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# Accuracy of virtual mounting at centric relation using personalized 3D-printed transfer key: a clinical in vivo study

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#### **Abstract**

**Aim** Previously, we developed a 3D-printed customized transfer key for virtual mounting of the face and maxillomandibular relationship at centric occlusion. The accuracy was evaluated in vitro using a phantom head model with simulated soft tissue. In the present study, we aimed to investigate the effect of the transfer key in humans with clinical situations.

**Methods** In the cross-sectional study, twenty volunteers with class I Angle occlusion were clinically registered for centric relation using a personal 3D-printed transfer key. The facial and intraoral (IOS) scans were recorded and integrated to build a virtual model patient via the transfer key. Large-view CBCT images were obtained and then segmented for 3D reconstruction as a reference. The deviation between the virtual model and the reference was evaluated using 3D superimposition, with min, max, mean, and root mean square (RMS) deviations calculated. We also calculated the difference between the virtual model and the reference at the upper and lower occlusal planes.

**Results** Superimposition demonstrated high deviations in the total head and face areas, especially on the chin and submandible sides, with mean and RMS deviations of 0.05 and 0.88 mm for the head and 0.17 and 1.26 mm for the face only. Significant differences were found between the head and face, with high agreements in the upper and lower arches, as indicated by the mean and RMS deviations of 0.008 and 0.34 mm for the upper arches, and 0.1 and 0.61 mm for the lower arches. Upper arches were mounted accurately in all teeth, while lower arches were more rotated at the incisors. The lower arches showed a higher deviation than the upper arches, with an occlusal plane discrepancy of 0.66° for the lower and 1.6° for the upper arches, respectively.

**Conclusions** The dental arches achieved the highest agreement, while deviations were noted in the facial regions. The 3D-printed customized transfer key effectively enhanced the virtual class I patient's accuracy. This novel approach offers a streamlined, patient-friendly solution for digital dental workflows.

Clinical trial number Not applicable.

**Keywords** Accuracy, Intraoral scanner, Face scanner, Transfer key, Digital dentistry

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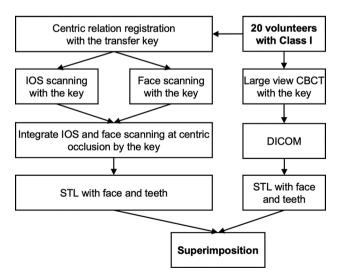
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#### Introduction

Accurate recording of the maxillomandibular relationship in centric relation (CR) is crucial for prosthodontic treatment planning and virtual articulator programming [1]. This involves deciding whether to position the mandible in maximal intercuspal position (MIP) or centric occlusion (CO). CR is the jaw relationship where the condyles sit in an anterior-superior position against the slopes of the articular eminences. CO refers to the position of the teeth when the jaw is at CR. The mandible rotates fully around a fixed axis in CR, making it a repeatable and reliable reference position. Ideally, MIP and CO should match, and choosing between MIP and CO for mounting depends on the clinical situation. MIP is suitable for patients with stable, healthy occlusion and no TMJ disorders. However, if there are occlusal issues or TMJ problems, mounting at CO provides a more accurate and therapeutic reference for planning treatment [2, 3]. Traditionally, facebows and physical interocclusal records transfer a patient's occlusal plane and CR to a mechanical articulator [4, 5]. In the digital era, equivalent "virtual facebow" techniques have been explored to mount digital dental models in the correct anatomical position [6]. Recent studies indicate that 3D facial scanning can perform comparably to conventional facebows for transferring cast orientation [4, 7, 8]. For optimal accuracy, combining a facial scan with an intraoral transfer device is recommended to capture both the occlusal relationship and facial reference planes simultaneously.

Previously, we developed a personalized 3D-printed transfer key as a digital facebow alternative and validated its accuracy in an in vitro study using a phantom head with soft tissue mimicked by silicone [1]. In that



**Fig. 1** Study design. Twenty volunteers with class I occlusion underwent centric relation registration with a 3D-printed transfer key. After IOS and face scanning, the data were integrated and compared to the CBCT references

Phase 1 study, the transfer key– consisting of an intraoral anterior deprogrammer and an extraoral face-orienting frame- enabled integration of intraoral scanner (IOS) data with facial scans, yielding a virtual patient model closely aligned to a cone-beam CT (CBCT) reference . The occlusal plane information was collected and integrated into the virtual phantom model using scanned data. The phantom results showed high trueness (Root mean square - RMS=0.5-0.7 mm for dental arches and whole head). They indicated that the dental arches could be mounted with minimal error, with only slight deviations observed in facial soft tissue regions. Importantly, the key can register the dental arches at CO with simplicity and accuracy. Building on these promising in vitro outcomes, the present Phase 2 study aimed to evaluate the transfer key in actual clinical conditions. Specifically, we investigated the accuracy of virtual mounting at CR in human participants using the 3D-printed customized transfer key. We hypothesized that the transfer key would enable precise alignment of digital dental models with the patient's facial scan, resulting in agreement with a CBCT-derived reference model, with minor deviations (similar to those observed in the phantom results). This study provides clinical validation for a novel, streamlined workflow that creates an integrated virtual patient.

# Methods

# Study design

This cross-sectional clinical study was designed as a single-cohort observation to test the accuracy of a digital CR mounting protocol in healthy adult volunteers. Ethical approval was obtained from the institutional review board (No. 736/HĐĐĐ-ĐHYD), and all participants provided written informed consent. A total of 20 volunteers (10 males, 10 females) aged 18-25 years with complete, permanent dentitions were recruited. Only subjects with Angle Class I occlusion and at least 28 natural teeth were included to standardize conditions. All volunteers had finished craniofacial growth and had no history of temporomandibular disorders or maxillofacial trauma. Exclusion criteria encompassed any prior orthognathic surgery, craniofacial pathology or congenital deformity, neurologic or psychiatric disorders (e.g., epilepsy) that could affect cooperation, and the presence of extensive restorations, orthodontic appliances, or metal prostheses in the head or oral region. Each volunteer underwent a CR record using the custom transfer key, digital scanning procedures, and a reference CBCT scan. Figure 1 outlines the overall workflow of the study, in which the 3D-printed key was used to record the CR, integrate intraoral and facial scans into a virtual patient, and compare the results to the CBCT-derived reference.

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# 3D-printed transfer key design and manufacturing

The transfer key was designed as a two-component device to capture the maxillomandibular relationship and facial orientation. An individualized key was modeled for each participant's dental arch morphology using CAD software (Autodesk Fusion 360, Autodesk, USA). The key design included: (1) an intraoral insert part serving as an anterior deprogrammer or jig, and (2) an extraoral receptacle part as a rotatable cross-shaped frame (Fig. 2A). The intraoral part had a flat occlusal bite plane intended to contact only the lower incisors, preventing posterior tooth contact when the mandible is guided to CR. This acts similarly to a Lucia jig in relaxing the jaw and establishing a repeatable CR position. The extraoral

part extended out of the mouth. It featured a horizontal bar and vertical rod, forming a cross that could be aligned with the facial midline (vertical) and the interpupillary line (horizontal) (Fig. 2B). A spherical swivel joint connected the intraoral and extraoral components, allowing the extraoral frame to rotate and be positioned according to the subject's facial reference planes. Once properly oriented, the joint could be tightened to lock the two parts in position [1]. The key was fabricated with a stereolithography 3D printer (Formlabs Form 3B, Formlabs, USA) using a biocompatible resin (White Resin FLGPWH04). According to the manufacturer's instructions, the printed key was post-processed (washed and UV-cured). The resulting device was lightweight and

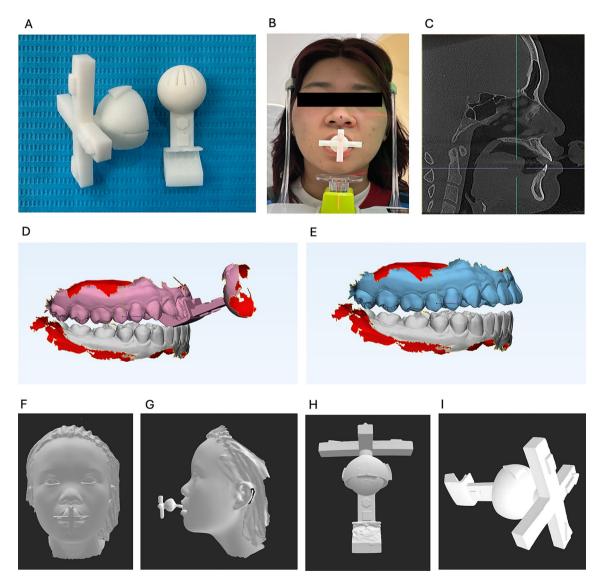


Fig. 2 Centric relation registration with a 3D-printed transfer key. A Transfer key compartments were designed and fabricated by 3D printing. B Volunteer during CBCT capture. C Large view CBCT image of the head. D Full arches scan at centric occlusion with transfer key. E Full arches scan at centric occlusion without the transfer key. The upper jaw was scanned two times, with and without the transfer key. F&G 3D image of the scanned head with transfer key mounting at centric relation. H & I 3D image of the scanned transfer key with the registered jig

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custom-fitted for each volunteer's anterior dentition and facial dimensions. Before use, the fit of the key's intraoral component was verified in the patient's mouth, and any necessary minor adjustments were made to ensure stability and comfort.

#### Centric relation registration and key setup

Each participant's centric relation was recorded using the transfer key with the aid of an occlusion lecturer. The subject was seated upright and asked to close lightly on the intraoral deprogrammer element of the key. Gentle manual guidance (bimanual manipulation) was applied to ensure the condyles were seated in an anterior-superior position in the glenoid fossae, corresponding to the CR position. In this position, only the lower incisors contacted the flat bite plane of the key's insert, while the posterior teeth remained discluded without tooth-to-tooth contact. This arrangement allowed any muscle engrams to release and the mandible to hinge freely at CR. An articulating paper was used briefly to confirm the contact point of the lower incisors on the bite plane. Once the jaw position was verified, quick-setting auto polymerizing resin was added to secure the key's position. These resin indices effectively locked the maxilla, mandible, and key together at the recorded CR position. With the mandible thus stabilized, the extraoral frame of the key was adjusted so that one arm aligned with the facial midline and the transverse arm was parallel to the line connecting the pupils. This ensured the recorded occlusal plane orientation was related to the actual horizontal and midsagittal planes of the face. The swivel joint connecting the key components was then tightened to fix the orientation, helping it preserve both the interarch relation and facebow-like orientation. The subject was instructed to maintain a gentle closing force on the key until all records were complete [1, 5].

#### Scanning data acquisition

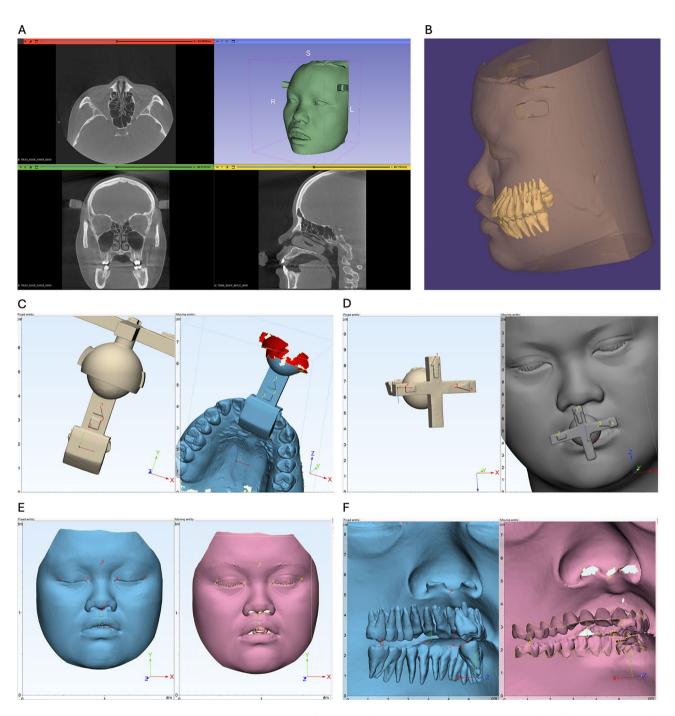
With the transfer key in place and CR recorded, digital scans were obtained to create the virtual patient model (Fig. 2D-I). First, the IOS scans of the dentition were taken using an IOS (Trios 3, 3Shape, Denmark), the prepare scan mode was used for the upper arch without the key to record the complete tooth anatomy unobstructed at the same position. Then, the IOS was used to scan the upper and lower arches and the transfer key as follows: The maxillary arch was scanned together with the attached transfer key and resin locks, with the key holding the jaws in the CR position, noting that the intraoral insert part of the key was scanned. This captured the key's intraoral portion and its relationship to the upper teeth. The mandibular arch was likewise scanned (without the key, since the lower teeth were not directly attached to the key). Then the bites (CO position) were recorded. During these scans, care was taken not to alter the indexing of the resin locks so that the maxilla-mandible relationship could be reproduced (Fig. 2D). Taken together, we obtained the correct position scans of 2 arches and the maxilla-mandible relationship with and without the key for later integration.

Next, a facial scan was conducted to capture the participant's face and the external part of the transfer key. The participant's head was positioned naturally with the eyes looking straight ahead, ensuring that the lines connecting the pupils and the lines from the eye corners to the tops of the ears were parallel to the floor, with the bite stabilized at centric occlusion using the transfer key. A structured-light facial scanner (MetiSmile, Shining3D, China) was used to scan the subject's head and face from multiple angles while the extraoral frame of the key was still in position (the subject closed again on the key during the face scan). This produced a 3D face mesh with the transfer key's cross-bar visible across the lips (Fig. 2F, G). Finally, the transfer key (with the resin indices still attached) was scanned separately outside the mouth using a laboratory scanner (E1, 3Shape) to obtain a high-resolution 3D model of the key itself (Fig. 2H, I). The series of scans collected thus included: (1) maxillary arch with key, (2) maxillary arch without key, (3) mandibular arch, (4) facial scan with key, and (5) key alone. These datasets would later be aligned to reconstruct the virtual head with jaws in CR.

#### **CBCT capture and STL conversion**

Immediately after the scanning procedures, the volunteer (still wearing the transfer key and resin indexes to maintain CR) underwent a large 16×18 cm field-ofview (FOV) CBCT scan (Rainbow CT, Dentium, Korea) to capture the entire head (Fig. 2B). Each subject was instructed to remain in light occlusion on the bite key during the scan to ensure the maxilla-mandible relationship matched the digital record after articulating paper marks checking. Scan settings (voxel size ~ 0.3 mm, 90 kV, appropriate mA) were chosen to image both hard and soft tissues of the head (Fig. 2C). The raw CBCT DICOM data were imported into Mimics Research software (v.21, Materialize NV, Belgium). Using thresholdbased and region-growing tools, teeth and the facial soft tissue surface were segmented from the CBCT as in previous reports [1, 9]. 3D Slicer imaging software was then used to refine and validate the segmentation (Fig. 3A) [10]. The transfer key, being resin, was partially visible in the scan; these artifacts were either segmented out or ignored by choosing thresholds that captured teeth and soft tissue but excluded the radiopaque key (any minor remnants of the key were manually removed in postprocessing by trimming in 3D Slicer/ Segment Editor/ Scissors). Predefined threshold sets were applied for

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**Fig. 3** The segmentation, integration, and superimposition processes from CBCT and 3D scans. **A** The segmentation procedure of the CBCT images. After segmenting specific regions by threshold selection, the face and jaws were refined using 3D Slicer. **B** 3D image of converted CBCT image of the head with the full arches at centric occlusion. **C** The integration of transfer key and upper arch scans. D integration of transfer key and face scans. **E & F** The superimposition of the virtual patient from face (**E**) and dental arches (**F**) by point selecting and auto-global registration

segmentation, specifically for prosthesis/teeth (800 to 3031 Hounsfield Unit, HU) and skin tissue (-718 to -177 HU). After segmentation, a three-dimensional reconstruction of the head was generated. This included the facial surface, upper and lower arches, with teeth in their actual CO position. The segmented structures were then exported as STL surface mesh files. The final reference

model for each subject was effectively a 3D digital cast of their head and dental arches, as seen on CBCT (Fig. 3B).

# IOS and face scan integration

The IOS and facial scans were integrated using 3-Matic Research software (v.13, Materialize NV). The 3D model of the key (from the lab scan) was imported and aligned

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to the partial key geometry present in both the face and upper arch scans. By superimposing the key's cross-shaped frame from the face scan with the same frame on the lab-scanned key model, the facial soft tissue data and dental data were brought into the same coordinate system (Fig. 3C, D).

First, the maxillary dental model obtained with the key was aligned with the in-lab-scanned key, essentially by best-fit matching of the key surfaces. Next, the in-lab-scanned key was used as the reference to merge with the facial scan. Then, the facial scan was merged with the dental arches using the transfer key as a shared reference object. This alignment was initially done by manually picking three or more corresponding landmarks on the key (e.g., tip of the vertical rod and ends of the horizontal bar) in the two scans, followed by an automated registration for fine-tuning. A global registration was then run on the entire merged surface to minimize any residual discrepancy between overlapping regions of the face and dental scans. The face mesh became accurately positioned relative to the upper jaw.

The in-lab-scanned key was deleted, and the upper arch with the key was replaced by the complete upper arch in the same position (in prepare mode of Trios 3 IOS). This replaced the partial dental data in the "with-key" scan with the complete tooth geometry from the second scan, yielding an accurate maxillary arch model in the CR position. Finally, the lower jaw, which was already related to the upper, was also in place in the composite model. The lower arch scan was then positioned relative to the upper arch using the recorded interarch relationship. Since the key had related upper and lower arches during scanning, the bite alignment was reproduced using the resin index contacts and the incisor contact point as constraints.

# **Superimposition process**

To evaluate the accuracy of the transfer key method, each participant's integrated virtual patient model (from IOS+face scans) was superimposed on the reference model (from CBCT) (Fig. 3E, F). The superimposition and deviation analysis were performed using 3-Matic Research software [11-14]. First, the two models were roughly aligned based on recognizable anatomic landmarks (N-points registration function) including 6 face points (Gl-Glabella, Ex- left and right Exocanthion, En- left and right Endocanthion, Sn-Subnasale); 6 teeth points: middle of the incisal edge of tooth 11, 31, distolingual cusp apex of teeth 17, 27, 37, 47 for the whole face and teeth superimposition. Then, a best-fit registration (global registration function) was executed over the entire head or a specified region to minimize distance errors between the point clouds. Because the face scan and the CBCT model might not capture the whole head (the back of the skull), the registration was primarily driven by overlapping facial regions and dental surfaces.

After alignment, the software computed the point-to-point deviations (distance between corresponding surface points) across the entire model. Color-coded deviation maps were generated to visualize areas of agreement (green) versus discrepancy (blue for negative deviation, where the experimental image > reference image, red for positive deviation where experimental image < reference image) between the two models for each subject (Fig. 4). Additionally, the minimum deviation, maximum deviation, mean deviation, and root mean square (RMS) deviation were calculated for specific regions of interest. RMS indicated the data-point clouds of surfaces, showing how two images deviated from zero, and low RMS indicated the good agreement of two images [1].

We focused on four key areas for analysis: the whole head, the facial soft tissue region, the upper dental arch, and the lower dental arch. The occlusal plane orientation was also compared by computing the angle between the plane formed by the upper teeth in the experimental model vs. the reference, and similarly for the lower teeth. These angles (difference in pitch of the occlusal plane) provide insight into any tilt of the virtual mounting relative to the true orientation.

# Statistical analysis

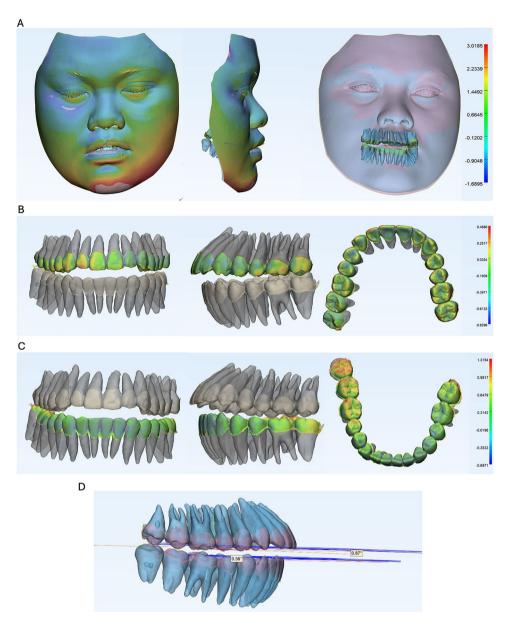
All quantitative data were aggregated for the 20 subjects. The distribution of each measure (mean deviation, RMS, etc., for each region) was tested for normality using the Shapiro–Wilk test. For comparing deviation magnitudes across different areas (head vs. face vs. arches), a Friedman test (non-parametric repeated measures ANOVA) was used with Dunn's post hoc tests. A paired t-test was used to compare the upper vs. lower occlusal plane discrepancy angles. Results are reported as mean  $\pm$  standard deviation (SD) or median [interquartile range]. A significance level of p<0.05 was set for all analyses. GraphPad Prism (v.10, GraphPad Software, USA) was used for the statistical analysis and plots. Post hoc powers were calculated by G\*Power (v 3.1.9.6) and confirmed to be >80%.

#### **Results**

# Virtual mounting at centric relation by personalized 3D-printed transfer key

All 20 volunteers completed the CR recording and scanning protocol using the customized transfer key. No participant had to be excluded due to inability to record or scan. The key was well tolerated, and no adverse events (such as soft tissue irritation or TMJ discomfort) were noted during the procedure. Using the transfer key, we were able to mount each subject's maxillary and mandibular digital models in a reproducible CR position and integrate them with the facial scan. Figure 2 illustrates

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**Fig. 4** The results of superimposition. **A** Head analysis of superimposition from the front, lateral, and back sides. **B** Upper arch analysis of superimposition from the front, lateral, and occlusal sides. **C** Lower arch analysis of superimposition from the front, lateral, and occlusal sides. **D** Upper and lower occlusal plane differences from the experiment and reference arches

the CR registration process and data acquisition in one representative subject, including the design of the key and its use during CBCT and IOS/face scanning. All components of the virtual patient construction were accomplished chairside. Visually, the integrated virtual patient models aligned well with the CBCT references. For example, when the 3D face scan with teeth was overlaid on the CBCT facial surface, there was an almost indistinguishable fit in most areas, and the upper and lower teeth from the IOS data matched the CBCT tooth surfaces closely. Notably, because the subject had the key in place during CBCT, the maxillary and mandibular STL models from CBCT were inherently in the same CR/CO

relationship, and no need for further alignment. We refer to this CBCT-derived composite as the reference virtual patient model, representing the ground truth for subsequent accuracy comparisons.

Figure 3 shows an overview of the integration and superimposition process. Using the key, the resultant virtual mounting at CR captured each patient's occlusal relationship and facial orientation. The lower arch was virtually articulated to the upper arch by aligning the digitized resin lock impressions to their corresponding tooth surfaces. This ensured the mandibular teeth fit into the indexed position captured at CR. This yielded an assembled maxilla-mandible model in CO by the key (in

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this study, CO = CR position by definition of our registration). The outcome was a fully integrated virtual patient model: it contained the facial soft tissues, aligned with the maxillary and mandibular dentitions, articulated at the recorded CR. The coordinate system of this model was inherently related to the patient's cranial anatomy via the transfer key reference (midline and interpupillary orientation preserved). This model represents the experimentally obtained virtual mounting using the transfer key method.

#### Total head and face deviation

Two approaches were utilized to analyze different aspects: (1) the whole-head analysis, where the face and dental structures were used for registration to examine overall head deviation; and (2) a face or dental-arch analysis, where the registration was the same to the whole-head but the analysis was separated for face or upper or lower arch only to specifically examine how well the interested areas coincided when the other areas were not considered.

Quantitative deviation analysis revealed a high level of agreement between the virtual mountings and the CBCT references for the total head structures, with minor discrepancies mostly in some soft tissue regions (Table 1; Fig. 4A). When the entire head was considered, the mean surface deviation between the experimental model and reference was 0.099 mm, and the RMS deviation was 0.88 mm. The face-only area showed slightly larger differences: mean deviation 0.17 mm with RMS 1.26 mm. These results indicate that the transfer key method overall reproduced the head position with sub-millimeter trueness. The color scale map visualization (Fig. 4A) consistently showed concentrations of deviation (up to 1.6–3 mm, in blue or red) along the inferior chin, jawline, and occasionally at the edges of the ears or hair.

In contrast, the central facial areas (nose, lips, midface) and the forehead showed a near-green color, indicating differences of less than 1 mm. The maximum point-to-point deviations for the whole-head superimposition ranged from 5 to 7 mm in some subjects (typically at the peripheral borders of the model), whereas 95% of all head surface points were within 1 to 2 mm. Statistically, a significant difference was found when comparing the magnitude of deviations in the face region to those in the dental arch regions (p<0.001), with the face showing larger errors on average (Fig. 5A-D). The total head deviation (including teeth and soft tissues) confirms that the virtual orientation of the maxilla relative to the skull was captured reasonably well by the transfer key method.

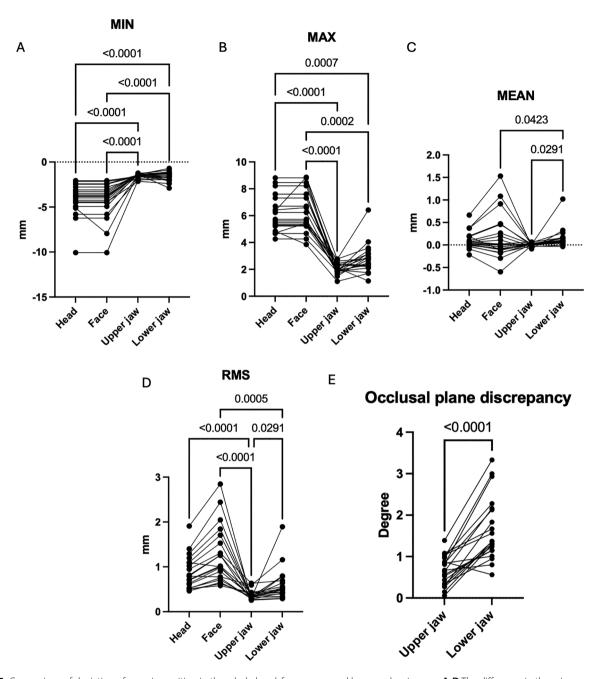
#### Upper and lower arches deviation

The dental arches achieved the highest accuracy in the virtual mounting. After aligning the models, the upper arch in the experimental virtual patient was almost indistinguishable from the CBCT reference model. The mean deviation for the maxillary teeth surfaces was only 0.008 mm, with an RMS deviation of 0.34 mm. The maxillary dentition was reproduced in the virtual articulator position with minor error. The mandibular arch showed a slightly greater difference, with a mean deviation of 0.10 mm and RMS 0.61 mm, although this was higher than the upper arch. The color scale for the upper arch (Fig. 4B) was almost entirely green, indicating an excellent fit of all maxillary teeth. Most areas were also green for the lower arch (Fig. 4C), but a subtle pattern emerged at the incisor region. In some subjects, the lower incisors appeared slightly more labial or lingual in the virtual model than in the reference, showing a minor rotation or translation of the lower jaw. This corresponds with the observation that the lower incisor segment had the most significant deviation within the lower arch, whereas

**Table 1** Values of mean ± sd [quartile]nd median [Quartile] of min, max, mean, RMS (root mean square) of deviation [quartile]n head, face, [quartile]nper jaw, [quart

Group	Head	Face	Upper jaw	Lower jaw
MIN (mm)	-4.115±1.818	-4.256 ± 2.001	-1.554±0.2541	-1.560±0.5137
	-3.801	-3.801	-1.452	-1.520
	[-4.823, -2.858]	[-4.823, -2.858]	[-1.642, -1.396]	[-1.916, -1.257]
MAX (mm)	$6.245 \pm 1.362$	$6.365 \pm 1.520$	$2.064 \pm 0.4274$	$2.815 \pm 1.093$
	5.984	5.984	1.984	2.756
	[5.234, 7.524]	[5.299, 7.599]	[1.827, 2.400]	[2.229, 3.170]
MEAN (mm)	$0.09979 \pm 0.1942$	$0.1703 \pm 0.5062$	$0.008430 \pm 0.03439$	$0.1558 \pm 0.2202$
	0.05055	0.006700	0.01460	0.1004
	[-0.007125, 0.1887]	[-0.1110, 0.4082]	[-0.01110, 0.02718]	[0.06113, 0.1607]
RMS (mm)	$0.8772 \pm 0.3729$	$1.262 \pm 0.6312$	$0.3638 \pm 0.09881$	$0.6132 \pm 0.3703$
	0.7947	1.011	0.3366	0.4998
	[0.5478, 1.098]	[0.7602, 1.662]	[0.3065, 0.4084]	[0.4012, 0.7627]
Occlusal plane (degree)			$0.6550 \pm 0.3551$	$1.654 \pm 0.7642$
			0.6550	1.365
			[0.3325, 0.9450]	[1.150, 2.153]

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**Fig. 5** Comparison of deviation of superimposition in the whole head, face, upper, and lower arches images. **A-D** The difference in the min, max, mean, and RMS (root mean square) deviation values, **E** The occlusal plane discrepancy between the upper and lower arches of virtual mounting compared to the CBCT reference (n = 20, A-B: Friedman test with Dunn's multiple comparisons posthoc test, E: matched t-test)

posterior teeth were very well aligned. The lower arch errors were statistically higher when comparing upper vs. lower arch deviations (p<0.05).

Regarding occlusal plane orientation, the transfer key preserved the plane closely, though a slight discrepancy was noted, particularly for the maxillary plane. The average angle between the virtual upper occlusal plane and the reference upper occlusal plane differed by about  $0.66^{\circ} \pm 0.36^{\circ}$ . The difference in the mandibular occlusal plane was around  $1.65^{\circ} \pm 0.76^{\circ}$ . This suggests the mandible in

the virtual mounting was tilted slightly relative to the proper orientation (within  $\sim 1-2$  degrees). The difference between upper and lower occlusal plane errors was significant (p < 0.001), with the upper arch showing the smaller tilt. Figure 5 summarizes the numerical deviations for head, face, upper arch, and lower arch regions (Fig. 5A–D) and the occlusal plane differences (Fig. 5E). In summary, the dental portion of the virtual patient matched the CBCT well, confirming that the 3D-printed

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transfer key can transfer the interarch relationship to the virtual environment with a high degree of accuracy.

#### Discussion

Our current study's findings support that the 3D-printed transfer key is a valuable addition to digital dentistry, enabling clinicians to achieve accurate virtual mounting at CR and thereby enhancing the predictability and efficiency of digital dental workflows. This Phase 2 clinical study demonstrates that a 3D-printed customized transfer key can reliably and accurately transfer a patient's centric relation record into the digital domain. The key allowed integration of intraoral and facial scans to create virtual patient models nearly identical to those generated from CBCT, particularly in the dentition. The findings are consistent with our previous in vitro results, where the same transfer key concept yielded minimal deviations in a phantom head setup [1]. In the clinical setting, we observed only slightly increased discrepancies (e.g., facial RMS  $\sim 1.3$  mm here vs. 0.85 mm in vitro [1]), which can be attributed to real-world factors such as patient movement, soft tissue variability, and scan noise. Patient movement and stability of soft tissue during the capture process could be potential sources of the small facial deviations, especially at regions where the face scan data were less dense or the skin may have shifted between scans [15]. The slightly higher deviation in the face region suggests more variability in soft tissue alignment, likely due to differences in how the facial scan and CBCT capture skin surfaces (for instance, areas like the chin and submandibular border showed the most significant discrepancies). However, it should be noted that these mean facial discrepancies were still minimal in absolute terms and were within clinically acceptable ranges for facial context [16-18]. Notably, the error magnitude for the dental arches remained mean ~ 0.008-0.1 mm, suggesting that the technique can meet the precision demands of prosthodontic workflows [14].

Our results align with the growing literature indicating that digital techniques can replace or augment traditional facebows and articulators [19-21]. For instance, Revilla-León et al. (2023) conducted an in vivo pilot study comparing CR records obtained by different intraoral scanner workflows, with and without an optical jaw-tracking device (Modjaw) [22]. They found that the method of recording CR significantly influenced accuracy and that combining IOS scans with a jaw tracking system improved trueness compared to IOS alone. Those findings underscore that a purely digital approach to CR is feasible and that supplemental devices, such as jaw trackers or, in our case, a transfer key, can enhance accuracy. Our approach offers an alternative to high-end jaw tracking by using a static 3D-printed jig to achieve comparable precision in mounting the casts. Notably, the transfer key method does not require expensive equipment beyond IOS device and face scanner, making it an accessible clinical option.

Using an anterior deprogrammer and face reference for virtual mounting is analogous to the Kois deprogrammer facebow technique, which other authors have adapted for digital workflows. This involves recording CR with a Kois deprogrammer and then scanning the record with an IOS, similar to what we did with the 3D-printed key [23, 24]. Our present study moves beyond technique description to quantitatively validate the outcome of such a process. In agreement with the literature, we found that the CR record is consistently maintained (here via the rigidly locked key), and facial and intraoral data integration can be very accurate. Inoue et al. (2024) reported that 3D facial scans alone for cast transfer can achieve results similar to conventional facebow mounting [6]. Our findings extend this by showing that when a custom transfer device is incorporated, the virtual mounting is oriented correctly and precisely captures the interarch relationship, thereby addressing both requirements of a facebow transfer. This supports the notion that a welldesigned digital transfer key can replace the traditional facebow + centric bite record in a digital workflow.

One intriguing outcome was the slight discrepancy in occlusal plane angle, with the virtual arches tilted  $\sim 1-2^{\circ}$ relative to the CBCT reference. While small, this was statistically significant. A possible reason is that the face scan alignment, using the key's crossbar, may have a slight angular error if the patient's head shifted or if the key alignment was not perfectly level. We interpret that the error likely stems from how the face scan alignment was done-minor angular deviations in aligning the facial reference could more directly affect the mandible orientation. Future improvements to the protocol could include incorporating an additional reference, such as a laser level or gravity indicator, to double-check the horizontal alignment of the transfer key during the recording process. Alternatively, one could use fiducial markers on the face to aid in more precise superimposition of facial scans [8]. Nonetheless, an angular error of  $\sim 1-2^{\circ}$ is minor in practical terms; it would have a negligible impact on intercuspation or bite relationships, though it could slightly affect how the case relates to an arbitrary hinge axis. Moreover, slight flexibility or settling of the mandible is possible, as only the incisors contact the deprogrammer, allowing the mandibular position to shift minimally during recording. Despite this, the differences were minor clinically.

The major limitations of this study include the relatively small sample size and the homogeneity of the participant pool. All volunteers had Class I normal occlusion and were young adults with full natural dentitions. This was deliberate to minimize variables and focus on the

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method's baseline performance. However, clinical reality presents many variations- patients with Class II or III relationships, edentulous arches, or those requiring increased vertical dimension changes might pose additional challenges for a transfer key. The transfer key design and protocol might need modifications for such cases (for example, adhesive index materials for edentulous ridges or different insert shapes for deep bite vs. open bite cases). Another limitation is that we did not directly compare our method against other digital or conventional CR recording methods. We used the CBCT as a reference, but did not, for instance, compare it to a conventional facebow mounting of stone casts. A comparative study could be conducted to benchmark the transfer key against a standard facebow mounting in terms of resulting prosthesis fit or occlusal accuracy.

It is also worth noting that our accuracy assessment inherently assumes the CBCT-based model is an accurate "ground truth." CBCT itself has some degree of distortion, and segmentation of the CBCT introduces minor errors in the surface model. Nonetheless, those errors are typically 0.1-0.3 mm for hard tissues, which is small compared to the differences we measured in the face region [9, 25]. Our CBCT segmentation protocol has been reported previously, indicating its high accuracy [1, 26]. Moreover, in this study, the DCOM data served as an available reference, incorporating both facial and jaw information at centric occlusion. Similarly, another study utilized CBCT data to assess the accuracy of virtual facebow records [27]. Thus, using CBCT as a reference is reasonable, but in an absolute sense, both the experimental and reference models have some uncertainty. Another practical consideration is radiation exposure and cost: we used CBCT for research validation; however, the goal of this workflow is to avoid the need for CBCT in everyday practice for mounting. In routine clinical use, one would rely solely on the transfer key and scanning; our findings suggest that this approach would still yield clinically acceptable accuracy for mounting. In 2023, Raffone et al. demonstrated in vitro that a direct virtual mounting technique, which matches intraoral and face scans using a transfer jig, is reliable. They emphasized the need to confirm these findings in vivo [28]. Our study confirms and adds confidence that fully digital mounting can be achieved clinically. Testing the workflow in actual class I patient treatments would be valuable, for example, using the virtual mounting to design prostheses or orthodontic appliances and evaluating the fit/outcome. This could include full-mouth rehabilitation cases, where mounting accuracy is critical for occlusal equilibration, or orthognathic surgical planning cases, where integrating dental models with facial scans is essential. Applying the transfer key concept to edentulous patients could revolutionize how we digitally record maxillo-mandibular relations for complete dentures.

#### **Conclusion**

Within the limitations of this study, the 3D-printed customized transfer key proved effective in clinically transferring and preserving the centric relation and face orientation of the jaws in a virtual environment with mean deviation from 0.008 to 0.17 mm and RMS from 0.34 to 1.26 mm. The integrated virtual patient models generated via the transfer key showed sub-millimeter agreement with the CBCT-derived reference standard, especially in the dental arch region, where deviations were negligible. Minor discrepancies were observed in facial soft tissue alignment but remained within 1 mm. The occlusal plane orientation was maintained within 1-2 degrees of accuracy. These results suggest that the transfer key technique can be a reliable procedure in a fully digital workflow for class I cases. Future work should explore the use of the transfer key in a broader range of patients and treatments, refine the device for easier use, and investigate combining static transfer keys with dynamic jaw tracking for a comprehensive digital articulation solution.

#### Abbreviations

IOS Intraoral scanner RMS Root mean square CR Centric relation

MIP Maximal intercuspal position

CO Centric occlusion TMJ Temporomandibular joint

CBCT Cone-beam CT FOV field-of-view

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#### **Author contributions**

NCNN, NDMN, ONHN, AHQN: Study conception and design, Acquisition of data and analysis, Drafting of the manuscript, Critical revision. NCNN, NDMN, ONHN: Design implementation, data acquisition, Critical revision. KDN, HHP, KHN: Acquisition of data, Critical revision. JEK, HTH: Study conception and design, Critical revision. All authors read and approved the final manuscript.

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#### Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

# **Declarations**

# Ethics approval and consent to participate

The study was adhered to Declaration of Helsinki and ethical approval was obtained from the institutional review board (Board of Ethics in Biomedical

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Research at the University of Medicine and Pharmacy at Ho Chi Minh City, No. 736/HDĐĐ-ĐHYD), and all participants provided written informed consent.

#### Consent for publication

Participants gave written informed consent for their personal or clinical details along with any identifying images to be published in this study.

#### **Competing interests**

The authors declare no competing interests.

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