

Effect of Customized Healing Abutment on Peri-Implant Tissues Compared with Conventional Healing Abutment: A Randomized Controlled Trial

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ABSTRACT

Background: To compare peri-implant hard and soft tissue alterations associated with customized and conventional healing abutments.

Methods: This study involved 18 male and female patients with severely compromised non-restorable teeth requiring immediate implant placement. The Patients selected in this study were arbitrarily allocated into two groups: Group I: 9 patients by normal immediate implants with standard healing abutments. Group II: 9 patients underwent immediate implant placement with custom healing abutments. Digital scans were obtained before extraction and again six months following implant placement. The resulting digital datasets were then used to assess peri-implant soft tissue changes across the different time intervals. Additionally, the esthetic outcome of the peri-implant soft tissues was assessed using the Pink Esthetic Score (PES). each parameter of PES was appointed a score varying from 0 to 2 with higher scores reflecting superior esthetic appearance. Statistical consequence was confirmed at $P \leq 0.05$.

Results: A) Soft tissue alteration; Including Vertical tissue alterations (mm), Volumetric tissue alteration (mm³) and Horizontal tissue alterations (mm), Standard healing abutment group presented statistically meaningfully higher alterations than Customized healing abutment group.

B) Pink Esthetic Score (PES); At base line, after three besides six months, Standard healing abutment group exposed statistically meaningfully lower total PES score than Customized healing abutment group.

Conclusion: Customized healing abutments showed superior preservation of peri-implant soft tissue morphology and provided better tissue outcomes throughout healing than conventional healing abutments.

Keywords: Dental implants, soft tissue alteration, Pink Esthetic Score (PES).

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INTRODUCTION

Loss of a tooth may result in functional, biological, and esthetic complications. These changes can include drifting of neighboring teeth, overeruption of opposing teeth, impairment of masticatory efficiency, and potential disturbances in occlusal stability.¹ Immediate implant placement has been proposed as a plan to minimize tissue alterations subsequent tooth withdrawal and help maintain surrounding hard and soft tissue architecture.² The long-term success and stability of dental implants depend greatly on healthy peri-implant soft tissues, which create a protective barrier around the restoration and help preserve surrounding implant structures.

When these tissues become inflamed or infected, progressive destruction of the surrounding bone may occur, compromising implant stability and potentially leading to implant loss.³ After implant placement, alterations in gingival architecture should be kept to a minimum to preserve the pre-extraction soft tissue profile. Modified healing abutments can help preserve the natural gingival contours throughout healing, thereby supporting optimal oral health, functional outcomes, and esthetic appearance.⁴ The use of this abutment facilitates controlled healing and maturation of the peri-implant tissues deprived of compromising the establishment of osseointegration.⁵

In addition, this approach may decrease the requirement for numerous surgical involvements by avoiding a second-stage procedure, thereby decreasing postoperative uneasiness, morbidity accompanying with flap elevation, and the total period of treatment. It also facilitates more efficient soft tissue conditioning while minimizing the risk of micromovements related to immediate loading, making it a minimally invasive treatment option.⁶

METHODS

Study setting and population

Patients enrolled in this clinical study were selected from the Department of Oral Medicine, Periodontology, Oral Diagnosis, and Dental Radiology at the Faculty of Dental Medicine, Al-Azhar University (Assiut Branch). Authorized participants were those scheduled for the extraction of a single non-restorable tooth. The study protocol received approval from the Institutional Ethics Committee at the Faculty of Dental Medicine, Al-Azhar University. Written informed consent was acquired from all participants after requesting a thorough detail of the study processes. Eligible participants included: (1) adults ≥ 18 years; (2) patients requiring extraction of a non-restorable tooth followed by immediate single implant placement in the maxillary or mandibular arch, excluding third molars; (3) individuals with adjacent and contrasting natural dentition; (4) cases with sufficient mesiodistal and interocclusal space for implant insertion and final prosthetic rehabilitation; (5) intact socket walls before extraction; and (6) adequate apical bone support to ensure primary implant stability ≥ 30 Ncm. Patients were excepted if they encountered any of the next conditions: (1) presence of periodontal disease; (2) systemic or local conditions contraindicating implant surgery; (3) heavy smoking habit exceeding 10 cigarettes per day; or (4) active infection at the intended implant site.

Sample size calculation and power analysis

Sample size evaluation was conducted using G*Power v3.1 software (Franz Faul, Universität Kiel, Germany) based on the predefined values of significance level, statistical power, and effect size. Parameters included $\alpha = 0.05$, effect size (f) = 1.8, power = 0.90, and two study groups. The analysis determined a minimum requirement of 16 participants (8 per group).⁷ To compensate for an anticipated 10% dropout rate, the sample size increased to 18 participants.

Study Population

Eighteen Patients classified randomly into the following groups:

Group I: Nine patients underwent immediate implant placement using a conventional healing abutment.

Group II: Nine patients received immediate implant placement with a customized healing abutment.

Preoperative preparation

Before implant placement, all participants underwent phase I periodontal therapy to establish an oral environment conducive to optimal healing. Preoperative cone-beam computed tomography (CBCT) scans were acquired for implant arranging and surgical guide fabrication. Imaging was performed using a Sirona 3D CBCT system operating at 90 kV and 10 mA, with a field of view of 18×20.6 cm, an acquisition time of 23 seconds, and a voxel size of 300 μm . Additionally, intraoral digital scans were obtained for all patients before surgery to generate Standard Tessellation Language (STL) files. These digital records were utilized in

the fabrication of the surgical guide and served as baseline data for evaluating peri-implant soft tissue adjustments. Soft tissue conditions surrounding the implants were assessed by comparing the preoperative scans with those obtained six months after treatment in both customized and conventional healing abutment groups. The STL datasets and Digital Imaging and Communications in Medicine (DICOM) files were introduced into computer-guided planning software (Real Guide) and subsequently superimposed. Implant positioning was planned virtually to achieve optimal implant placement based on the available bone anatomy and the intended screw-retained prosthetic restoration. A tooth-supported fully guided surgical template was then fabricated following

a prosthetically constrained implant placement protocol.

Surgical Protocol

A non-restorable tooth was identified for withdrawal understood by immediate implant placement. Within the preoperative preparation protocol, patients were given 2 g amoxicillin one hour before surgery and instructed to perform a pre-surgical rinse with 0.2% chlorhexidine mouthwash. Local anesthetic administration was achieved using articaine hydrochloride combined with epinephrine (1:100,000). Tooth extraction was performed using a flapless and minimally atraumatic technique. Periotomes and extraction forceps were utilized to assist atraumatic elimination of the tooth while preserving the surrounding alveolar bone. After extraction, the socket was carefully cleaned and irrigated with sterile saline to remove granulation tissue, followed by assessment of socket wall integrity. Subsequently, the digitally fabricated surgical guide was positioned intraorally, and its fit was verified by confirming the accurate adaptation of the reference windows to the adjacent teeth. Osteotomy preparation was then completed due to the manufacturer's guided surgery protocol utilizing a guided surgical kit in conjunction with the digital surgical template. To achieve adequate primary implant stability, the osteotomy was extended approximately 2 mm beyond the root apex. Site preparation was then completed using a sequential drilling protocol under copious saline irrigation until the planned osteotomy dimensions were obtained.

Customized Healing Abutment fabrication

The customized healing abutment was fabricated from resin using a specialized one-piece template as previously described.⁸ Briefly, a Ti-base was positioned within the template, and a nanohybrid flowable composite resin was vacuumated into the surrounding space until the mold cavity was completely filled. The material was then polymerized using a light-curing unit for 40 seconds. Following polymerization, the customized healing abutment was carefully retrieved from the template. Minor modifications were performed when necessary to achieve the desired dimensions, and the composite surface was subsequently completed and polished operating polishing brushes, discs, and polishing paste to obtain a smooth surface finish (Fig 1, 2).

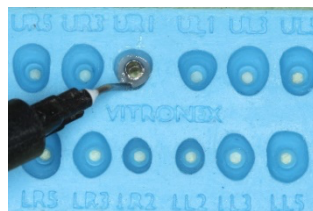


fig 1. One-piece template



Fig 2. Customized healing abutment

Implant placement

Implant placement was performed via the digital surgical guide to guarantee precise positioning according to the preoperative treatment plan. Following implant insertion, the healing abutment was selected based on the patient's

assigned study group. Participants in Group I received a conventional healing abutment (Fig. 3), whereas those in Group II received a customized healing abutment (Fig. 4).

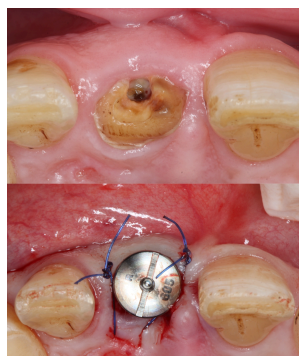


Fig 3. Immediate situation for group I patients

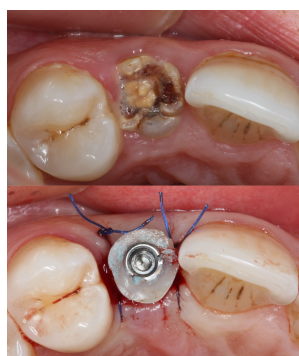


Fig 4. Immediate situation for group II patients

Prosthetic Protocol

Following a healing period of three months, a digital impression was obtained for prosthetic rehabilitation. A screw-retained zirconia crown was subsequently fabricated and connected to a titanium Ti-base. The crown–Ti-base assembly was then secured to the implant using a screw-retained approach.⁹

Study Outcomes

Clinical Evaluation

A) Soft tissue alterations; were assessed by evaluating vertical tissue alterations, including papillary height and mid-facial mucosal height, as well as volumetric and horizontal tissue changes. These measurements were obtained through analysis of intraoral scans acquired preoperatively and six months postoperatively.

The generated STL datasets were collected, superimposed, and investigated utilizing dedicated software (Materialise Magics 23.01, Materialise, Leuven, Belgium). The digital

assessment protocol was established on the methodology previously described by Fernandes et al.¹⁰

B) Pink Esthetic Score (PES);

The esthetic consequence of the peri-implant soft tissues was evaluated utilizing the Pink Esthetic Score (PES). This index assesses five main factors: mesial and distal papillae, facial mucosal contour and height, and a composite evaluation of facial root convexity along with soft tissue color and texture at the implant site. Each parameter was assigned a score ranging from 0 to 2, with higher scores reflecting superior esthetic appearance and better integration of the peri-implant soft tissues with the surrounding dentition.¹

Statistical Analysis

The collected data was coded, organized, and statistically examined. All analyses were accomplished utilizing IBM SPSS Statistics (Statistical Package for the Social Sciences), version 23.

RESULTS

The study involved 18 adult participants (9 men and 9 women), aged 22–45 years. All were candidates for immediate implant placement and were allocated to two groups at random. Throughout the treatment and follow-up periods, no participant reported abnormal pain or significant discomfort. Furthermore, no postoperative problems, such as allergic outcomes or abscess formation, were detected. The results obtained from the current investigation provide a comparative evaluation of the two study groups, as described in table 1.

Soft Tissue Parameters

Soft tissue alterations were calculated at standard and at the six-month follow-up visit. Descriptive and inferential statistical studies, involving means, standard variations, and p-values, were achieved to compare changes within each study group and between the two.

Vertical Linear Tissue Alterations (mm);

Regarding papillary height changes, involving the mesial papilla, distal papilla, and overall papilla height, the standard healing abutment group exhibited significantly greater alterations compared with the customized healing abutment group. These variations were statistically meaningful, with p-values < 0.001 and effect sizes of 0.522, 0.546, and 0.575 for the mesial, distal, and overall papillary measurements, respectively (Fig 5,6).

Similarly, assessment of the mid-facial mucosal height revealed significantly greater tissue alterations in the standard healing abutment group than in the customized healing abutment group (p = 0.006), with a large effect size (1.479) as described in table 2.

Volumetric alteration (mm3);

Analysis of volumetric tissue changes revealed that patients treated with standard healing abutments experienced significantly greater buccal and overall volumetric alterations compared with those receiving customized healing abutments. The stated differentiations were highly knowing statistically (p < 0.001), with effect sizes of 7.168 and 5.016, respectively as described in table 3.

Horizontal tissue alterations(mm);

The analysis of horizontal linear soft tissue alterations demonstrated significantly greater changes in the typical healing abutment group related to the customized healing

abutment group. This finding was observed at the buccal aspect as well as in the overall horizontal measurements, with highly substantial differences concerning with the two groups (p < 0.001) and achieve sizes of 2.718 and 2.092, respectively as described in table 4.

B) Pink Esthetic Score (PES);

Between-group comparison:

At baseline, three months, and six months, the customized healing abutment group confirmed substantially higher total PES scores assessed through the standard healing abutment group. Statistically substantial differences were perceived involving the two groups across all assessment time points, with p-values of 0.001, 0.001, and 0.007 and corresponding effect sizes of 2.193, 2.497, and 1.474, respectively.

Within-group comparison:

Both groups exhibited significant changes in total PES scores over time, with statistically significant time-dependent effects observed in the standard and customized healing abutment groups (p < 0.001), yielding effect sizes of 0.975 and 0.954, correspondingly. Further pairwise comparisons in the standard healing abutment group showed an important reduction in PES scores after three months, followed by an additional important decrease between the third- and sixth-month evaluations as described in table 5.

Table 1: Descriptive statistics for Patients’ demographic data

Base line characteristics	Standard healing abutment (n = 9)	Customized healing abutment (n = 9)
Gender [n, (%)]		
Female	4 (44.4%)	5 (55.6%)
Male	5 (55.6%)	4 (44.4%)
Age [Mean, SD]	32.8 (7.9)	35.2 (6.9)

Table 2: Factual statistics along with repeated-measures ANOVA and Student’s t-test were used to compare vertical changes (mm) between the two groups

Measure	Site	Standard healing abutment (n = 9)		Customized healing abutment (n = 9)		P-value	Effect size †
		Mean	SD	Mean	SD		
Papilla height	Mesial	0.6	0.15	0.34	0.08	<0.001*	0.522
	Distal	0.64	0.16	0.34	0.12	<0.001*	0.546
	Overall	0.62	0.15	0.34	0.1	<0.001*	0.575
Mid-facial mucosa height		0.63	0.26	0.34	0.07	0.006*	1.479

*: Meaningful at P ≤ 0.05, †: Partial Eta Squared for papilla height and Cohen’s (d) for mid-facial mucosal height

Table 3: Factual statistics and Student's t-test outcomes comparing volumetric changes (mm³) between the two groups.

Site	Standard healing abutment (n = 9)		Customized healing abutment (n = 9)		P-value	Effect size (d)
	Mean	SD	Mean	SD		
Buccal	26.58	1.13	14.79	2.03	<0.001*	7.168
Total	36.32	2.14	22.6	3.22	<0.001*	5.016

*: Significant at $P \leq 0.05$ **Table 4:** Factual statistics and Student's t-test outcomes comparing horizontal displacement (mm) between the two groups.

Site	Standard healing abutment (n = 9)		Customized healing abutment (n = 9)		P-value	Effect size (d)
	Mean	SD	Mean	SD		
Buccal	0.43	0.08	0.26	0.04	<0.001*	2.718
Total	0.61	0.13	0.4	0.06	<0.001*	2.092

*: Significant at $P \leq 0.05$ **Table 5:** Factual statistics and Mann–Whitney U test results comparing total PES between both groups, along with Friedman's test assessing within-group changes over time.

Time	Standard healing abutment (n = 9)		Customized healing abutment (n = 9)		P-value	Effect size (d)
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Base line	10 (9, 12) A	10.22 (1.09)	12 (11, 14) A	12.44 (1.01)	0.001*	2.193
3 months	7 (5, 9) B	7.33 (1.22)	11 (9, 13) B	10.78 (1.56)	0.001*	2.497
6 months	5 (3, 7) C	5 (1.5)	7 (6, 7) C	6.78 (0.44)	0.007*	1.474
P-value	<0.001*		<0.001*			
Effect size (w)	0.975		0.954			

*: Meaningful at $P \leq 0.05$

DISCUSSION

Physiological tissue remodeling following tooth extraction has encouraged clinicians and researchers to adopt treatment strategies aimed at preserving the pre-existing tissue architecture. Immediate implant placement (IIP), in which immediate implant placement, performed by placing the implant directly into the socket immediately after tooth extraction, has been proposed as an effective approach for maintaining alveolar ridge dimensions, particularly in the buccolingual direction. Studies have shown that, when compared with late implant placement protocols, IIP is related with superior preservation of buccolingual bone width, with statistically significant differences reported at the time of the second-stage surgical procedure.¹² Peri-implant tissues differ structurally from those surrounding natural teeth, as they are largely composed of soft tissue and provide a less robust biological seal. As a result, prosthetic contours should be carefully designed to support healthy tissue adaptation and minimize the risk of soft tissue complications. Moreover, the design and type of healing

abutment play a crucial role in shaping and preserving peri-implant soft tissue architecture during healing.¹³

In recent years, clinicians have shown growing interest in anatomically shaped healing abutments because of their potential role in supporting peri-implant tissue maturing and preserving tissue contours during healing.¹⁴ This clinical study aimed to evaluate and compare the clinical and radiographic performance of customized and conventional healing abutments in conjunction with immediate implant placement. Eighteen patients with a single tooth indicated for replacement in the maxillary anterior esthetic zone were recruited, where the conservation of soft tissue architecture and esthetic integration constituted major treatment objectives.

In the customized healing abutment group, the emergence profile was intentionally shaped with a gradual concave configuration extending from the implant–abutment junction toward the cemento–enamel junction (CEJ). This contour provides additional space in the interproximal regions, potentially facilitating better support and preservation of the papillary tissues compared with a straight emergence profile. Accordingly, papilla height measurements revealed a smaller

reduction in the customized healing abutment group after six months (-0.34 mm) than in the prefabricated healing abutment group (-0.62 mm). These findings indicate that customized healing abutments may offer a more favorable approach for maintaining peri-implant papillary architecture. Similar observations have been reported in previous studies⁵, which demonstrated enhanced preservation of gingival papillae with customized healing abutments, whereas conventional abutments were associated with greater papillary recession.

The customized healing abutment was designed with a broader emergence angle and increased dimensions, enabling a closer replication of the natural root contour. Such a configuration may enhance strengthen for the immediate soft tissues and sponsor to the preservation of peri-implant tissue morphology. Consistent with this concept, the results of the current study demonstrated less total volumetric change (TVv) in the customized healing abutment group compared with the conventional healing abutment group. Similar findings have been documented in earlier investigations.¹⁰

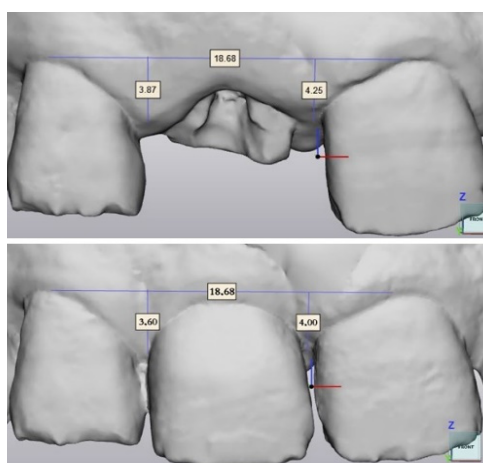


Fig 5. Papilla height changes for group I patients

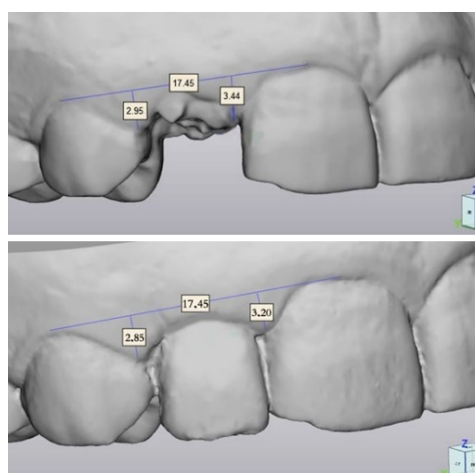


Fig 6. Papilla height changes for group II patients

After six months of follow-up, the reduction in soft tissue volume was recorded as -22.6 mm^3 in the customized group, whereas the conventional group exhibited a greater reduction of -36.32 mm^3 . These findings indicate that customized healing abutments may be more effective in maintaining peri-implant buccal soft tissue volume and minimizing tissue remodeling. Therefore, the usage of customized healing abutments could provide clinical benefits in preserving soft tissue contours and enhancing the long-term constancy of peri-implant tissues.

With regard to abutment morphology, the customized healing abutments were fabricated with larger and anatomically contoured profiles, whereas the conventional prefabricated healing abutments generally exhibited a smaller, circular configuration. Previous studies have suggested that the limited dimensions and simplified

geometry of prefabricated healing abutments may compromise their capacity to adequately provision peri-implant soft tissues and establish a natural emergence profile.¹⁵ The present findings are consistent with this concept, as greater mean total change (MTC) was observed in the prefabricated healing abutment group after six months (-0.61 mm) compared with the customized healing abutment group (-0.40 mm). This favorable outcome may be related to the anatomical design of the customized healing abutment, which closely replicates the contour of the natural tooth root and extends toward the cemento-enamel junction (CEJ). Such a morphology may provide to maintaining the original soft tissue architecture by promoting proper adaptation, maturation, and steadying of the peri-implant tissues during healing.

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The improved conservation of peri-implant soft tissue contours associated with customized healing abutments may have a positive influence on the final esthetic result. In this study, esthetic outcomes were evaluated using the Pink Esthetic Score (PES), a well-established and objective tool for assessing the appearance of peri-implant soft tissues surrounding single implants. Comparison of PES values between the pre-extraction stage and the definitive prosthetic restoration revealed only a slight decrease in the customized healing abutment group. Conversely, a more substantial reduction in PES was observed among patients treated with conventional healing abutments. These observations support previous findings reported in the literature¹¹, suggesting that customized healing abutments are more effective in preserving peri-implant esthetics and maintaining favorable soft tissue architecture throughout the healing period.

In the present investigation, both study groups exhibited a progressive increase in marginal bone loss throughout the observation period. However, the recorded bone loss values at six months remained within the accepted limits for successful

The findings of the current study recommend that the design characteristics of customized healing abutments are interrelated and collectively influence peri-implant tissue behavior. In immediate implant placement, the customized healing abutment is fabricated to closely mimic the anatomy of the extraction socket, with its size and morphology tailored according to the socket dimensions. As a result, customized healing abutments generally exhibit a wider emergence angle than conventional prefabricated healing abutments, which are typically manufactured with dimensions only marginally larger than the implant platform. In addition, the emergence profile of a customized abutment shows a smoothly progressive concave shape extending from the implant–abutment interface toward the CEJ. The combined effect of these design features may contribute to improved soft tissue adaptation and maturation, thereby changing the overall peri-implant tissue response and enhancing tissue preservation around the implant.

CONCLUSIONS

Within the constraints of this study, customized healing abutments yielded better clinical results than standard conventional healing abutments. Patient-specific healing abutments showed better maintenance of peri-implant soft tissue form and higher PES results and reduced marginal bone loss during the observation period. Therefore, Customized healing abutments can be a useful strategy to improve both aesthetic and biological results after immediate implant placement.

RECOMMENDATIONS

- 1- Longer-term prospective studies with extended follow-up are advised to evaluate the sustained clinical and radiographic outcomes of customized healing abutments.
- 2- Further large-scale randomized controlled trials with more diverse patient groups are needed to reinforce existing evidence on the effectiveness of customized healing abutments.

AUTHORS' CONTRIBUTION

Conceptualization: Mostafa Ismail Ahmed, Ibraheem Mahmoud Mwafey, Mahmoud Ali Elsaid, Ashraf Marawan El Azzazy.
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Formal analysis: Ibraheem Mahmoud Mwafey, Mahmoud Ali Elsaid, Ashraf Marawan El Azzazy.

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Writing-Review & Editing: Mostafa Ismail, Ibraheem Mahmoud Mwafey, Mahmoud Ali Elsaid, Ashraf Marawan El Azzazy.

COMPETING INTERESTS

The authors report that there are no conflicts of interest to declare.

ETHICAL APPROVAL

Ethical approval was granted by the Ethics Committee of the Faculty of Dental Medicine, Al-Azhar University (approval No. AUAREC20240006-5).

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INFORMED CONSENT

Information consent was obtained from all participants.

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