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DURATION OF ALIGNER FABRICATION DEPENDING ON COMPONENTS OF DIGITAL PROTOCOLS

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ТРИВАЛІСТЬ ВИГОТОВЛЕННЯ ЕЛАЙНЕРІВ В ЗАЛЕЖНОСТІ ВІД СКЛАДОВИХ ЦИФРОВИХ ПРОТОКОЛІВ

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Summary/Резюме

The proliferation of digital methods for aligner fabrication by orthodontists in clinical settings, concurrent with traditional approaches, has necessitated the establishment of standardized time norms and conditional labor intensity units (CULs). These metrics are essential for the equitable accounting of professional labor, remuneration calculation, and patient cost estimation.

In this context, the *objective* of this investigation was to enhance the efficacy of orthodontic care provision in Ukraine through the quantification of temporal requirements for digital protocols in aligner fabrication and placement, as performed directly by orthodontists in clinical environments.

The primary *subject* of investigation comprised dental practitioners operating in diverse healthcare institutions across various regions of Ukraine, with the research focus on the nomenclature of contemporary orthodontic interventions available in the country.

The secondary *subject* of investigation was the duration of orthodontic care provision in Ukraine. The research focus encompassed methodological approaches for quantifying the duration of digital protocols in aligner fabrication and placement, as executed by orthodontists in clinical settings, and the subsequent establishment of time standards and conditional labor intensity units for these specialized dental procedures.

Methodological approach:

- Analytical: To delineate the structure and nature of orthodontist labor expenditure in the fabrication and placement of aligners.
- Chronometric: To ascertain the total duration of aligner fabrication and placement processes.
- Mathematical: To determine departmental time standards for orthodontic procedures related to aligner fabrication and placement.
- Statistical: For the processing and analysis of research outcomes.

Chronometric measurements of aligner fabrication and placement protocols, as performed by orthodontists in clinical settings, were conducted in medical institutions across Odessa, Kyiv, Cherkasy, Mykolaiv, and Ivano-Frankivsk from 2022 to 2024.

The study observed aligner fabrication processes executed by 8 orthodontists,

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encompassing: production on gypsum dental models derived from traditional impressions, on 3D-printed dental models based on traditional impressions, on 3D-printed dental models from digital impressions, and the fabrication of flexible aligners via 3D printing utilizing digital impressions and STL files.

A total of 32 technological protocols, performed by 8 orthodontists of varying qualifications, were analyzed.

The chronometric data were recorded in a specially developed “Orthodontist Working Time Card.” Prior to analysis, the labor expenditures were indexed according to the established methodology into permanent labor costs (Tp), independent of the number of structural elements, and variable-repeating labor costs (Tvr), entirely dependent on these factors. The resultant indicators were aggregated using the officially sanctioned formula TS = Tp + Tvr.

The investigation revealed four primary methods of elastic aligner fabrication employed in Ukrainian orthodontic clinics:

1. Vacuum thermoforming of aligners on gypsum models cast from traditional dental impressions;
2. Vacuum thermoforming of aligners on 3D-printed dental models derived from traditional impressions;
3. Vacuum thermoforming of aligners on 3D-printed dental models generated from digital impressions;
4. Direct 3D printing of aligners from STL files.

Results indicated that the most time-efficient method is the traditional protocol of aligner fabrication via vacuum thermoforming on gypsum dental models, with a duration of 69% relative to the shortest digital protocol.

Regarding digital protocols, their durations exhibited minimal variation (3% difference). The most time-intensive was the hybrid digital protocol involving aligner fabrication on 3D-printed models derived from traditional impressions, exceeding the duration of aligner fabrication on 3D-printed models from digital impressions and direct 3D printing from STL files by 15-18%.

Keywords: *orthodontic care efficiency, malocclusions, dentofacial deformities, clear aligners, oral cavity status, digital protocols, intraoral scanning, additive manufacturing, chronometric analysis.*

Цифрові методи виготовлення лікарями-ортодонтами елайнерів в умовах клініки знайшли достатньо широкого розповсюдження поряд з традиційними методам, що призвело до необхідності встановлення на них нормативів і норм часу у вигляді умовних одиниць трудомісткості (УОТ) для повноцінного і справедливого обліку праці фахівців, розрахунку заробітної плати, калькуляції вартості для пацієнтів.

У звґязку з цим, *метою даного дослідження с*тало підвищення ефективності надання стоматологічної допомоги населенню України шляхом визначення тривалості цифрових протоколів виготовлення і встановлення елайнерів безпосередньо лікарем-ортодонтом в клінічних умовах.

Першим *об'єктом* дослідження є лікарі-стоматологи, що працюють в лікувальних закладах різної форми власності в різних регіонах країни, а предметом дослідження стала номенклатура сучасних видів ортодонтичної допомоги в Україні.

Другим *об'єктом* дослідження стала тривалість надання стоматологічної ортодонтичної допомоги в Україні, а предметом дослідження – методичні заходи і прийоми визначення тривалості цифрових протоколів виготовлення і встановлення елайнерів особисто лікарем-ортодонтом в клінічних умовах та встановлення нормативів

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часу і умовних одиниць трудомісткості надання цих видів медичної допомоги.

Методи дослідження: аналітичний – для визначення структури та характеру трудових витрат лікаря-ортодонта при виготовлені і встановлені елайнерів особисто лікарем-ортодонтом; хронометраж – для визначення загальної тривалості процесу виготовлення і встановлення елайнерів особисто лікарем-ортодонтом; математичний – для визначення величини відомчих нормативів часу роботи лікаря-ортодонта при виготовлені і встановлені елайнерів особисто лікарем-ортодонтом; статистичний – для обробки результатів дослідження.

Хронометражні виміри протоколів виготовлення і встановлення елайнерів особисто лікарями-ортодонтами в клінічних умовах проводилися нами в лікувальних установах Одеси, Києва, Черкас, Миколаєва та Івано-Франківська на протязі 2022-2024 років.

Спостерігали процеси виготовлення 8 лікарями-ортодонтами елайнерів на гіпсових моделях щелеп, виготовлених на основі традиційних відбитків, на моделях щелеп, що надруковані на 3D-принтері на основі традиційних відбитків щелеп, на моделях щелеп, що надруковані на 3D-принтері на основі цифрових відбитків щелеп та виготовлення гнучких елайнерів методом друку на 3-D принтері на основі цифрових відбитків щелеп та STL-файлів.

Всього було досліджено 32 технологічних протоколи, що були виконані 8 лікарями-ортодонтами різної кваліфікації.

Отримані результати хронометражних досліджень були внесені в спеціально розроблену «Хронокарту робочого часу лікаря-ортодонта». Перед цим трудові витрати фахівців проіндексували, згідно методики, на постійні витрати робочого часу фахівців (Тп), які не залежать від кількості конструкційних елементів та змінно-повторювані витрати робочого часу (Тзп), які цілком залежать від даних чинників. Знайдені показники підсумували за офіційно затвердженою формулою НЧ = Тп + Тзп.

Виявилось, що в клініці ортодонтії в Україні застосовують основні чотири способи виготовлення еластичних кап і елайнерів:

1. Вакуумне формування елайнерів на гіпсових моделях, що були відлиті по традиційним відбиткам щелеп;
2. Вакуумне формування елайнерів на 3D–друкованих моделях щелеп, виготовлених на основі традиційних відбитків щелеп.
3. Вакуумне формування елайнерів на 3D–друкованих моделях щелеп, виготовлених на основі цифрових відбитків щелеп.
4. 3D-друк елайнерів з STL-файлів.

Отримані результати показали, що найбільш ефективним, за часом виконання, є традиційний протокол виготовлення елайнерів методом вакуумного формування на гіпсових моделях щелеп. Його тривалість складає 69% від тривалості найкоротшого цифрового протоколу.

Стосовно цифрових протоколів, то між собою їх тривалість практично однакова (різниця 3%), а самим розтягнутим у часі виявився змішаний цифровий протокол виготовлення елайнерів на 3D-друкованих моделях з традиційних відбитків щелеп. В порівнянні з виготовленням елайнерів на 3D-друкованих моделях з цифрових відбитків щелеп та 3D-друком елайнерів з STL-файлів, його тривалість на 15-18% довша.

Ключові слова: *ефективність надання стоматологічної допомоги, зубощелепні аномалії і деформації, елайнери, стан порожнини рота, цифрові протоколи, сканування, 3D-друк, хронометраж.*

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Introduction

Recent years have witnessed a significant increase in the popularity of orthodontic treatment modalities utilizing clear aligners among both dental practitioners and patients. The indications for such interventions encompass a wide spectrum of malocclusions.

The fundamental principle of this treatment modality lies in the strategic distribution of tooth movement force vectors in both spatial and temporal dimensions. The aligner serves as both a fixation device and a force source, while "activators" composed of photopolymerizable material, strategically positioned on the teeth, function as force-transmitting elements. The orthodontist can modulate the pressure exerted by these elements through the selective addition or reduction of material.

Moreover, the mobility of the appliance and the potential for intra-treatment adjustments significantly mitigate or eliminate adverse effects on the patient's periodontal tissues, a common concern with fixed orthodontic appliances. However, in comparison to stationary appliances, there exists a risk of treatment discontinuation by patients lacking sufficient motivation, who may independently cease aligner usage.

Contemporary aligner fabrication protocols in clinical settings invariably incorporate preliminary diagnostic measures, including the analysis of dentofacial anatomical elements and primary occlusal relationships utilizing various computational software.

The process of aligner fabrication and installation in clinical practice represents a confluence of virtually all modern digital methodologies in orthodontic care.

In current orthodontic practice, four primary methods of aligner fabrication are employed: vacuum thermoforming on gypsum dental models derived from traditional impressions, on 3D-printed dental models based on traditional or digital impressions, and the direct fabrication of flexible aligners from STL files via additive manufacturing, utilizing digital dental impressions.

A comprehensive analysis of relevant regulatory documents pertaining to the accounting of orthodontic labor in Ukraine has revealed a notable absence of objective labor standards for orthodontists employing modern digital methodologies. Such standards, upon approval by the Ministry of Health of Ukraine, could serve as official labor norms in the form of conditional labor intensity units (CULs), analogous to those existing in other domains of domestic dentistry.

Materials and Methods

The **objective** of this investigation is to enhance the efficacy of orthodontic care provision to the Ukrainian population through the quantification of temporal requirements for digital protocols in aligner fabrication and placement, as performed directly by orthodontists in clinical environments.

The primary subject of investigation comprised dental practitioners operating in diverse healthcare institutions across various regions of Ukraine, with the research focus on the nomenclature of contemporary orthodontic interventions available in the country.

The secondary subject of investigation was the duration of orthodontic care provision in Ukraine. The research focus encompassed methodological approaches for quantifying the duration of digital protocols in aligner fabrication and placement, as executed by orthodontists in clinical settings, and the subsequent establishment of time standards and conditional labor intensity units for these specialized dental procedures.

Methodological approach:

- Analytical: To delineate the structure and nature of orthodontist labor expenditure in the fabrication and placement of aligners.
- Chronometric: To ascertain the total duration of aligner fabrication and placement processes.
- Mathematical: To determine departmental time standards for orthodontic procedures related to aligner fabrication and placement.
- Statistical: For the processing and analysis of research outcomes.

To quantify the duration of orthodontic procedures in aligner fabrication and place-

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ment, and to establish corresponding time standards and CULs, we employed the officially sanctioned methodology of the Ministry of Health of Ukraine for determining labor expenditures in dentistry, as modified by V. A Labunets (1999).

In accordance with this methodology, given that the nature of the orthodontist's labor process during the clinical stages of specialized care provision consists of a series of discrete, sequential manipulations comprising repetitive and constant elements of the primary operation, time expenditures are preliminarily indexed into permanent time costs (Tp), which are independent of the number of constructional elements or specialized actions (e.g., patient consultation, impression acquisition, scanning), and variable-repeating time costs (Tvr), which are entirely dependent on these factors (e.g., digital processing of a specific quantity of scans or files).

The methodology for indexing time expenditures by nature and content proceeds as follows: The expert-observer initially segments the production process into discrete technological stages with logical completeness. Subsequently, the content of work at each stage is evaluated, and the correlation of these manipulations in terms of labor expenditure characteristics is determined.

Based on the acquired data, in accordance with methodological requirements, the summation of Tp and Tvr indicators is performed. The resultant value is presented as the desired time standard for specific categories of orthodontic care:

TS = Tp + Tvr, where:

TS - time standard; Tp - permanent time costs; Tvr - variable-repeating time costs.

Statistical processing of chronometric results involves the determination of the weighted arithmetic mean duration for each process stage, without calculating the error of this indicator.

In alignment with the provisions of the official methodology for determining labor expenditures in dentistry, where the calculation of CULs (conditional labor intensity units) for a dentist's clinical work utilizes the volume of medical care provided during 60 minutes of working time, CUL indicators are computed using the following formula:

CUL = TS x 1CUL,

where: CUL - conditional labor intensity units (in absolute numbers); TS - time standard (in minutes); 1CUL - conditional indicator of one conditional labor intensity unit (in minutes).

Results

Chronometric measurements of aligner fabrication and placement protocols, as performed by orthodontists in clinical settings, were conducted in medical institutions across Odessa, Kyiv, Cherkasy, Mykolaiv, and Ivano-Frankivsk from 2022 to 2024.

The study observed aligner fabrication processes executed by 8 orthodontists, encompassing: production on gypsum dental models derived from traditional impressions, on 3D-printed dental models based on traditional impressions, on 3D-printed dental models from digital impressions, and the fabrication of flexible aligners via 3D printing utilizing digital impressions and STL files.

A total of 32 technological protocols, performed by 8 orthodontists of varying qualifications, were analyzed.

The chronometric data were recorded in a specially developed "Orthodontist Working Time Card." Prior to analysis, the labor expenditures were indexed according to the established methodology into permanent labor costs (Tp), independent of the number of structural elements, and variable-repeating labor costs (Tvr), entirely dependent on these factors. The resultant indicators were aggregated using the officially sanctioned formula

TS = Tp + Tvr.

In orthodontic clinics across Ukraine, four primary methods of elastic aligner and cap fabrication are employed:

1. Vacuum thermoforming of aligners on gypsum models cast from traditional dental impressions

In this method, the orthodontist manually models activators using photopolymerizable restorative material or dental acrylic, positioning them on gypsum models of dental arches in accordance with their professional judgment

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regarding the optimal application of force vectors on individual teeth in both spatial and temporal dimensions.

The specialized equipment required for this procedure includes an automated impression material dispenser, vibration table, model trimmer, vacuum forming unit, dental micromotor, and electric wax spatula.

The total working time for an orthodontist in the fabrication and placement of aligners produced on gypsum dental models via vacuum thermoforming is as follows:

1. Consultation phase - 36.06 min. (0.6 CUL);
2. Acquisition of traditional dental impressions utilizing an automated impression material dispenser - 32.77 min. (0.5 CUL);
3. Aligner fabrication via vacuum thermoforming - Single arch - 59.71 min. (1.0 CUL); Both arches - 89.72 min. (1.5 CUL).
4. Placement of activators in the oral cavity and aligner fixation - Single arch - 76.58 min. (1.3 CUL); Both arches - 130.02 min. (2.2 CUL).

2. Vacuum thermoforming of aligners on 3D-printed dental models derived from traditional dental impressions

In this approach, 3D models are generated based on scans of gypsum dental models using a stationary scanner. The orthodontist positions activators in virtual space utilizing specialized computer-aided design software for aligner modeling. The aligners are subsequently formed using a vacuum thermoformer, mechanically processed, and installed in the patient's oral cavity.

Essential equipment for this method includes an automated impression material dispenser, vibration table, model trimmer, stationary scanner, additive manufacturing 3D printer, computer with appropriate software, photopolymerization unit, ultrasonic cleaner, and dental micromotor.

The total working time for an orthodontist in the fabrication and placement of aligners produced on 3D-printed dental models from traditional impressions acquired using an automated impression material dispenser and formed via vacuum thermoforming is as follows:

1. Consultation phase - 36.06 min. (0.6 CUL).
2. Acquisition of dental impressions utilizing an automated impression material dispenser - 32.77 min. (0.5 CUL).
3. Aligner fabrication on 3D-printed dental models via vacuum thermoforming - Single arch - 194.92 min. (3.3 CUL); Both arches - 310.46 min. (5.2 CUL).
4. Placement of activators in the oral cavity and aligner fixation - Single arch - 76.58 min. (1.3 CUL); Both arches - 130.02 min. (2.2 CUL).

3. Vacuum thermoforming of aligners on 3D-printed dental models generated from digital dental impressions.

This method involves the production of 3D-printed models using an additive manufacturing 3D printer based on digital dental impressions, followed by the formation of caps and aligners using a vacuum thermoformer.

Required equipment includes an intraoral scanner, additive manufacturing 3D printer, computer with appropriate software, photopolymerization unit, ultrasonic cleaner, and dental micromotor.

The total working time for an orthodontist in the fabrication and placement of aligners produced on 3D-printed dental models from digital impressions via vacuum thermoforming is as follows:

1. Consultation phase - 36.06 min. (0.6 CUL).
2. Acquisition of digital dental impressions using an intraoral scanner - 39.4 min. (0.7 CUL).
3. Aligner fabrication on 3D-printed dental models via vacuum thermoforming - Single arch - 152.09 min. (2.5 CUL); Both arches - 224.86 min. (3.7 CUL).
4. Placement of activators and aligner fixation - Single arch - 76.58 min. (1.3 CUL); Both arches - 130.02 min. (2.2 CUL).

4. Direct 3D printing of aligners from STL files.

In this approach, the entire fabrication process occurs in a virtual environment using STL files, followed by direct printing on an

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additive manufacturing 3D printer.

Essential equipment includes an intraoral scanner, additive manufacturing 3D printer, computer with appropriate software, photopolymerization unit, ultrasonic cleaner, and dental micromotor.

The total working time for an orthodontist in the fabrication and placement of aligners produced via 3D printing based on STL files is as follows:

1. *Consultation phase - 36.06* min. (0.6 CUL).
2. Acquisition of digital dental impressions using an intraoral scanner - 39.4 min. (0.7 CUL).
3. Aligner fabrication based on STL files - Single arch - 141.92 min. (2.4 CUL); Both arches - 214.69 min. (3.6 CUL).
4. Placement of activators and aligner fixation - Single arch - 76.58 min. (1.3 CUL); Both arches - 130.02 min. (2.2 CUL).

Discussion

Analysis of the chronometric data obtained for various aligner fabrication methodologies in orthodontic clinical settings revealed that the most time-efficient approach is the vacuum thermoforming of aligners on gypsum dental models with manual placement of activators. This method relies on the orthodontist's subjective assessment of force vector application on individual teeth. The total duration for this procedure is 205.12 minutes (3.4 CULs) for a single dental arch and 288.57 minutes (4.8 CULs) for both arches.

The second most time-efficient methodology is the fully digital protocol utilizing STL files generated from intraoral scanning of the patient's dentition, followed by direct 3D printing of aligners. This process requires 293.96 minutes (5.0 CULs) for a single arch and 420.17 minutes (7.0 CULs) for both arches.

The third position in terms of temporal efficiency is occupied by the process of vacuum thermoforming aligners on 3D-printed models generated from digital dental impressions. This method necessitates 304.13 minutes (5.1 CULs) for a single arch and 430.34 minutes (7.2 CULs) for both arches.

The most time-consuming approach is the hybrid method of aligner fabrication, which involves vacuum thermoforming aligners on 3D-printed models derived from traditional dental impressions. This process requires 340.33 minutes (5.7 CULs) for a single arch and 509.26 minutes (8.5 CULs) for both arches.

These findings present several points worthy of discussion:

1. Efficiency of Traditional Methods: The superior time efficiency of the conventional process for planning, modeling, and fabricating aligners without digital technologies is noteworthy. Its duration is approximately 69% of the shortest digital protocol. This efficiency can be attributed to the simplicity of the process and the orthodontist's direct involvement in every step, eliminating the need for digital data processing and manipulation.
2. Advantages and Limitations of Conventional Approaches: The primary advantage of the traditional method lies in its technological simplicity, negating the need for specialized staff training or costly equipment. However, this approach is not without limitations. The efficacy of treatment may be questionable due to the lack of objective criteria for treatment planning, particularly in terms of precise force vector distribution, which is a key feature of specialized orthodontic software used in digital methods.
3. Comparative Analysis of Digital Protocols: Among the digital protocols for aligner fabrication, the direct 3D printing from STL files emerged as the most time-efficient. It demonstrated a 3% shorter duration compared to the digital protocol involving vacuum thermoforming on 3D-printed models obtained from digital impressions. This marginal difference suggests that both methods are comparable in terms of time efficiency, with the choice between them potentially influenced by other factors such as material costs, equipment availability, and specific case requirements.
4. Inefficiency of Hybrid Approaches: The

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hybrid digital protocol, involving vacuum thermoforming of aligners on 3D-printed models obtained from traditional dental impressions, proved to be the most time-consuming. Its duration exceeded other digital protocols by 15-18%. This inefficiency can be attributed to the combination of time-consuming traditional impression-taking with the additional steps required for digitization and 3D printing, essentially combining the drawbacks of both traditional and digital methods without fully leveraging the benefits of either.

5. Implications for Clinical Practice: These findings have significant implications for orthodontic practice. While digital methods offer advantages in terms of precision and the ability to objectively plan force application, they do not necessarily translate to time savings in the clinical setting. Practitioners must weigh the benefits of digital accuracy against the efficiency of traditional methods, particularly in practices with high patient volumes.
6. Technological Investment Considerations: The time efficiency of traditional methods raises questions about the cost-effectiveness of investing in digital technologies for aligner fabrication. However, it's crucial to consider that time efficiency is just one factor in the overall value proposition of digital orthodontics. Other factors, such as treatment predictability, patient comfort, and the ability to easily modify treatment plans, may justify the additional time investment.
7. Future Research Directions: This study opens avenues for further research. Long-term studies comparing treatment outcomes between traditionally fabricated aligners and those produced through various digital protocols would provide valuable insights into the clinical efficacy of these methods. Additionally, research into optimizing digital workflows to improve time efficiency could potentially address the current time disadvantage of digital methods.

These findings underscore the complex interplay between technological advancement and clinical efficiency in orthodontic practice. While digital methods offer numerous advantages, their implementation must be carefully considered in the context of overall practice efficiency and patient care quality.

Conclusion

The results of this chronometric study provide valuable insights into the time efficiency of various aligner fabrication methods in orthodontic practice. Several key conclusions can be drawn:

1. Time Efficiency of Traditional Methods: The conventional process of planning, modeling, and fabricating aligners without digital technologies remains the most time-efficient approach. Its duration is approximately 69% of the shortest digital protocol, highlighting the continued relevance of traditional skills in modern orthodontic practice.
2. Variability in Digital Protocols: Among the digital protocols, direct 3D printing from STL files emerged as the most time-efficient. However, the marginal difference (3%) between this method and vacuum thermoforming on 3D-printed models from digital impressions suggests that both approaches are comparable in terms of time efficiency.
3. Inefficiency of Hybrid Approaches: The hybrid digital protocol, combining traditional impressions with 3D printing, proved to be the least time-efficient, with a duration 15-18% longer than other digital methods. This finding cautions against partial digitization of workflows, which may compound inefficiencies rather than streamline processes.
4. Balancing Efficiency and Precision: While traditional methods demonstrate superior time efficiency, it is crucial to consider the potential trade-offs in terms of treatment planning precision and objective force distribution, which are key advantages of digital methodologies.
5. Implications for Clinical Decision-Making: These findings provide orthodontists with valuable data to inform their choice of

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aligner fabrication method. The decision should balance time efficiency with other factors such as treatment predictability, ease of modifications, and patient-specific requirements.

6. Need for Holistic Evaluation: While this study focuses on time efficiency, a comprehensive evaluation of aligner fabrication methods should also consider factors such as material costs, equipment investments, treatment outcomes, and patient satisfaction.

In conclusion, this research demonstrates that while digital technologies offer numerous advantages in orthodontic practice, they do not necessarily translate to time savings in aligner fabrication. The significant time efficiency of traditional methods suggests that a balanced approach, potentially combining traditional skills with digital technologies, may be optimal for many orthodontic practices. Future research should focus on optimizing digital workflows to improve time efficiency while maintaining the precision and flexibility that digital methods offer.

These findings contribute to the ongoing dialogue about the integration of digital technologies in orthodontic practice and provide a foundation for evidence-based decision-making in clinical settings. As the field continues to evolve, it will be crucial to continuously reassess and optimize protocols to ensure the highest standards of patient care and practice efficiency.

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