in 28 pediatric patients aged 7–12 years, the Trios 3 (Color2017, 3shape, Denmark) scanner and the alginate impression method were used, and In terms of time required to capture impressions, the two approaches were comparable. This was acceptable since there was no difference in the overall durations of the digital and traditional impression groups when the total durations were compared (11).

In a study conducted in 2019, for digital and conventional recordings from 59 children aged 9-15, they discovered that the patient experience during intraoral scan was statistically superior than alginate impression in terms of comfort, gag response, respiration, smell/sound, taste/vibration, and all anxiety-related remarks. There was no discernible difference in chairside time between the two methods. (8).

Finally, in the study of Yılmaz et al. in 2021, in which the comfort and preferences of 39 young and adult patients were evaluated according to the impression method, they found that There was no statistically significant difference between the digital scan and the traditional impressions in tray selection, scanning of the maxillary arch, scanning of the mandibular arch, and overall time. They also discovered that the digital approach was more pleasant in terms of overall sensation, breathing difficulties, smell-taste discomfort, queasiness, and gag reaction (64).

3. SUBJECTS AND METHODS

Our study was approved by the Clinical Research Evaluation and Ethics Committee of the Faculty of Medicine at Yeditepe University (Decision No. 1677, Date: November 16, 2022). The Informed Consent Form was filled out by the parents of all volunteers under the age of 18, and by the patients over the age of 18, after receiving information about the study.

3.1. Subjects

This prospective, controlled clinical study consisted of 63 patients who applied for treatment at Yeditepe University Faculty of Dentistry, Department of Orthodontics and met the inclusion criteria of the study groups. Participants with a history of dental phobia or a hyperactive gag reflex were excluded since circumstances are continually changing throughout the impression-taking procedure.

Inclusion criteria:

1. No previous history of orthodontic treatment.
2. Lack of past experience with alginate impressions or intraoral scanning.
3. No dental morphological defects, restoration, decay or prosthesis.
4. No congenital dental agenesis
5. No congenital craniofacial deformities
6. Good physical and mental health

Patients in our study were excluded considering the following criteria:

1. Patients with dental phobia.
2. Patients with hyperactive gag reflex.

3.2. Material Collection and Evaluation

The patients were grouped according to the age. Group 1 included patients who were 8–12 years old, Group 2 included patients who were 13–17 years old, and Group 3 included patients who were 18 years old and above. Each group consisted of 21 patients. Gender distribution of the groups were shown on Table 1.

Table 1. Gender Distribution of the Groups

Gender Distribution	Age Groups					
	8-12		13-17		≥18	
	n	(%)	n	(%)	n	(%)
Female	10	47.6	9	42.8	10	47.6
Male	11	52.4	12	57.2	11	52.4
Total	21	100	21	100	21	100

Study design is depicted in the following scheme (Figure 3.2.1.)

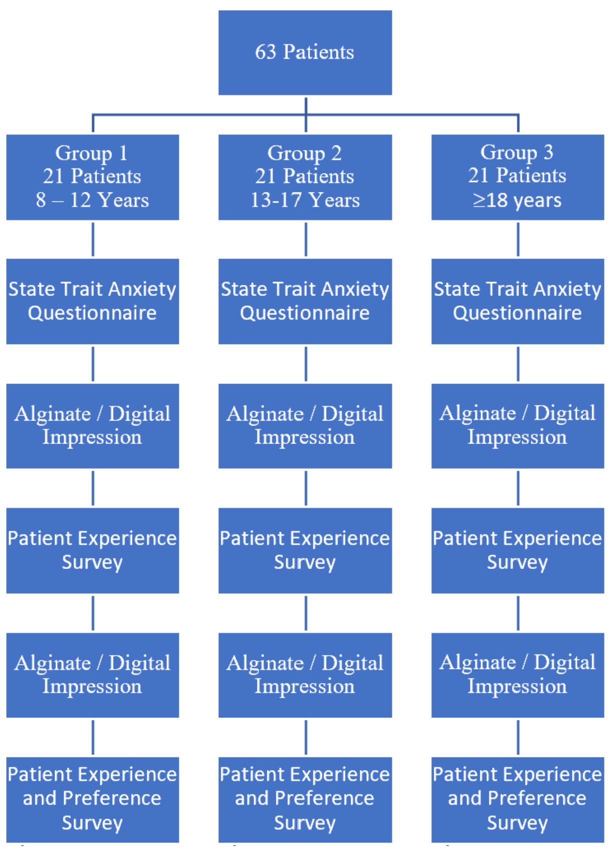

Figure 3.2.1. Study Design

Since the anxiety level of the person may affect the duration of the procedure, each patient's anxiety level was evaluated by State-Trait Anxiety Inventory (STAI) test prior to the intervention

(Figure 3.2.1.) STAI test has a total of 20 questions. The State Anxiety Scale consists of "not at all," "somewhat," "a lot," and "totally."

After the anxiety test, it was determined which impression method would be applied to the patient first. For patients whose dental records would be taken with alginate (Kromopan®, Lascod, Florence, Italy) and digital (iTero Element 2, Align Technologies, San Jose, Calif.) impression methods (Figure 3.2.2.), the measurement method was randomly selected using the software on the www.randomizer.org site.

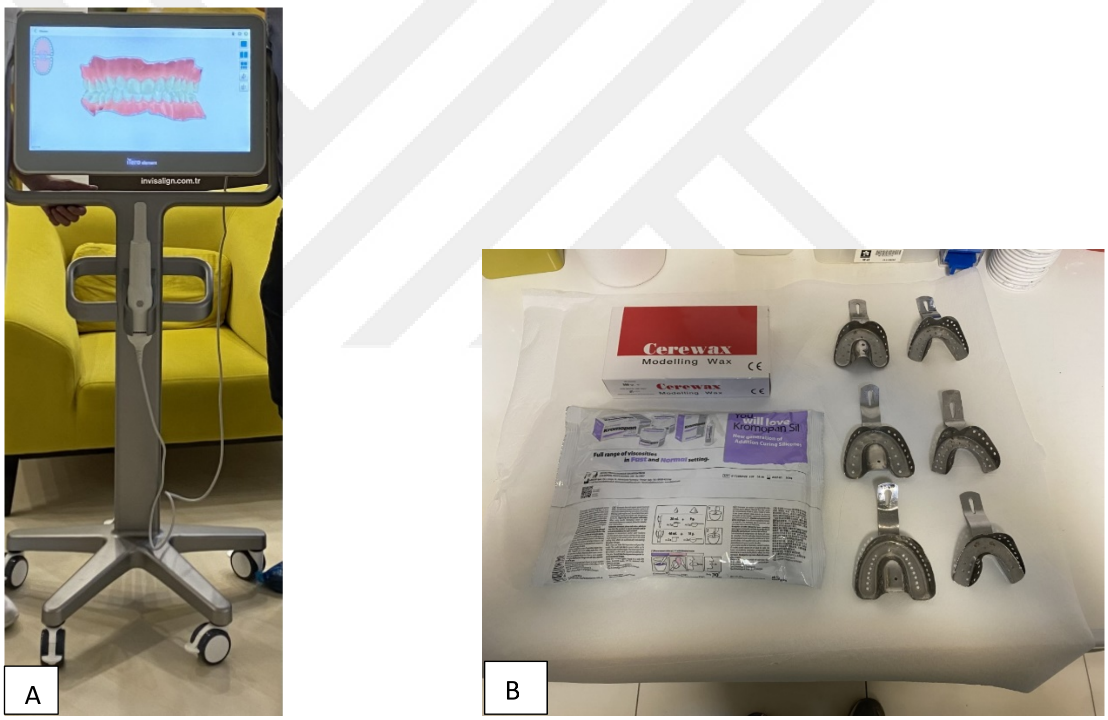

Figure 3.2.2. iTero Element 2 (A) and alginate, wax, and impression trays (B)

Following randomization and determination of the first and second impression method for each patient, the patient was first undergone the assigned impression method and filled a 10-question questionnaire to evaluate patient experience (Patient's perception questionnaire) (Figure 3.2.3.). The perception questionnaire used in this study aimed to measure discomfort, gag reflex, difficulty to breathe, time perception, pain, temperature changes, taste and dry mouth during impression procedure. After the second impression method was applied, the same patient's perception questionnaire was repeated in addition to patient's preference questionnaire. The patient's preference questionnaire three questions to evaluate patient's preference regarding the impression methods. (Figure 3.2.4.). Similar to the study by Glisic et al. (8)) the questionnaires were scored on a modified 100-mm Visual Analogue Scale (VAS) with elements from face rating scales for Group 1 and 2. In the smiley face scale (WBS, or Wong-Baker FACES® Pain Rating Scale), which is an improved version of the visual analog scale (VAS) for pediatric patients, a smiling face at the lowest score "0" indicates that the patient completely agrees, while sad face with tears at the highest score "10" indicates that the patient does not agree at all.

In Group 3 Patients aged 18 years and older were asked to mark the 100-mm line with a visual analog scale. "0" means that they completely agree, and "100" means that they do not agree at all. Each VAS score was measured to the nearest millimeter. And then VAS scores from 0 to 100 were converted to a 10-point scale in order to consistently compare the patient's perception and preference among groups. For the last question of the preference questionnaire, "What is your preferred impression method?", the patient had to select among answers "Conventional", "Digital", and "Doesn't matter".

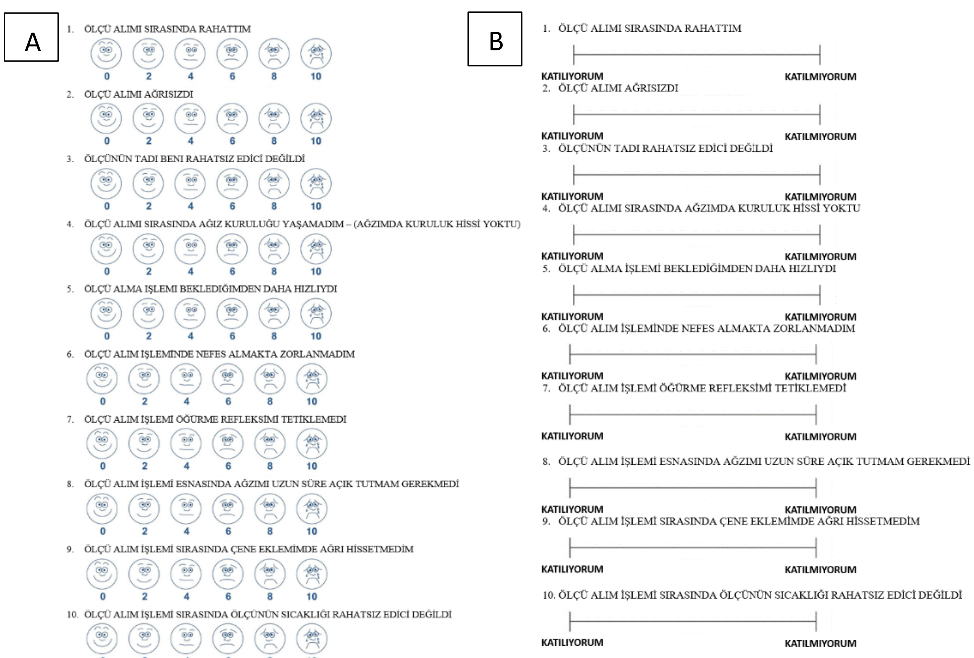

Figure 3.2.3. Patient's perception questionnaire scored by Wong-Baker scale for patients in Groups 1 and 2 (A) and by visual analog scale (VAS) for patients in Group 3 (B)

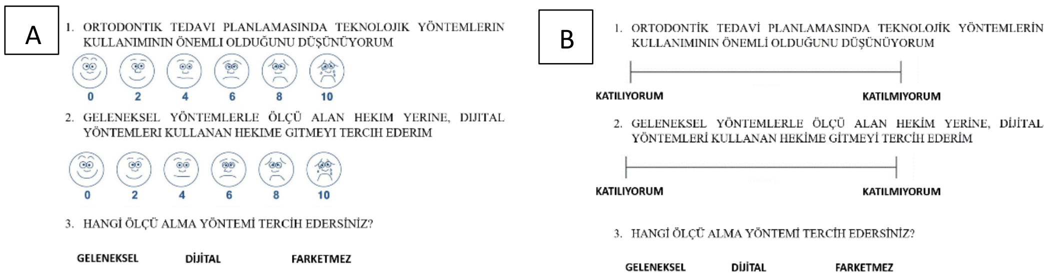

Figure 3.2.4. Patient's preference questionnaire scored by Wong-Baker scale for patients in Groups 1 and 2 (A) and by visual analog scale (VAS) for patients in Group 3 (B)

3.2.1. Intraoral Impression Methods

3.2.1.1. Conventional Impression Method

For the conventional impression technique, perforated metal trays, a bowls, mixing spoons were prepared for maxillary and mandibular dental impressions, and also hot water-filled bowls, and wax were prepared for bite registration.

The following steps were completed for conventional impression records:

- Patient registration and tray selection,
- Preparing the mouth by asking the patient to clean their mouth with water and blow off air on the tooth surfaces.
- Choosing the correct tray for maxillary and mandibular arches.
- The seat position was adjusted to be upright during the recording of the impression. The patient is advised to breathe through his or her nose in order to be more comfortable and avoid triggering the gag reflex.
- Alginate impression material was used to create conventional impressions from both arches. The lower jaw and upper jaw impressions of the patients were taken with Lascod Kromopan alginate (LASCOD, Florence, Italy).
- The amount of alginate to be mixed (powder/liquid ratio) was made using a scaled spoon in order not to affect the time and impression consistency.

In accordance with the manufacturer's instructions, the chromatic phase indicators were used as a guide for accurate mixing and insertion into the oral cavity. (Figure 3.2.5.) Good reproduction of the tooth morphology and soft tissues, centered tray position, satisfactory retention of the impression material to the tray, and no cavities or air bubbles were evaluated as an acceptable impression procedure.

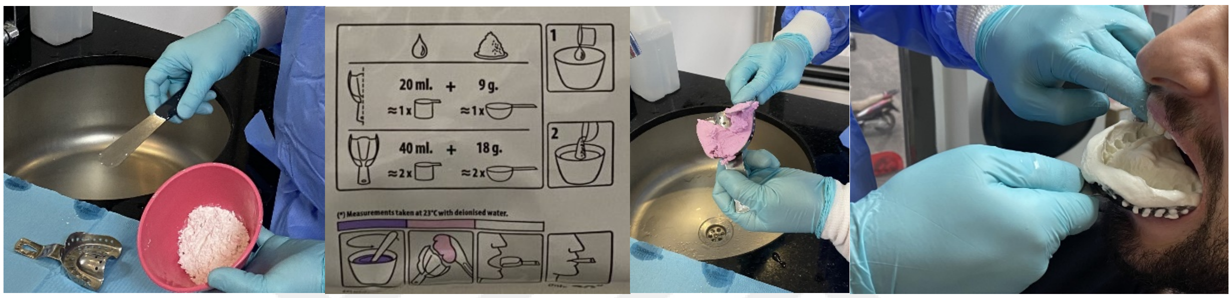

Figure 3.2.5. Application of the conventional impression method

- After the alginate impressions of the lower and upper jaws were taken from the patients, the bite registration was taken. Enough softened dental wax (Cerewax, Istanbul, Turkey) heated with hot water was used to cover the whole upper arch, from the upper incisors to at least the first permanent molars on both sides of the arch. Then by asking the patient to bite, bite registration was taken at maximum intercuspation.
- This procedure, starting from tray selection and including bite registration, was recorded as chairside time for the conventional impression method for each patient.

3.2.1.2. Digital Impression Method

The following steps were completed for digital impression records:

- Scanning the complete occlusal surface, beginning from either side’s terminal molar
- Continuing by rolling to the lingual and scanning the complete lingual surface

- Rolling over to the buccal side and scan from the molar to the midline. Moving to the opposite side’s terminal molar and scanning to the midline to complete the buccal surface
- Finishing the scanning of the dental arch by rolling over the anterior teeth. Beginning from the lingual area of the cuspid and lateral incisor and rolling over to labial surface. Repeating on the opposite side. (Figure 3.2.6.)

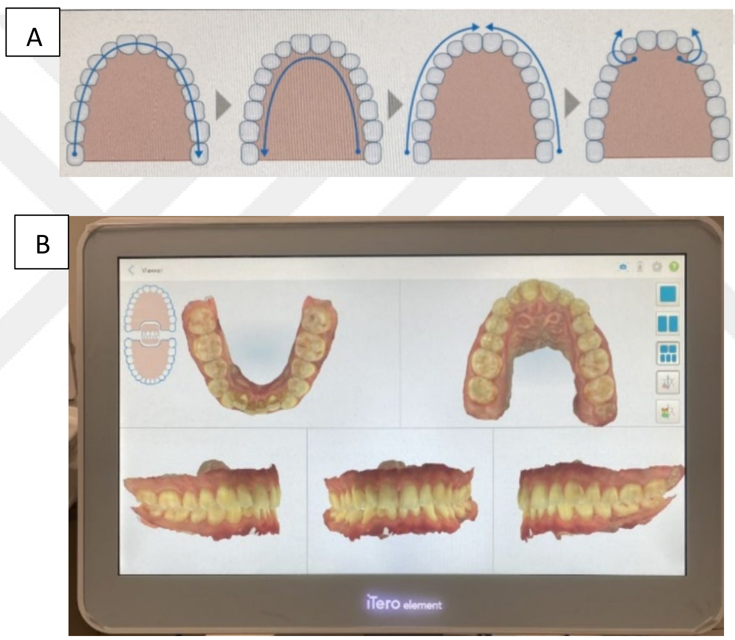

Figure 3.2.6. The schematic image of the path which was followed while digital scanning (A) and 3D intraoral images obtained by digital scanning (B)

For bite registration,

- Scanning the patient while biting in centric occlusion
- Being sure to scan the bite in a previously captured area
- Centering the wand between the upper and lower arches and slowly moving the wand in a wave type motion to ensure sufficient capture of the occlusion (Figure 3.2.7.)

- After the bite registration process was completed, the next step was for the system to create a 3D study model, and the working time was recorded. (Figure 3.2.8.)
- The chairside time of the digital impression method was recorded during double jaw scanning and bite registration.

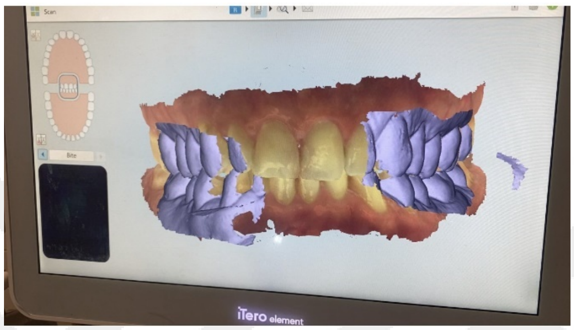

Figure 3.2.7. The schematic image of the path which was followed during the bite registration scan with the digital impression method and the bite registration image of the scanned 3D model

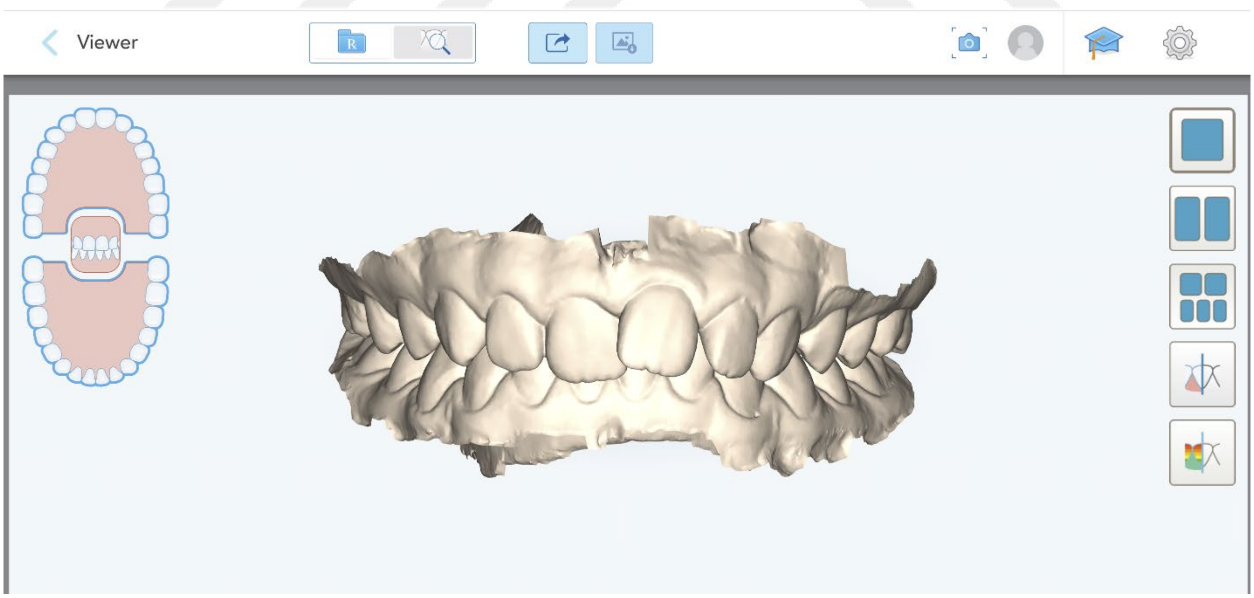

Figure 3.2.8. Intraoral view of the patient with a 3D model

In both impression taking techniques, the completion of the procedure was continued until a clinically acceptable result was obtained.

3.3. Reliability of the Questionnaires

In order to evaluate the reliability of the questionnaires and consistency of the answers given to the questionnaires, the same impression procedures were repeated for 10 patients with an interval of 2 weeks and the patients were asked to fill the same questionnaires.

3.4. Statistical Method

Statistical analyses were carried out in this study using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program. In addition to descriptive statistical approaches (mean, standard deviation, median, and interquartile range), the Shapiro-Wilk normality test was used to assess the normal distribution. For non-normally distributed data, to compare digital and conventional impression methods Wilcoxon Test was used whereas for normally distributed data, paired t test was used. For inter age groups comparisons, Kruskal Wallis test was used. Dunn's multiple comparison was used to compare subgroups. Pearson correlation test was performed to establish the correlations between variables. To assess the repeatability of conventional and digital impression techniques and reliability of the questionnaires, the intraclass correlation coefficient was employed, and the alpha Cronbach value was used to establish the reliability of conventional, digital, and state STAI measurements. The significance level for the findings was set at $p<0.05$.

Based on the observed effect sizes, experimental statistical power analyses were conducted to determine the power of the study using G * power 3.1 program (Heinrich Heine Universitat, Dusseldorf, Germany). The sample size was calculated based on the ability to detect 0.68 min of chairside time difference among the study group. (Treatment comfort, time perception, and preference for conventional and digital impression techniques: A comparative study in young patients) (13) The calculation indicated that for a study with a power of 0.80 and an alpha of 0.05, we required a total of 63 subjects (21 patients for each group).

4. RESULTS

4.1.Evaluation of Reliability of Questionnaires

For questionnaire reliability of the conventional impression method, the Alpha Cronbach value was 0.824. For questionnaire reliability of digital impression method, the Alpha Cronbach value was 0.786. The overall Alpha Cronbach value was above the desired value of 0.700. (Table 4.1.1)

Table 4.1.1. The consistency of the answers given to the survey questions

	Alfa Cronbach Value
Questionnaire Reliability of Conventional Impression Method	0.824
Questionnaire Reliability of Digital Impression Method	0.786

Intraclass correlation values varied of perception questionnaire for the conventional impression method varied from 0.845 to 1.000, which was higher than the acceptable limit of 0.700. (Table 4.1.2.)

Table 4.1.2. Intraclass correlation coefficients of perception questionnaire for the conventional impression method

Conventional Impression Method	Intraclass Correlation Coefficient	%95 Confidence Interval
I was comfortable during the impression-taking procedure	0.845	0.816-0.952
The impression-taking process was painless	1.000	1.000-1.000

The taste of the impression didn’t make me feel uncomfortable	0.950	0.855-0.988
During the impression, I didn’t have dry mouth	1.000	1.000-1.000
The impression process was faster than I expected	0.960	0.879-0.995
I didn't have difficulty breathing during the impression-taking process	1.000	1.000-1.000
My gag reflex wasn’t triggered during taking impression	0.986	0.944-0.997
I didn’t have to keep my mouth open for a long time during the impression-taking process	0.970	0.881-0.993
I didn’t felt pain in my jaw joint during the impression-taking process	1.000	1.000-1.000
The temperature of the impression wasn’t uncomfortable during the impression-taking process	1.000	1.000-1.000

Intraclass correlation values of perception questionnaire for the digital impression method varied from 0.958 to 1.000, which was higher than the acceptable limit of 0.700. (Table 4.1.3.)

Table 4.1.3. Intraclass correlation coefficients of perception questionnaire for the digital impression method

Digital Impression Method	Intraclass Correlation Coefficient	%95 Confidence Interval
I was comfortable during the impression-taking procedure	0.958	0.876-0.981
The impression-taking process was painless	1.000	1.000-1.000
The taste of the impression didn’t make me feel uncomfortable	1.000	1.000-1.000
During the impression, I didn’t have dry mouth	1.000	1.000-1.000
The impression process was faster than I expected	1.000	1.000-1.000
I didn't have difficulty breathing during the impression-taking process	0.968	0.954-0.994

My gag reflex wasn't triggered during taking impression	0.992	0.948-0.998
I didn't have to keep my mouth open for a long time during the impression-taking process	1.000	1.000-1.000
I didn't feel pain in my jaw joint during the impression-taking process	1.000	1.000-1.000
The temperature of the impression wasn't uncomfortable during the impression-taking process	0.977	0.924-0.995

Intraclass correlation values of preference questionnaire varied from 0.955 to 0.963, which was higher than the acceptable limit of 0.700. (Table 4.1.4.)

Table 4.1.4. Intraclass correlation coefficient of patient's preference questionnaires

Patient Preference Questionaires	Intraclass Correlation Coefficient	%95 Confidence Interval
I believe it is crucial to use technological methods in orthodontic treatment planning.	0.955	0.870-0.989
I prefer to go to a physician who uses digital methods instead of a physician who takes impressions using traditional methods.	0.963	0.859-0.991

4.2. Chairside Time

There was no statistically significant difference in the mean chairside time of conventional impression method among age groups ($p > 0.05$) (Table 4.2.1.). On the other hand, for the digital impression method, a statistically significant difference was observed among the 8–12 age, 13–17 age, and ≥18 age groups for chairside time ($p<0.001$) (Table 4.2.1.). The chairside time of digital impression method in the 8–12 age group was statistically shorter than that of the 13–17 age group and ≥18 age group ($p<0.001$). The chairside time of digital impression method in the 13–17 age group was statistically shorter than that of the ≥ 18 age group ($p<0.05$) (Table 4.2.2.).

Table 4.2.1. Comparison of chairside time among different age groups for conventional and digital impression methods

Chairside time (min)	Age Groups						
	Group 1 8-12 years		Group 2 13-17 years		Group 3 ≥18 years		p‡
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	
Conventional Method	9.5±1.27	9.47 (8.37-10.27)	8.98±0.88	9.13 (8.25-9.4)	9.46±1.27	9.36 (8.41-10.3)	0.315
Digital Method	3.67±0.53	3.56 (3.37-4.18)	4.7±0.74	4.5 (4.26-5.29)	5.32±0.92	5.22 (4.5-5.83)	**0.0001*** **

‡Kruskal Wallis Test, *** p<0.001

Table 4.2.2. Comparison of chairside time of digital impression method between age groups

Dunn's Multiple Comparison Test	p
8-12 years /13-17 years	**0.0001*** **
8-12 years /≥18 years	**0.0001*** **
13-17 years /≥18 years	**0.029***

* p<0.05, *** p<0.001

In comparison of the conventional impression method and the digital impression method, a statistically significant difference was observed among the 8–12 age, 13–17 age, and ≥18 age groups for chairside time (p<0.001) (Table 4.2.3.).

Table 4.2.3. Comparison of chairside time for the conventional impression method and the digital impression method in age groups

Chairside time (min)	Conventional Method	Digital Method	Difference	**p***
8-12 years	9.50±1.27	3.67±0.53	5.83±1.31	**0.0001*** **
13-17 years	8.98±0.88	4.70±0.74	4.28±0.97	**0.0001*** **
≥18 years	9.46±1.27	5.32±0.92	4.13±1.18	**0.0001*** **

Paired t test, *** p<0.001

4.3. STAI

There was a statistically significant difference in mean state anxiety scores between the 8-12 age group, the 13-17 age group, and the ≥18 age group (p< 0.01) (Table 4.3.1.). The mean STAI of the ≥18 age group was found to be lower than that of the 8-12 age group and the 13-17 age group (p <0.05 and p< 0.001, respectively); no statistically significant difference was observed between the mean ages of the 8-12 and 13-17 age groups (p >0.05) (Table 4.3.2.).

Table 4.3.1. Comparison of STAI among different age groups

	Age Groups						
	8-12		13-17		≥18		p‡
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	
State Anxiety	31.19±6.5	30 (27-34.5)	28±5.51	26 (24-31)	24.76±3.49	24 (22-27)	**0.001** *

‡Kruskal Wallis Test * p<0.05

Table 4.3.2. Comparison of STAI between age groups

Dunn's Multiple Comparison Test	State Anxiety

8-12 years /13-17 years	0.103
8-12 years /≥18 years	**0.0001*** **
13-17 years /≥18 years	**0.027***

* p<0.05, *** p<0.001

4.4.Correlation between State Anxiety and Chairside Time

No statistically significant correlation was observed between the state STAI values and the duration of the conventional impression method (r=0.170, p>0.05). (Table 4.4.1.)

A statistically significant negative correlation was observed between the state STAI values and the duration of digital impression method (r=-0.266, p<0.05). (Table 4.4.1.)

Table 4.4.1. Correlation between STAI Test and Chairside Time of Impression Method Using Pearson Correlation Test

		State STAI Test
Conventional Method	r	0.170
	p	0.183
Digital Method	r	**-0.266**
	p	**0.035***

* p<0.05

4.5.Patient's Perceptions

4.5.1. Patient's perception of conventional impression method among different age groups

For the conventional impression method, there was no statistically significant differences in perceptions of the patients in different age groups (p>0.05) except for the perception of the temperature (Table 4.5.1.1.).

A statistically significant difference was observed in the evaluation of the question "The Temperature of the Impression Was Uncomfortable" after the conventional impression-taking process for the 8–12, 13–17, and ≥18 age groups (p = 0.0001). The mean of the 8–12 age group was found to be statistically significantly higher than the mean of the 13–17 and ≥18 age groups (p = 0.002, p = 0.0001); no statistically significant difference was observed between the means of the 13–17 and ≥18 age groups (p>0.05). The responses to the remaining survey questions showed no statistically significant differences between age groups. (Table 4.5.1.2.)

Table 4.5.1.1. Patient's perception of conventional impression method among different age groups

Conventional Method	Age Groups						
	Group 1 8-12 years		Group 2 13-17 years		Group 3 ≥18 years		p‡
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	
I was comfortable during the impression-taking procedure	1.71±1.59	2 (0-3)	2.29±1.93	2 (1-4)	2±1.67	2 (0-4)	0.675
The impression-taking process was painless	0.57±0.93	0 (0-2)	0.19±0.6	0 (0-0)	0.1±0.44	0 (0-0)	0.069
The taste of the impression didn't make me feel uncomfortable	1.86±2.01	2 (0-3.5)	2.1±2.14	2 (0-3)	0.95±1.36	0 (0-2)	0.132
During the impression, I didn't have dry mouth	1.9±2.05	2 (0-4)	0.95±1.2	0 (0-2)	1.14±1.2	2 (0-2)	0.295
The impression process was faster than I expected	2.14±1.85	2 (0-4)	2±1.67	2 (0-4)	2.38±0.81	2 (2-2)	0.756
I didn't have difficulty breathing during the impression-taking process	0.95±1.36	0 (0-2)	1.19±1.47	1 (0-2)	0.86±1.49	0 (0-2)	0.531

My gag reflex wasn't triggered during taking impression	1.14±1.74	0 (0-2)	1.29±2.03	0 (0-2)	0.57±1.43	0 (0-0)	0.245
I didn't have to keep my mouth open for a long time during the impression-taking process	1.62±1.5	2 (0-2)	2.14±1.96	2 (0-3.5)	1.67±1.53	2 (0-2.5)	0.618
I didn't feel pain in my jaw joint during the impression-taking process	0.95±2.16	0 (0-1)	0.33±0.73	0 (0-0)	0.1±0.44	0 (0-0)	0.199
The temperature of the impression wasn't uncomfortable during the impression-taking process	1.76±1.34	2 (0-2)	0.52±0.87	0 (0-1.5)	0.38±0.81	0 (0-0)	**0.0001*** **
Conventional Method Total	14.9±11.05	14 (6-22	13.14±8.19	10 (6-18)	9.71±8.42	8 (2-13)	0.138

‡Kruskal Wallis Test, *** p<0.001

Table 4.5.1.2. Comparison of perception about conventional impression method between groups

Dunn's Multiple Comparison Test	The temperature of the impression wasn't uncomfortable during the impression-taking process
8-12 Years / 13-17 Years	**0.002***
8-12 Years / ≥18 Years	**0.0001*** **
13-17 Years /≥18 Years	0.519

* p<0.05, *** p<0.001

4.5.2. Digital Impression Method

For digital impression method, a statistically significant difference was observed between the "I was comfortable during the measurement" responses of the 8–12 age, 13–17 age, and ≥18 age groups ($p < 0.01$). The mean score of the 8–12 age group was higher than that of the 13–17 and ≥18 age groups ($p = 0.047$ and $p = 0.004$, respectively); no statistically significant difference was observed between the means of the 13–17 and ≥18 age groups ($p > 0.05$). (Table 4.5.2.1.)

A statistically significant difference was found between the averages of " During the impression, I didn't have dry mouth" among 8–12 age, 13–17 age, and ≥18 age groups ($p<0.05$). The mean of the 8–12 age group was found to be higher than that of the 13–17 age group ($p = 0.006$); no statistically significant difference was observed between the means of the other groups ($p > 0.05$). (Table 4.5.2.1.)

There was a statistically significant difference between the scores given to "I didn't have to keep my mouth open for a long time" of 8–12 age, 13–17 age, and ≥18 age groups. ($p<0.05$). The mean score of the ≥18 age group was found to be higher than that of the 8-12 age group and the 13-17 age group ($p = 0.024$ and $p = 0.003$, respectively); no statistically significant difference was observed between the mean scores of the 8-12 and 13-17 age groups ($p > 0.05$). (Table 4.5.2.1.)

Table 4.5.2.1. Patient's perception of digital impression method among different age groups

Digital Method	Age Groups						
	Group 1 8-12 years		Group 2 13-17 years		Group 3 ≥18 years		p‡
	Mean±SD	Median	Mean±SD	Median	Mean±SD	Median	
I was comfortable during the impression-taking procedure	1.14±1.49	0 (0-2)	0.33±0.73	0 (0-0)	0.1±0.44	0 (0-0)	**0.008***
The impression-taking process was painless	0±0	0 (0-0)	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.368

The taste of the impression didn't made me feel uncomfortable	0.29±0.72	0 (0-0)	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.159
During the impression, I didn't have dry mouth	1.05±1.36	0 (0-2)	0.19±0.87	0 (0-0)	0.38±0.81	0 (0-0)	**0.014***
The impression process was faster than I expected	0.86±1.2	0 (0-2)	0.29±0.72	0 (0-0)	0.95±1.02	0 (0-2)	0.066
I didn't have difficulty breathing during the impression-taking process	0.1±0.44	0 (0-0)	0.1±0.44	0 (0-0)	0.1±0.44	0 (0-0)	0.999
My gag reflex wasn't triggered during taking impression	0.19±0.6	0 (0-0)	0.1±0.44	0 (0-0)	0.1±0.44	0 (0-0)	0.769
I didn't have to keep my mouth open for a long time during the impression-taking process	0.95±1.2	0 (0-2)	0.62±0.92	0 (0-2)	2±1.55	2 (0-4)	**0.006***
I didn't felt pain in my jaw joint during the impression-taking process	0.38±0.81	0 (0-0)	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.062
The temperature of the impression wasn't uncomfortable during the impression-taking process	0.38±0.81	0 (0-0)	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.062
Digital Method Total	3.19±3.61	2 (1-4)	2.76±4.02	2 (0-4)	5.05±4.03	4 (2-8)	**0.047***

‡Kruskal Wallis Test, * $p<0.05$

Table 4.5.2.2. Comparison of perception about digital impression method between groups

Dunn's Multiple Comparison Testi	I was comfortable	I didn't feel dry in my mouth	I didn't have to keep my mouth open for a long time	Total
8-12 years /13-17 years	**0.047***	**0.006***	0.400	0.335
8-12 years /≥18 years	**0.004***	0.079	**0.024***	0.075
13-17 years /≥18 years	0.165	0.187	**0.003***	**0.024***

* p<0.05

4.6. Comparison of Two Impression Methods within Age Groups

4.6.1. Comparison of Two Impression Methods in 8-12 Age Group

In the 8–12 age group, there was no statistically significant difference in the mean scores of "I was comfortable during the impression-taking procedure" between conventional and digital methods (p >0.05). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question "The impression-taking process was painless" (p<0.05). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The taste of the impression didn't make me feel uncomfortable " (p<0.05). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " During the impression, I didn't have dry mouth (I didn't feel dry in my mouth)" (p<0.05). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The impression process was faster than I expected" ($p<0.05$). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I didn't have difficulty breathing during the impression-taking process " ($p<0.05$). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " My gag reflex wasn’t triggered by taking an impression " ($p<0.05$). (Table 4.6.1.)

In the 8–12 age group, there was no statistically significant difference in the mean scores of " I didn’t have to keep my mouth open for a long time during the impression-taking process " between conventional and digital methods ($p >0.05$). (Table 4.6.1.)

In the 8–12 age group, there was no statistically significant difference in the mean scores of " I didn’t feel pain in my jaw joint during the impression-taking process " between conventional and digital methods ($p >0.05$). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The temperature of the impression wasn’t uncomfortable during the impression-taking process " ($p<0.05$). (Table 4.6.1.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the total score averages ($p = 0.0001$). (Table 4.6.1.)

Table 4.6.1. Comparison of conventional and digital impression scores in Group 1 (8–12 years)

	Conventional Method		Digital Method		
8-12 Age Group	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	p‡

I was comfortable during the impression-taking procedure	1.71±1.59	2 (0-3)	1.14±1.49	0 (0-2)	0.210
The impression-taking process was painless	0.57±0.93	0 (0-2)	0±0	0 (0-0)	**0.014***
The taste of the impression didn't make me feel uncomfortable	1.86±2.01	2 (0-3.5)	0.29±0.72	0 (0-0)	**0.007***
During the impression, I didn't have dry mouth	1.9±2.05	2 (0-4)	1.05±1.36	0 (0-2)	**0.046***
The impression process was faster than I expected	2.14±1.85	2 (0-4)	0.86±1.2	0 (0-2)	**0.016***
I didn't have difficulty breathing during the impression-taking process	0.95±1.36	0 (0-2)	0.1±0.44	0 (0-0)	**0.014***
My gag reflex wasn't triggered during taking impression	1.14±1.74	0 (0-2)	0.19±0.6	0 (0-0)	**0.02***
I didn't have to keep my mouth open for a long time during the impression-taking process	1.62±1.5	2 (0-2)	0.95±1.2	0 (0-2)	0.115
I didn't feel pain in my jaw joint during the impression-taking process	0.95±2.16	0 (0-1)	0.38±0.81	0 (0-0)	0.197
The temperature of the impression wasn't uncomfortable during the impression-taking process	1.76±1.34	2 (0-2)	0.52±0.93	0 (0-1)	**0.02***
Total	9.5±1.27	9.47 (8.37-10.27)	3.67±0.53	3,56 (3,37-4,18)	**0.0001*****

‡Paired t test, * p<0.05, *** p<0.001

4.6.2. Comparison of Two Impression Methods in 13-17 Age Group

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I was comfortable during the impression-taking procedure " ($p = 0.0001$). (Table 4.6.2.)

In the 13–17 age group, there was no statistically significant difference in the mean scores of " The impression-taking process was painless " between conventional and digital methods ($p>0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The taste of the impression didn’t make me feel uncomfortable " ($p<0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " During the impression, I didn’t have dry mouth (I felt dry in my mouth)" ($p<0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The impression process was faster than I expected " ($p<0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I didn't have difficulty breathing during the impression-taking process " ($p<0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " My gag reflex wasn’t triggered by taking an impression " ($p<0.05$). (Table 4.6.2.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I didn’t have to keep my mouth open for a long time during the impression-taking process " ($p<0.05$). (Table 4.6.2.)

In the 13–17 age group, there was no statistically significant difference in the mean scores of " I didn’t feel pain in my jaw joint during the impression-taking process " between conventional and digital methods ($p >0.05$) (Table 4.6.2.).

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The temperature of the impression wasn't uncomfortable during the impression-taking process " ($p<0.05$) (Table 4.6.2.).

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the total score averages ($p = 0.0001$) (Table 4.6.2.).

Table 4.6.2. Comparison of conventional and digital impression scores in Group 2 (13–17 years)

13-17 Age Group	Conventional Method		Digital Method		p‡
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
I was comfortable during the impression-taking procedure	2.29±1.93	2 (1-4)	0.33±0.73	0 (0-0)	**0.0001*****
The impression-taking process was painless	0.19±0.6	0 (0-0)	0.1±0.44	0 (0-0)	0.564
The taste of the impression didn't make me feel uncomfortable	2.1±2.14	2 (0-3)	0.1±0.44	0 (0-0)	**0.001***
During the impression, I didn't have dry mouth	0.95±1.2	0 (0-2)	0.19±0.87	0 (0-0)	**0.005***
The impression process was faster than I expected	2±1.67	2 (0-4)	0.29±0.72	0 (0-0)	**0.002***
I didn't have difficulty breathing during the impression-taking process	1.19±1.47	1 (0-2)	0.1±0.44	0 (0-0)	**0.002***
My gag reflex wasn't triggered during taking impression	1.29±2.03	0 (0-2)	0.1±0.44	0 (0-0)	**0.009***

I didn't have to keep my mouth open for a long time during the impression-taking process	2.14±1.96	2 (0-3.5)	0.62±0.92	0 (0-2)	**0.003***
I didn't feel pain in my jaw joint during the impression-taking process	0.33±0.73	0 (0-0)	0.1±0.44	0 (0-0)	0.102
The temperature of the impression wasn't uncomfortable during the impression-taking process	0.52±0.87	0 (0-1.5)	0±0	0 (0-0)	**0.02***
Total	8.98±0.88	9.13 (8.25-9.4)	4.7±0.74	4.5 (4.26-5.29)	**0.0001*****

‡Paired t test, * p<0.05, *** p<0.001

4.6.3. Comparison of Two Impression Methods in the 18 and Above Age Group

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I was comfortable during the impression-taking procedure " (p = 0.001). (Table 4.6.3.)

In the 18 and above age group, there was no statistically significant difference in the mean scores of " The impression-taking process was painless " between conventional and digital methods (p >0.05). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The taste of the impression didn't make me feel uncomfortable " (p<0.05). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " During the impression, I didn't have dry mouth (I didn't feel dry in my mouth)" (p<0.05). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The impression process was faster than I expected" (p = 0.0001). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " I didn't have difficulty breathing during the impression-taking process" ($p<0.05$). (Table 4.6.3.)

In the 18 and above age group, there was no statistically significant difference in the mean scores of " My gag reflex wasn't triggered by taking an impression " between conventional and digital methods ($p >0.05$). (Table 4.6.3.)

In the 18 and above age group, there was no statistically significant difference in the mean scores of " I didn't have to keep my mouth open for a long time during the impression-taking process " between conventional and digital methods ($p >0.05$). (Table 4.6.3.)

In the 18 and above age group, there was no statistically significant difference in the mean scores of " I didn't feel pain in my jaw joint during the impression-taking process " between conventional and digital methods ($p >0.05$). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the averages of the question " The temperature of the impression wasn't uncomfortable during the impression-taking process" ($p<0.05$). (Table 4.6.3.)

Conventional impression method scores were found to be statistically significantly higher than digital method measurements according to the total score averages ($p = 0.0001$). (Table 4.6.3.)

Table 4.6.3. Comparison of the measurement scores of the two impression methods in the survey questions of the patients aged 18 and older

	Conventional Method		Digital Method		
≥18 Age Group	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	p‡
I was comfortable during the impression-taking procedure	2±1.67	2 (0-4)	0.1±0.44	0 (0-0)	**0.001***

The impression-taking process was painless	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.317
The taste of the impression didn't make me feel uncomfortable	0.95±1.36	0 (0-2)	0±0	0 (0-0)	**0.008***
During the impression, I didn't have dry mouth	1.14±1.2	2 (0-2)	0.38±0.81	0 (0-0)	**0.005***
The impression process was faster than I expected	2.38±0.81	2 (2-2)	0.95±1.02	0 (0-2)	**0.0001*****
I didn't have difficulty breathing during the impression-taking process	0.86±1.49	0 (0-2)	0.1±0.44	0 (0-0)	**0.023***
My gag reflex wasn't triggered during taking impression	0.57±1.43	0 (0-0)	0.1±0.44	0 (0-0)	0.102
I didn't have to keep my mouth open for a long time during the impression-taking process	1.67±1.53	2 (0-2.5)	2±1.55	2 (0-4)	0.541
I didn't feel pain in my jaw joint during the impression-taking process	0.1±0.44	0 (0-0)	0±0	0 (0-0)	0.317
The temperature of the impression wasn't uncomfortable during the impression-taking process	0.38±0.81	0 (0-0)	0±0	0 (0-0)	**0.046***
Total	9.46±1.27	9.36 (8.41-10.3)	5.32±0.92	5.22 (4.5-5.83)	**0.0001*****

‡Paired t test, * p<0.05, *** p<0.001

4.7.Evaluation of Patient Preference

4.7.1. Patient's preference about two impression methods

In each age group, digital impression method was mostly preferred over conventional impression method. In Group 1 (8-12 years old), 62% of the patients; in Group 2 (13-17 years old), 81% of the patients and in Group 3 (>18 years old), 71 % of the patients preferred the digital impression method. However, there was no statistically significant difference among age groups in terms of impression method preferences of the patients (Table 4.7.1.).

Table 4.7.1. Patient preference in different age groups

Which impression method do you prefer?	Conventional Method		No Preference		Digital Method	
Age 8-12	4	19.05%	4	19.05%	13	61.90%
Age 13-17	0	0.00%	4	19.05%	17	80.95%
Age ≥18	0	0.00%	6	28.57%	15	71.42%

Table 4.7.2. Comparison of patient's preferences among age groups

Which impression method do you prefer?	Conventional Method n	No Preference n	Digital Method n	p
Age 8-12	4	4	13	0.059
Age 13-17	0	4	17	
Age ≥ 18	0	6	15	
Total	4	14	45	

In the evaluation of patient preferences, no statistically significant difference was observed between the 8–12 age, 13–17 age, and ≥18 age groups in the mean scores of "I believe it is crucial to use technological methods in orthodontic treatment planning" ($p > 0.05$). (Table 4.7.3.)

In the evaluation of patient preferences, no statistically significant difference was observed between the 8–12 age, 13–17 age, and ≥18 age groups in the mean scores of " I prefer to go to an orthodontist who uses digital methods instead of an orthodontist who takes impressions using traditional methods." ($p > 0.05$). (Table 4.7.3.)

Table 4.7.3. Evaluation of patient preference according to age groups

	Age Groups						
	8-12 Years n:21		13-17 Years n:21		≥18 Years n:21		
	Mean ±SD	Median (IQR)	Mean ±SD	Median (IQR)	Mean ±SD	Median (IQR)	p‡
I believe it is crucial to use technological methods in orthodontic treatment planning	1±1.79	0 (0-2)	0.86±1.35	0 (0-2)	0.29±0.72	0 (0-0)	0.285
I prefer to go to an orthodontist who uses digital methods instead of an orthodontist who takes impressions using traditional methods.	1.52±2.82	0 (0-2)	1.14±1.49	0 (0-2)	0.57±1.12	0 (0-1)	0.434

‡Kruskal Wallis Test

5. DISCUSSION

5.1. Discussion of Purpose and Methods

Taking intraoral impressions to produce dental models is an integral part of the orthodontic diagnosis, treatment and outcome evaluation. Because of ongoing research and development, orthodontists have access to new tools to aid in diagnosis and treatment. Recent advancements in three-dimensional imaging technology have permitted the switch to digital models for efficiency, use, durability, and storage savings. Recent advancements in three-dimensional imaging technology have permitted the switch to digital models for efficiency, use, durability, and storage savings. (13). However, for most orthodontists to adopt these new scanning technologies, their clinical effectiveness must be approved. The accuracy of intraoral scanners is a very important determinant of clinical effectiveness, which was proven by many studies (7,65,66), however time requirement of the method, the ease of use by the operator, and its acceptance and preference by the patients are also decisive factors. Several studies were conducted to evaluate the chairside time and patient's experience and preference of intraoral scanning over conventional impression techniques and they revealed some conflicting results (63,67–69). As with many of the latest technological items, one of the most analyzed topics with intraoral scanners is the operating speed. However, owing to bias and differences in methods, there is currently no clear agreement in the literature on the chairside time of various impression procedures (70). A comparative study on young orthodontic patients showed that although the conventional impression methods took less chairside time, orthodontic patients aged 10 to 17 years preferred digital impressions over alginate impression (13). On the other hand, Grunheid et al. (7) found that, in an older orthodontic patient group with a mean age of 20 years, alginate impressions were faster and more preferred compared to digital impressions. The age of the patient may be a factor determining the chairside time and preference of the orthodontic patients with a wide age range (children to adults). Therefore the aim of our study was to evaluate and compare chairside time, patient perception and patient preference of patients aged 8-12 years, 13-17 years and 18 years and over, receiving intraoral scan and conventional alginate impression.

Patient anxiety, tension, and fear are major concerns in dentistry, and the impact of many dental treatments on patients has been examined (71,72). Because many patients suffer from anxiety during impression process, some studies have used anxiety questionnaires to evaluate stress. The STAI-TX 1 scale was used to measure state anxiety in our thesis study because it was widely used in psychological tests and preferred in studies of dental anxiety. (10,73). It's logical to believe that the ability of digital solutions to increase comfort will also be useful in decreasing patient worry.

In our study, we used VAS for adults and Wong-Baker scale for adolescents and children. The visual analog scale is a psychological response scale that may be included into surveys. It is a measuring tool for subjective qualities or attitudes that cannot be quantified directly. Respondents indicate their degree of agreement with a statement by expressing a location along a continuous line between two end points when responding to a VAS question. In dentistry, VAS has been commonly used and proven to be accurate for measuring pain and anxiety (74). Furthermore, recent studies in orthodontics evaluated patient's perceptions and preferences by VAS (75). Therefore the questionnaires in our study were scored using VAS. For the children and adolescents, we used the Wong-Baker Scale, a modified version of the VAS scale, so that pediatric patients could give more consistent and understandable answers to the questions. To be able to consistently compare both scores, VAS scores which were measured on 0-100 mm scale were converted to 0-10 mm scale.

The items that were investigated in our study focused on the patient's perception about comfort, pain, gagging, shortness of breath, smell, taste irritation, and temperature differences from the patient's point of view at traditional or digital impression taking. These factors are among the major complaints of patients during the intervention.

The gag reflex is stimulated while taking a conventional impression, which makes the patient feel a lot less comfortable, particularly if the gag reflex is sensitive (68). The stimulation of the gag reflex during the impression process is often described as the worst dental experience by some patients (13). Furthermore, the smell and taste of conventional impression materials might cause discomfort (76).

In order to standardize and homogenize the research population, volunteers with no prior experience with any impression technique were included. Homogenizing the study population is a well-established clinical research approach for evaluating patient acceptability and stress while maximizing objectivity and minimizing bias. This method is critical for reporting on patient experiences with dental impressions when the patient has no prior experience with them.

In our study, we used alginate impression material because it is widely used for orthodontic purposes. Because of its inexpensive cost, simplicity of manipulation, hydrophilic qualities, ease of removal of saliva and blood from its surface, and reasonably high patient comfort, alginate is the most commonly used impression material in orthodontics. The most significant negative is that it loses dimensional stability over time. Traditional alginate impressions, it is believed, are not clinically acceptable and may need to be redone if not poured within 30 minutes. Because the time elapsed between taking the measurement and performing the digital modeling process can take 2-3 days, this dimensional stability problem is critical when alginate impressions must be sent to a remote digital modeling laboratory for impression surface scanning without pouring plaster (77).

It is crucial to wait until the impression has hardened before removing it from the patient's mouth for conventional alginate impressions. The success of the impression can only be verified afterwards, and no further processing is available. According to Yuzbasioglu et al. (10), the precision of the final master cast is dependent on a variety of parameters, including the water/powder ratio, vacuum or manual mixing (78,79), and the kind of dentalstone and its compatibility with impression materials (80). These potential sources of inaccuracy are reduced if the "digital working model" is immediately derived from the intraoral scan (10). The strain in compression, elastic recovery, compressive strength, and tearing energy of an impression material all contribute to its accuracy.

The Kromopan alginate material we used in our study, the impression can be taken with great quality and an easy check during the working stages with the indication of chromatic phase (purple: mixing, pink: tray loading, white: insertion in mouth). The chromatic phase indicator allows you to prepare impressions without having to worry about temperature or water hardness changes. Temperature changes affect working and setting times, and the color indication reflects this. The chromatic phase indicator ensures that the components are well mixed and placed in the mouth at the appropriate time. The compound becomes purple after combining water and powder, and it is now time to mix. The color pink signals that it is time to pour the compound into the impression tray. When the tray should be put into the oral cavity, the white color signals this. In our study, in which we evaluated the processing time of the conventional method, these properties of the Kromopan material allowed the operator to be more consistent in the duration of the procedure performed on each patient.

The conventional impression is often poorly accepted by patients in terms of comfort. Patients typically report suffocation and vomiting, and some even refuse to have their impressions taken (10). Therefore, patients with hyperactive gag reflex were not included in our study as it would affect the patient's comfort and the duration of the procedure.

The effectiveness of digital and traditional impressions is greatly dependent on the experience of the operators. According to one study, the time required for clinically acceptable intraoral scans reduces with experience, as does the time needed to create a digital record (81). This also affects the patient's perception and preference. Therefore, all the digital impressions were made by the same experienced operator in the field of intraoral scanner.

According to studies on the precision and accuracy of intraoral scanners, various scanning patterns in the digital scan method impact working time and accuracy (7,82,83). As a result, for all digital scans in this study, the single scanning pattern specified in the intraoral scanner company user guide was followed.

5.2.Discussion of the Results

This study was to evaluate whether patient's views and opinions concerning digital intraoral scanners, as well as the patient processing time for different impression techniques and if the patient's state anxiety affects this time, changed among age groups. The few studies that assesed the use of intraoral scanners and patient perception in the orthodontic field reveald different results (7,9–13,63,64).

Due to bias and differences in techniques, there is no clear agreement in the literature on the chairside duration of different impression procedures When the chairside time of different impression methods were compared in our study, the traditional impression process (approximately 9-9.5 min) took much longer than the digital impression process. (approximately 4-5 min). Time saving with the use of intraoral scanning was approximately 4-5 minutes. Similar to our findings, there are studies showing that the digital impression method took less time (63,68,69). On the contrary, some studies found that the traditional method took less time (67,84).

Furthermore, there are recent studies that show no statistical difference between the two methods (11,64). These contradictory findings may be due to the use of different intraoral scanners. In a study conducted by Burzynski et al. (14) in 2018 with 180 patients, scans with iTero showed an mean time of 7 minutes, Trios 8.4 minutes, and an mean chairside time of 6.4 minutes for alginate impressions. There were differences in the amount of time required to create each impression type, with the TRIOS digital impression taking substantially longer than the iTero and alginate impressions. However, this study used 60 different patients for each impression technique, and the prior impression experience was not equal among the groups. Significant variations were also detected in the evaluation of technician skill and the significance of new technology, with iTero participants evaluating technicians with higher skill levels and perceiving that new technology was essential in an orthodontic practice. In their research of 50 individuals, Schepke et al. (63) found that the mean duration of taking a digital impression was 6 minutes and 39 seconds compared to 12 minutes and 13 seconds for a conventional impression. Conversely, Burhard et al. (13) determined the chairside times for alginate impression method (9.7±1.8 minutes) and the digital intraoral scanners CEREC Omnicam (10.7±1.8 minutes) and Lava C.O.S. (17.8±6.4 minutes) for chairside times in their study on young orthodontic patients. Although the duration of conventional impression procedure reported by Burhard et al. (13) is very similar to our findings, the significant difference between the durations of digital impression procedures may be explained by the use of different intraoral scanners. Intraoral scanners' software and hardware are always being enhanced. As a result, comparisons of digital scans with traditional impressions, whose technology is typically unchanging, may vary depending on when the research was conducted and which scanner was used. On the other hand, in a recent study where a group of children aged between 7 to 13 years was evaluated, Yılmaz and Aydın found longer scanning time compared to conventional method. They noted that the main difference was caused by the duration of bite scanning procedure. Bite registration from the buccal surfaces of the teeth might lead to increase in operating time because to the scanner head's small, the vestibular sulcus's different depths, and the existence of missing or erupting teeth in pediatric patients. Also, in the previous studies, it was emphasized that the chairside time may vary with the operator experience (8). In our study, the operator has more than 5 years of experience with the use of digital scanners and is routinely used in orthodontic practice. When we evaluated the chairside time based on the patient's age, we determined that the chairside time in the traditional technique was not statistically significant across the groups.

However, when using the digital method, the chairside duration for patients in the younger age group was statistically lower. Supporting this idea, the longest scanning time was found in the older group where 2nd and sometimes 3rd molars were already erupted. As the number of the erupted teeth increased, the scanning time also increased.

When we evaluated the chairside time and patient anxiety, we found that as the patients got younger, the level of state anxiety went up. This means that the younger patients are more anxious before dental impressions as shown by Caltabiano et al. (85) However, we couldn't reveal any correlation between the anxiety levels at the beginning of the conventional impression procedure and duration of the procedure. On the other hand, the duration of digital impression method was negatively correlated with the patient's anxiety level. We think that this finding cannot be explained by a direct cause and consequence relationship between the anxiety and the chairside time but rather with an indirect correlation between the shorter duration of the impression due to a shorter dental arch in children between 8-12 years old. Our findings support that the initial anxiety of the patients did not lead to an extension of the impression method neither in digital or conventional impression. In the literature, there are studies showing no significant differences were found between the two techniques in terms of stress (State Anxiety Scale) (10,73). Yilmaz et al.(11) found no statistically significant difference between the anxiety scores of the two impression techniques in their study, despite claiming that the patient's anxiety level would decrease after the procedure because the digital measurement method is more comfortable.

In general, the perception of conventional impression method did not differ between different age groups. Only the temperature feeling scores of the impression material were higher in the 8–12 age group than in the other age groups, showing that they are more sensitive to temperature changes compared to older age groups. On the other hand, all the age groups similarly perceived the alginate impression method in terms of comfort, taste, dry mouth feeling, respiratory distress, its effect on the gag reflex, the duration of keeping the participant's mouth open, and the feeling of impression-taking speed.

In contrast to conventional method, the perception of the digital impression method by the patients differed between age groups. Intraoral scanning was less comfortable for 8–12 years old children compared the other groups. The discomfort might be caused by the scanning tip's size and its interference with the patient's coronoid process. In younger patients having smaller oral cavity, the scanning tip may become relatively large and may cause discomfort during scanning. As scanning technology advances, the creation of a smaller scanning tip may enhance patient comfort. We utilized iTero in our study since it is one of the most used 3D scanners in orthodontic treatments. Different 3D scanners with smaller scanner tips may be more acceptable for younger patients. In a study by Grünheid et al. (7), participants preferred the traditional impression method over the digital method due to the shape and size of the camera head of the scanner.

Another difference in perception of digital impression was revealed between age groups in terms of feeling mouth dryness. The feeling of dry mouth was scored higher in the 8-12 age group compared to the 13-17 age group. The fact that the 8-12 age group was more anxious than the other groups and that the participants had to keep their mouths open throughout the digital scanning process may have contributed to the younger age group experiencing dry mouth. However, we couldn't reveal any significant difference between these two groups regarding keeping the mouth open for a long period although the intraoral scanning lasted longer in 13-17 years old children. As mentioned by Burhardt et al (13), the individual scoring of time perception seems subjective and does not always follow the objective time measurements. Furthermore, keeping the mouth open for a long period during digital impression was perceived differently by older patients. The participants in the 18-year-old and older group had higher statistical scores for the perception that they kept their mouth open for a long time compared to the other two groups. This may be due to the fact that adult patients have higher expectations from the digital system, or because full arch scanning including the 2nd and 3rd molars led to a prolonged scanning time.

When overall perception about the digital impression was compared among groups, we found that 13–17 age perceived intraoral scanning more positively compared to the other groups. This may be due to the fact that they are keen on digital technologies, more tolerant to the scanner's tip compared to the younger age group, and the processing time is shorter than for the 18-year-old and older group.

In general, the overall perception of the digital method is better than the conventional method in all age groups. Similar to our study, in other studies in which patient perception was evaluated, the digital method was found to be more positively perceived compared to the conventional method (10–12,14,64). However, in terms of comfort, the comparison of the conventional and digital methods within age groups revealed that the perception of the comfort is the same for both methods in 8–12 years old children group. This is an interesting finding since one can expect that digital impression is more comfortable in pediatric patients because of its several advantages.

However, in our study population, young children didn’t differentiate it from alginate impression in terms of comfort. In contrast to our findings, Yılmaz and Aydın (11) reported that digital impression method was more comfortable for children aged 7 to 13 years. The difference in the perceptions of the same age children of both studies may be due to using different intraoral scanners. Yılmaz and Aydın (11) used Trios with a smaller scanning head compared to iTero, which may cause less discomfort during scanning. On the other hand, in our study, 8-12 years old children considered the digital impression method as a better method in terms of taste, dry mouth feeling, total time, breathing ease, gag reflex, and temperature perception in accordance with the findings of Yılmaz and Aydın (11).

Similar to the results in the 8–12 age group, the 13–17 age group's scores on perception with the digital technique, including patient comfort, are more in favour of the digital method. Supporting our findings, Burhardt et al. (13) who assessed 10 to 17 years old young patients, showed that when the total perception scores for the queasiness, uncomfortable feeling, breathing difficulty, and gag reflex were summed, the digital impression scores were rather low compared to alginate impression, indicating a more positive perception toward intraoral scanning.

In adult patients, most of the findings were similar to those of the other two groups. However, there was no significant difference between the digital and conventional methods when the scores of feeling pain during the impression procedure and triggering the gag reflex were examined. The reason for this may be that none of the methods caused discomfort as long as the patients do not have a hyperactive gag reflex with increasing age.

When the preferences of the different age groups were evaluated, we found that the majority of the subjects preferred intraoral scanning as a method of impression. The shorter chairside time and overall positive perception about digital impression method of all age groups might have played a role in the preferences of the patients. According to Grunheid et al. (7), the decisive factor is the chairside time. In accordance with our findings, Schepke et al. (63), where they studied 50 adult patients, found that the digital method had a shorter processing time, and 80% of the patients preferred the digital method to the conventional method. On the other hand, Yılmaz and Aydın reported slightly higher percentages of digital preferences (75%) for pediatric patients compared to our findings although the duration of each method was the same (11). Furthermore, other studies reported digital preference despite the shorter duration of the conventional method (12,13). It appears that the duration of the impression technique is not the only motivation of the patients when preferring the impression method. Several advantages of the intraoral scanning such as comfort, ease of breathing, not triggering gag reflex might be the additional factors considered by children and adults.

In our study, although the number of those who prefer the digital method in each age group was higher than those who are undecided or those who prefer the conventional method, we couldn't reveal any statistically significant difference in terms of the number of those who prefer the digital method among the groups or in terms of the scores for using technological methods in orthodontics. In future studies, increased number of patients should be evaluated to clarify the digital or conventional preferences of different age groups.

Another limitation of our study is that we only evaluated one intraoral scanning system. Other digital systems and procedures may provide different outcomes. As a consequence, it cannot be assumed that all digital impression systems provide the same results.

6. CONCLUSION

In our prospective study conducted on three different age groups regarding the chairside, patient's perception and preference about conventional and digital impression methods, the following conclusions were reached:

1- Chairside time of digital impression method was shorter compared to the conventional impression method in each age group. Chairside time of conventional impression did not differ among different age groups whereas intraoral scanning took shorter in children with 8-12 years compared to older patients.
2- All age groups perceived digital scanning more positively compared to the alginate impression.
3- Overall perception of alginate impression was the same for all age groups.
4- Patient's perception of digital impression differed between different age groups. 8-12 years old children reported less comfort compared to older groups. Adults perceived digital scanning as a method causing them to keep their mouth open for a longer period compared to younger patients. Overall perception of the digital method was more positive for the 13-17 years old patients.
5- The majority of patients preferred digital impression over conventional impression method although the age of the patients did not play a role in their preference.

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8. APPENDICE

8.1. Ethical Approval

YEDİTEPE ÜNİVERSİTESİ KLİNİK ARAŞTIRMALAR ETİK KURULU KARAR FORMU

Araştırmanın Açık Adı	**"Farklı Yaş Gruplarında Hastaların Ölçü Tekniği Tercihlerinin Değerlendirilmesi"**
VARSA ARAŞTIRMANIN PROTOKOL KODU	

ETİK KURUL BİLGİLERİ	ETİK KURULUN ADI	**Yeditepe Üniversitesi KAEK (2012-KAEK-70)**
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BAŞVURU BİLGİLERİ	KOORDİNATÖR/SORUMLU ARAŞTIRMACI UNVANI/ADI/SOYADI	Prof. Dr. Derya Çakan / Dt. Muhammed Batuhan Nizam			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ UZMANLIK ALANI	Ortodonti AD.			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ BULUNDUĞU MERKEZ	Yeditepe Üniversitesi Diş Hekimliği Fakültesi			
	VARSA İDARİ SORUMLU UNVANI/ADI/SOYADI				
	DESTEKLEYİCİ				
	PROJE YÜRÜTÜCÜSÜ UNVANI/ADI/SOYADI (TÜBİTAK vb. gibi kaynaklardan destek alanlar için)				
	DESTEKLEYİCİNİN YASAL TEMSİLCİSİ				
	ARAŞTIRMANIN FAZI VE TÜRÜ	FAZ 1	☐		
		FAZ 2	☐ ✓		
		FAZ 3	☐		
		FAZ 4	☐		
		Gözlemsel ilaç çalışması	☐		
		Tıbbi cihaz klinik araştırması			
		İn vitro tıbbi tanı cihazları ile yapılan performans değerlendirme çalışmaları			
		İlaç dışı klinik araştırma	☐		
		Diğer ise belirtiniz	☐		
	ARAŞTIRMAYA KATILAN MERKEZLER	TEK MERKEZ ☒	ÇOK MERKEZLİ ☐	ULUSAL ☒	ULUSLARARASI ☐

16. 11. 2022

ASLI GİBİDİR

Prof. Dr. Turg ELİK
Yeditepe Ü itesi KAEK Başkanı

YEDİTEPE ÜNİVERSİTESİ KLİNİK ARAŞTIRMALAR ETİK KURULU KARAR FORMU

Araştırmanın Açık Adı	**"Farklı Yaş Gruplarında Hastaların Ölçü Tekniği Tercihlerinin Değerlendirilmesi"**
VARSA ARAŞTIRMANIN PROTOKOL KODU	

	Belge Adı	Tarihi	Versiyon Numarası	Dili
DEĞERLENDİRİLEN BELGELER	ARAŞTIRMA PROTOKOLÜ	31.10.2022	1	Türkçe ☒ İngilizce ☐ Diğer ☐
	BİLGİLENDİRİLMİŞ GÖNÜLLÜ OLUR FORMU	31.10.2022	1	Türkçe ☒ İngilizce ☐ Diğer ☐
	OLGU RAPOR FORMU	31.10.2022	1	Türkçe ☒ İngilizce ☐ Diğer ☐
	ARAŞTIRMA BÜTÇESİ	31.10.2022	1	Türkçe ☒ İngilizce ☐ Diğer ☐

	Belge Adı		Açıklama
DEĞERLENDİRİLEN DİĞER BELGELER	KLİNİK ARAŞTIRMA BAŞVURU FORMU	☐	
	GÖZLEMSEL	☐	
	RETROSPEKTİF	☐	
	TIBBİ CİHAZ	☐	
	TC KLİNİK ARAŞTIRMA (AKADEMİK)	☐	
	TC GÖZLEMSEL KLİNİK ARAŞTIRMA	☐	
	TC İN VİTRO KLİNİK ARAŞTIRMA	☒	
	SİGORTA	☐	
	ARAŞTIRMA BÜTÇESİ	☒	
	BİYOLOJİK MATERYEL TRANSFER FORMU	☐	
	ÖZGEÇMİŞLER	☒	
	HELSİNKİ BİLDİRGESİ	☒	
	ÇIKAR İLİŞKİSİ BELGESİ	☐	
	KURUM İZNİ	☒	
	CİDDİ ADVERS OLAY (CAO) BİLDİRİMİ	☐	
	SONLANIM BİLDİRİMİ BAŞVURU FORMU	☐	
KARAR BİLGİLERİ	**Karar No: 1677**	**Tarih: 09.11.2022**	

Yukarıda bilgileri verilen **"Farklı Yaş Gruplarında Hastaların Ölçü Tekniği T[illegible]ın Değerlendirilmesi"** klinik araştırmanın başvuru dosyası ile ilgili belgeler araştırmanın /çalışmanın gerekçe, amaç, yaklaşım v[illegible]eri dikkate alınarak incelenmiş ve uygun bulunmuş olup araştırmanın/çalışmanın başvuru dosyasında belirtilen merkezlerde gerçe[illegible]ınde etik ve bilimsel yönden yeterli bulunduğuna toplantıya katılan etik kurul üye tam sayısının salt çoğunluğu ile karar verilmiştir.

İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik kapsamında yer alan araştırmalar/çalışmalar için Türkiye İlaç ve Tıbbi Cihaz Kurumu'ndan izin alınması gerekmektedir.

ASLI GİBİDİR

16.11.2022

Prof. Dr. Turg[illegible]LİK
Yeditepe Ü[illegible]tesi KAEK Başkanı

YEDİTEPE ÜNİVERSİTESİ KLİNİK ARAŞTIRMALAR ETİK KURULU KARAR FORMU

Araştırmanın Açık Adı	**"Farklı Yaş Gruplarında Hastaların Ölçü Tekniği Tercihlerinin Değerlendirilmesi"**
VARSA ARAŞTIRMANIN PROTOKOL KODU	

KLİNİK ARAŞTIRMALAR ETİK KURULU	
ETİK KURULUN ÇALIŞMA ESASI	İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik, İyi Klinik Uygulamaları Kılavuzu
BAŞKANIN UNVANI / ADI / SOYADI:	Prof. Dr. Turgay Çelik

Unvanı/Adı/Soyadı	**Uzmanlık Alanı**	**Kurumu**	**Cinsiyet**		**Araştırma ile İlişki**		**Katılım ***		**İmza**
Prof. Dr. Turgay Çelik (Etik Kurul Başkanı)	Tıbbi Farmakoloji	Y.Ü. Eczacılık Fakültesi	E ☒	K ☐	E ☐	H ☑	E ☑	H ☐	
Prof. Dr. Ferda Özkan	Patoloji	Y.Ü. Tıp Fakültesi	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Prof. Dr. Pelin Yazgan	Fiziksel Tıp ve Rehabilitasyon	SBÜ Fatih Sultan Mehmet Eğitim ve Araştırma Hastanesi	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Prof. Dr. Esra Can (Etik Kurul Başkan Yrd.)	Diş Hekimi	Y.Ü. Diş Hekimliği Fakültesi	E ☐	K ☒	E ☐	H ☐	E ☐	H ☐	
Prof. Dr. Hasan Aydın	Endokrinoloji	Y.Ü. Tıp Fakültesi	E ☒	K ☐	E ☐	H ☐	E ☐	H ☐	
Prof. Dr. Yaşar Küçükardalı	İç Hastalıkları	Y.Ü. Tıp Fakültesi	E ☒	K ☐	E ☐	H ☑	E ☑	H ☐	
Doç. Dr. Gökhan Ertaş	Biyo Medikal	Y.Ü. Mühendislik Fakültesi	E ☒	K ☐	E ☐	H ☐	E ☐	H ☐	
Ceyda Çetin	Hukuk (Av.)	Y.Ü. Hastanesi İdari Ofisler	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Prof. Dr. Recep Erol Sezer	Halk Sağlığı	Y.Ü. Tıp Fakültesi	E ☒	K ☐	E ☐	H ☐	E ☐	H ☐	
Prof. Dr. Hatice Türe	Anesteziyoloji ve Reanimasyon	Y.Ü. Tıp Fakültesi	E [illegible]	K ☒	E ☐	H ☐	E ☐	H ☐	
Doç. Dr. Muhammed Hamitoğlu (Bildirimden Sorumlu Üye)	Eczacı	Y.Ü. Eczacılık Fakült-	[illegible]	K ☐	E ☐	H ☑	E ☑	H ☐	
Doç. Dr. Aylin Yaba Uçar	Histoloji ve Embriyoloji	Y.Ü. Tıp Fa-	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Dr. Öğr. Üyesi F. Ferda Kartufan	Anesteziyoloji ve Reanimasyon	[illegible]-itesi Medical [illegible]osmanpaşa [illegible]esi	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Dr. Öğr. Üyesi Hale Arık Taşyıkan	Halk Sağlığı	Y.Ü. Tıp Fakültesi	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	
Merve Çınar	Sivil Üye	Yönetici Asistanı-Üsküdar	E ☐	K ☒	E ☐	H ☑	E ☑	H ☐	

*:Toplantıda Bulunma

16.11.2022

ASLI GİBİDİR

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8.2. CV

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1998-2006 Özel Çağfen Koleji (Eskişehir)

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2011-2016 Yeditepe Üniversitesi Diş Hekimliği Fakültesi

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