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RESEARCH

Oxidized regenerated cellulose powder reduces perioperative bleeding and thigh swelling in total hip arthroplasty: a prospective interventional study

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Abstract

Background Total hip arthroplasty (THA) is an effective treatment for hip osteoarthritis; however, perioperative blood loss and postoperative thigh swelling are significant challenges that can delay recovery and increase patient discomfort. Minimally invasive THA and pharmacological interventions, such as tranexamic acid, have mitigated some complications; however, achieving localized hemostasis, particularly in cancellous bones, remains problematic. We aimed to evaluate the efficacy of oxidized regenerated cellulose (ORC) powder in reducing perioperative blood loss and postoperative thigh swelling following THA.

Methods This prospective interventional study included 152 patients who underwent primary unilateral THA via the direct anterior approach. The patients were divided into ORC ($n=74$) and non-ORC ($n=78$) groups. ORC powder was applied to three critical surgical sites: the acetabulum, femoral medullary canal, and the surrounding soft tissue. The estimated total blood loss (eTBL), postoperative blood loss (ePBL), thigh swelling, and hematologic parameters (hemoglobin, hematocrit, D-dimer, creatine kinase, and C-reactive protein) were assessed. Clinical outcomes were evaluated using the modified Harris Hip Score (mHHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and University of California, Los Angeles (UCLA) activity score at 3 months postoperatively.

Results The ORC group exhibited significantly lower eTBL and ePBL, smaller reductions in hemoglobin levels, and higher hematocrit levels up to postoperative day 7. Postoperative thigh swelling was significantly reduced in the ORC group, particularly on day 1, with a trend toward reduced swelling at all time points. However, there were no significant differences in the clinical scores between the groups at 3 months postoperatively.

Conclusions The ORC powder application during THA effectively reduced perioperative blood loss and postoperative thigh swelling. Powdered ORC has the potential to maximize efficacy in THA because of its ability to be applied to hemispherical acetabular surfaces and deep femoral medullary canals, effectively addressing bleeding from both soft tissue and cancellous bone.

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Trial registration This prospective interventional study was reviewed and approved by the Ethics Committee of Shizuoka Red Cross Hospital (Approval No: 2023-36) and was designed and conducted according to the rules of the Declaration of Helsinki. Written informed consent was obtained from patients or their families.

Keywords Total hip arthroplasty, Bleeding, Swell, Thigh swelling, Oxidized regenerated cellulose

Introduction

Total hip arthroplasty (THA) is a highly successful surgical intervention that alleviates pain and improves joint function in patients with hip osteoarthritis [1]. Among the various challenges associated with THA, the accurate placement of implants has been significantly improved with the use of robotic-assisted surgery [2, 3]. Regarding deep vein thrombosis, the safety of various agents, including enoxaparin and aspirin, has been investigated [4, 5]. In addition, improvements in bearing surfaces have been made to reduce polyethylene wear-induced osteolysis and to mitigate the occurrence of metallosis and pseudotumor associated with metal-on-metal articulations, thereby aiming to enhance long-term outcomes [6, 7]. However, perioperative blood loss remains a significant concern because it can lead to complications such as infection, increased postoperative swelling, and the need for blood transfusion, which, in turn, increases in-hospital mortality [8, 9]. Although sometimes caused by deep vein thrombosis or edema, thigh swelling is also a notable issue frequently associated with perioperative bleeding [10]. Postoperative swelling increases patient discomfort and slows recovery during rehabilitation [11].

Various efforts have been made to minimize these issues related to perioperative bleeding. One approach is to reduce the invasiveness of surgery. Advancements in surgical techniques such as minimally invasive THA have also contributed to reducing perioperative blood loss, involving smaller incisions and reduced soft tissue damage, which are associated with less intraoperative blood loss and faster recovery times [12].

In addition to surgical techniques, pharmacological approaches often contribute to controlling perioperative bleeding. These include intravenous or topical administration of tranexamic acid [13] and the use of oxidized regenerated cellulose (ORC) [14].

However, these attempts to make surgeries less invasive as well as the local application of tranexamic acid and ORC have primarily aimed at controlling bleeding from soft tissues. In THA, effective suppression of bleeding from the cancellous bone of the acetabulum and femur remains a significant challenge, and studies investigating this issue are lacking. Addressing both soft tissue and cancellous bone bleeding may be a promising approach to optimize surgical outcomes.

SURGIGEL (Johnson & Johnson, New Brunswick, NJ), an ORC hemostatic agent, is widely used to control localized bleeding by promoting platelet aggregation and serving as a scaffold for clot formation [15]. It has been shown to be effective in controlling intraoperative bleeding across a variety of surgical procedures [16–18]. In particular, powdered ORC offers the advantage of being easily distributed evenly over bleeding sites, making it suitable not only for soft tissues, but also for various tissue shapes, including osteotomy sites [17]. However, limited data exist regarding the efficacy thereof in orthopaedic procedures, particularly THA. We aimed to elucidate the effect of powdered ORC on perioperative bleeding, thigh swelling, and postoperative outcomes of THA.

Materials and methods

Patients

A consecutive series of THAs performed at our institution between August 2023 and August 2024 were included in this study. We included patients undergoing primary unilateral THA with preoperative diagnosis of osteoarthritis. The exclusion criteria were as follows: (1) presence of diseases other than osteoarthritis, including subchondral insufficiency fractures, femoral neck fractures, rheumatoid arthritis, and femoral head necrosis; (2) secondary osteoarthritis due to conditions such as Perthes disease or septic arthritis; (3) dislocated hips classified as Crowe type 3 or 4; (4) patients with coagulation disorders; (5) use of a cemented cup or stem; and (6) history of surgery on the affected hip. From August 2023 to February 2024, THAs were performed without ORC (non-ORC group), whereas from March to August 2024, ORC was used during THA (ORC group). Consequently, 152 THA cases (78 in the non-ORC group and 74 in the ORC group) were included. The sample size was determined based on a power analysis using preliminary data. As demographic data, we included age, sex, height, weight, and BMI. In addition, the Crowe classification was used as a preoperative indicator of high hip dislocation, and the Elixhauser Comorbidity Index was used to assess comorbidities [19, 20].

Surgery and ORC powder

A 1,000 mg dose of tranexamic acid was administered intravenously before the incision in all cases. During surgery, patients were placed in the supine position, and the operated leg was secured in a boot attached to a specialized traction table (Medacta, Switzerland) [21]. An un-scrubbed assistant controlled traction, flexion, rotation, adduction, and abduction as needed throughout the procedure. All THAs were performed using the direct anterior approach with this traction table. This technique involves a 7–8 cm incision made at the anterior aspect of the hip, preserving the intermuscular and neurovascular structures. All surgeries were performed by a single hip specialist (T.N.), who has performed more than 1,000 total hip arthroplasties using the direct anterior approach. MPACT cups and AMIS-P stems (Medacta, Switzerland) were used in all cases.

In the ORC group, SURGIGEL powder was used during THA at the following three points: (1) acetabulum after cup reaming, (2) femoral medullary canal after stem rasping, and (3) surrounding the soft tissue after implant placement. Before applying the powder, each area was irrigated with saline solution, and excess moisture was removed with gauze. The ORC powder was then applied, followed by 30 s of gauze compression. If adequate hemostasis was achieved, the excess powder was gently irrigated with saline solution and removed. If bleeding persisted, compression was extended up to a maximum of one minute. No hemostatic devices or agents other than tranexamic acid and SURGICEL powder were used. No drainage catheter was used in any cases.

Postoperative rehabilitation and medication

Postoperative rehabilitation commenced on the day after surgery, with full weight-bearing ambulation permitted as soon as possible. For postoperative analgesia, a non-steroidal anti-inflammatory drug (NSAID; Celecoxib 400 mg/day) was administered for 7 days, after which the dosage was gradually reduced according to the level of pain. In patients with impaired renal function or a history of NSAID allergies, 1,500 mg/day of acetaminophen was used instead of NSAIDs. Rivaroxaban (30 mg) was administered on postoperative day 2 for 7 days to prevent thrombosis. In patients with impaired renal function or body weight less than 40 kg, 15 mg rivaroxaban was used instead. Cooling was applied as necessary to manage swelling. During hospitalization, patients underwent training in activities of daily living, including stair climbing, and were discharged approximately 7–10 days postoperatively.

Table 1 Math formula

• Nadler formula
The estimated circulating blood volume (L) = k1*height (m)^3 + k2*weight (kg) + k3
-For men: k1 = 0.3669, k2 = 0.03219, and k3 = 0.6041
-For women: k1 = 0.3561, k2 = 0.03308, and k3 = 0.1833
• Gross formula
eTBL (ml) = The estimated circulating blood volume (ml) * (preHct (%) - postHct (%)) / aveHct (%)
- preHct (%): the Hct values measured preoperatively
- postHct (%): the lowest Hct values measured on postoperative days 1, 3, and 7
- aveHct (%) = (preHct (%) + postHct (%)) / 2
ePBL (ml) = eTBL (mL) - intraoperative blood loss (mL)

eTBL, estimated total blood loss; Hct, hematocrit; ePBL, estimated postoperative blood loss.

Primary and secondary outcomes

The primary outcomes were intraoperative blood loss, estimated total blood loss (eTBL), estimated postoperative blood loss (ePBL), and postoperative Hemoglobin (Hb) reduction. The intraoperative blood loss was calculated by suction bottle volume minus irrigation fluid and gauze weight. The eTBL and ePBL were calculated based on height, weight, and hematocrit (Hct) values, following methods described in previous reports (Table 1) [22, 23].

As secondary outcomes, blood parameters related to blood loss, hematoma formation and surgical invasiveness, including Hb, Hct, D-dimer, creatine kinase (CK), and C-reactive protein (CRP), were measured preoperatively and on postoperative days 1 and 7. In addition, thigh swelling was quantitatively assessed using thigh circumference, measured at the midpoint between the anterior superior iliac spine and the upper edge of the patella, preoperatively and on postoperative days 1, 3, 7, and 10. The measurement site for thigh circumference was marked with a permanent marker to ensure consistency in measurement location. Additionally, to eliminate interobserver measurement errors, all measurements were performed by a single orthopedic specialist (S.F.). Moreover, clinical scores were assessed 3 months postoperatively using the modified Harris Hip Score (mHHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and University of California, Los Angeles Activity Score (UCLA).

Data analyses and ethical approval

Mann-Whitney U test was used to compare the means between two groups. Differences in categorical variables were evaluated using the *Chi*-square test. Analyses were performed using Bell Curve for Excel ver.4.04 (Social Survey Research Information Co., Ltd. Tokyo, Japan). All statistical analyses were performed at a significance level of $P < 0.05$. The study design was approved by the appropriate ethics review board of our institution.

Results

There were no significant differences in the demographic data between the non-ORC and ORC groups (Table 2). The operation time was significantly longer in the ORC group than in the non-ORC group (Table 3).

Regarding the primary outcomes, intraoperative blood loss did not differ between the two groups, whereas eTBL and ePBL were significantly lower in the ORC group. Furthermore, the decrease in Hb on postoperative day 7 was significantly smaller in the ORC group (Table 3). No

Table 2 Patient demographics

	non-ORC	ORC	*p* value
number of patients	78	74	-
age (years)	69.1 ± 10.2	70.6 ± 8.4	0.561*
number of females	72 (92.3%)	69 (93.2%)	0.824**
height (cm)	154.0 ± 8.6	153.2 ± 6.0	0.914*
weight (kg)	58.1 ± 13.1	55.2 ± 10.6	0.279*
BMI (kg/m^2)	24.3 ± 4.0	23.5 ± 4.5	0.166*
Crowe type			0.846**
1	58 (74.4%)	54 (73.0%)	
2	20 (25.6%)	20 (27.0%)	
Elixhauser index			0.976**
0	43	42	
1–2	33	30	
3 or more	2	2	
Preop clinical score			
mHHS	57.7 ± 18.0	56.3 ± 17.0	0.490*
WOMAC	40.6 ± 20.1	41.7 ± 16.9	0.601*
UCLA	3.74 ± 1.03	3.46 ± 1.22	0.843*
Postop analgesia			
celecoxib	65 (83.3%)	59 (79.8%)	0.567**
acetaminophen	13 (16.7%)	15 (20.2%)	0.567**
Postop rivaroxaban			
30 mg	69 (88.4%)	66 (89.2%)	0.887**
15 mg	9 (11.6%)	8 (10.8%)	0.887**

*Mann-Whitney U test, ***Chi*-square test

BMI, Body mass index; Preop, preoperative; Postop, postoperative

Table 3 Primary outcomes

	non-ORC	ORC	*p* value
Operation time (min)	75.6 ± 25.1	84.4 ± 23.7	0.001*
Intraoperative blood loss (ml)	235 ± 162	230 ± 103	0.277
Hb decrease at day1 (g/dL)	1.82 ± 1.14	1.68 ± 0.92	0.354
Hb decrease at day7 (g/dL)	2.20 ± 1.23	1.77 ± 0.95	0.048*
eTBL (mL)	626 ± 145	557 ± 243	0.042*
ePBL (mL)	398 ± 169	327 ± 223	0.035*

Hb, Hemoglobin; eTBL, estimated total blood loss; ePBL, estimated postoperative blood loss

*Statistically significant ($p < 0.05$)

blood transfusions were administered perioperatively in any of the patients.

As for the secondary outcomes. Hct levels were significantly higher in the ORC group on the day after surgery and on postoperative day 7 (Table 4). Moreover, the D-dimer levels on postoperative day 7 were significantly lower in the ORC group. There were no significant differences in CK and CRP values after surgery. Temporal changes in the rate of thigh circumference enlargement are shown in Fig. 1. In both groups, thigh swelling peaked on postoperative day 3. In the non-ORC group, there was a > 4% increase in thigh circumference compared with preoperative measurements. On day 1 (D1), the ORC group showed significantly less swelling, and there was a trend toward less swelling in the ORC group at all time

Table 4 Perioperative blood data

	non-ORC	ORC	*p* value
Hb (g/dL)			
Preop	13.5 ± 1.5	13.1 ± 1.2	0.079
POD 1	11.6 ± 1.3	11.5 ± 0.9	0.392
POD 7	11.3 ± 1.4	11.4 ± 1.0	0.493
Hct (%)			
Preop	39.0 ± 1.6	39.1 ± 4.1	0.641
POD 1	32.9 ± 1.5	34.0 ± 2.8	0.016*
POD 7	32.8 ± 1.6	33.8 ± 3.1	0.001*
CK (IU/L)			
Preop	98.7 ± 50.2	101.3 ± 53.2	0.730
POD 1	313 ± 213	290 ± 146	0.845
POD 7	99.5 ± 61.8	99.6 ± 90.5	0.509
CRP (mg/dL)			
Preop	0.30 ± 0.81	0.33 ± 0.54	0.866
POD 1	3.63 ± 2.67	3.89 ± 2.00	0.307
POD 7	1.68 ± 1.42	2.13 ± 1.80	0.067
D-dimer (μg/mL)			
Preop	1.19 ± 1.08	1.48 ± 1.77	0.770
POD 1	11.6 ± 10.2	10.4 ± 7.7	0.819
POD 7	7.32 ± 3.80	5.90 ± 2.22	0.013*

Hb, Hemoglobin; Hct, Hematocrit; CK, Creatine kinase; CRP, C-reactive protein; Preop, Preoperative; POD, Postoperative day

*Statistically significant ($p < 0.05$)

points ($P = 0.002$ for D1, 0.268 for D3, 0.057 for D7, and 0.099 for D10). After 3 months, there were no differences between the groups in clinical scores, including mHHS, WOMAC, and UCLA activity scores (Table 5). No complications such as infection, hematoma, or granuloma were observed.

Discussion

Minimizing perioperative bleeding in THA is essential for enhancing patient outcomes and reducing the risk of complications [24]. Therefore, research has increasingly focused on strategies to effectively reduce both perioperative bleeding and surgical invasion.

In this study, eTBL and ePBL were significantly lower in the ORC group, demonstrating that the ORC group effectively suppressed bleeding in THA. Furthermore, perioperative blood test results, including Hb decrease, Hct, and D-dimer levels, supported the validity of this outcome. The operative time was significantly longer in the ORC group in this study. This was influenced by the additional time required for hemostatic compression and irrigation at each step of ORC powder application. Nevertheless, intraoperative blood loss did not increase in the ORC group compared to the non-ORC group.

The mechanism of hemostasis achieved by the intraoperative local application of ORC is considered to involve two main factors. First, upon contact with blood, it changes into a dark brown or black gelatinous material as a result of red blood cell degradation and the

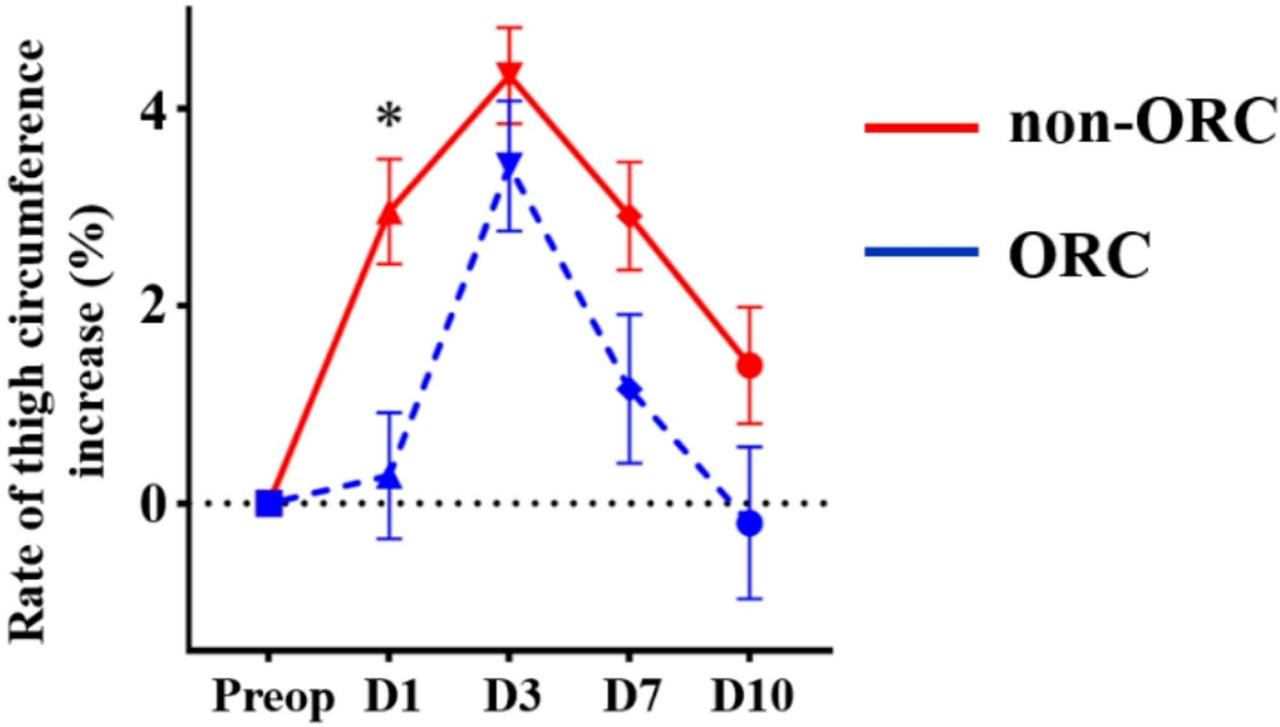

Fig. 1 Temporal changes in the rate of thigh circumference increase in the non-ORC group and ORC group
Values are presented as mean ± standard deviation
Preop, Preoperative; D, day. *Statistically significant (p < 0.05)

Table 5 Clinical scores at 3 postoperative months

	non-ORC	ORC	*p* value
mHHS	93.8 ± 4.7	93.8 ± 5.7	0.972
WOMAC	12.2 ± 9.1	12.8 ± 11.4	0.719
UCLA activity score	3.88 ± 0.46	3.89 ± 0.51	0.921

mHHS, modified Harris Hip Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; UCLA, The University of California, Los Angeles

formation of acid hematin, which facilitates clot formation. Additionally, the use of ORC creates a local low-pH environment that facilitates vasoconstriction and provides a scaffold for platelet adhesion and aggregation, thereby reducing blood loss [25]. Therefore, it is crucial to ensure precise application of ORC to areas prone to bleeding during surgery. The primary bleeding points in THA are as follows: (1) bleeding from small vessels in the soft tissue, (2) cancellous bone exposed after acetabular reaming, and (3) cancellous bone exposed after femoral rasping. In previous reports on the use of ORC in THA, its application was limited to sprinkling before wound closure, without spreading it on the surface of the cancellous bone [14, 26]. However, ORC has been reported to be effective in controlling bleeding from osteotomy sites as well. For instance, the utility of ORC fibrillar material has been reported in TKA [25], and the effectiveness of ORC powder has been demonstrated In Le Fort I osteotomy [17]. Powdered ORC can access the hemispherical cancellous bone after acetabular reaming and deep intramedullary spaces after femoral rasping, making it particularly effective in maximizing its potential during THA.

The ORC not only reduced perioperative blood loss but also alleviated thigh swelling. This finding also supports the notion that perioperative blood loss is a significant contributor to postoperative thigh swelling. Notably, in the ORC group, hematologic analysis revealed a significantly higher Hct value and a significantly smaller decrease in Hb levels on day 7, suggesting that ORC suppressed persistent postoperative bleeding within the surgical site. Although CK and CRP levels did not differ significantly between the groups, the significantly lower D-dimer levels observed in the ORC group on postoperative day 7 suggest that the use of ORC resulted in reduced postoperative hematoma formation. The thigh swelling tended to be suppressed at all time points. These results may be attributed to the application of the ORC to both soft tissues and cancellous bone, effectively controlling bleeding from both sources.

There were no differences in the clinical outcomes at 3 months postoperatively in this study. However, since the hemostatic effect and reduction in thigh swelling typically occur at an earlier postoperative stage, it is possible that the patient's condition, including pain, may have improved at an earlier time point. Further studies are needed to clarify these possibilities.

As an adverse effect of ORC, excessive use has been reported to lead to the formation of granulomas and infections [27, 28]. Thus, it is essential to properly rinse off excess ORC powder to prevent such complications [29]. In this study, no adverse events caused by ORC powder were observed.

The limitations of this study include the small sample size and the fact that it was not a randomized controlled trial. Furthermore, although blood data were evaluated on postoperative days 1 and 7 in this study, these time points may not have been optimal for assessing the effects of ORC. Although a standardized rehabilitation protocol was used at our hospital, it is possible that the rehabilitation regimen may have influenced postoperative thigh swelling and mobilization. In addition, ORC is relatively expensive, and whether the benefits obtained justify the associated costs remains a matter of debate.

Nevertheless, the strength of this study lies in its novel approach of demonstrating the immediate and ongoing hemostatic effects of ORC powder when applied to both cancellous bone and soft tissue, using a defined protocol for THA. Additionally, a unique aspect of this study is the quantitative evaluation of thigh swelling over time, which highlights the swelling reduction effect of the ORC. Further large-scale studies are needed to determine whether this perioperative hemostatic effect can reduce complications such as periprosthetic joint infections.

In conclusion, ORC powder is effective in reducing perioperative blood loss and mitigating postoperative thigh swelling in patients undergoing THA.

Abbreviations

THA	Total Hip Arthroplasty
ORC	Oxidized Regenerated Cellulose
eTBL	Estimated Total Blood Loss
ePBL	Estimated Postoperative Blood Loss
Hb	Hemoglobin
Hct	Hematocrit
CK	Creatine Kinase
CRP	C-Reactive Protein
D-dimer	D-dimer (Fibrin degradation product)
mHHS	Modified Harris Hip Score
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
UCLA	University of California, Los Angeles Activity Score
NSAID	Non-Steroidal Anti-Inflammatory Drug
BMI	Body Mass Index
POD	Postoperative Day

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Author contributions
H.I., S.F. and T.N. contributed to the study concept and design. H.I. and S.F. contributed to the acquisition of data. H.I., Y.M. and T.N. contributed to the analysis and interpretation of the data. H.I. drafted the manuscript. T.N. made significant contributions to the revision of the manuscript with important advice. All authors reviewed the manuscript and agreed to the submission of the final version.

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Data availability
Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained from the institutional review board of Shizuoka Red Cross Hospital (Approval No: 2023-36). Written informed consent was obtained from all participants prior to enrollment in the study.

Consent for publication
All participants provided written informed consent, which included consent for publication of anonymized data. No identifiable personal information, including images or videos, is included in this study.

Competing interests
The authors declare no competing interests.

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