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Short Communication

Feasibility and Clinical Outcomes of Individualized Bone Cement Prosthetic Replacement for Advanced Lunate Bone Necrosis

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Abstract

Purpose : To investigate the feasibility and clinical outcomes of individualized bone cement prosthetic replacement in treating advanced lunate bone necrosis.

Methods : Nineteen patients (age > 45) diagnosed with advanced lunate bone necrosis underwent the removal of the necrotic lunate bone and replaced with an individualized bone cement prosthetic between January 2010 and December 2020. The visual analogue scale (VAS), range of motion (ROM), grip strength, MMWS (mayo modified wrist score), DASH (disability of arm, shoulder, and hand), carpal height ratio (CHR), ulnar carpal distance ratio (UDR), scaphoid translation ratio (STR), radio scaphoid angle (RSA), and the osteoarthritic were also measured to evaluate the results after at least 1year of follow-up.

Results : Nineteen patients were followed up for an average of 63.21 months. At the last visit, the patient's VAS score was (1.47 ± 0.47) points, and ROM was (130.53 ± 21.34)°, showing improvement compared to preoperative($P < 0.05$), although still slightly limited compared to the unaffected side ($P < 0.05$); the grasp force, MMWS, and DASH scores significantly improved after surgery ($P < 0.05$), with no further deterioration in wrist joint function compared to postoperative results ($P > 0.05$). At the last visit, the CHR improved to (0.50 ± 0.06)° and the RSA to (58.8 ± 6.91)° compared to preoperative values ($P < 0.05$); however, the CHR was still slightly lower than the healthy side ($P < 0.05$). No significant changes in UDR and STR were observed after surgery ($P > 0.05$). Additionally, 1 case of bone cement was slightly displaced, and 3 cases showed signs of wrist joint osteoarthritis during the follow-up period.

Conclusion : Individualized bone cement prosthetic treatment was effective for advanced lunate bone necrosis in middle-aged and elderly individuals. It helped restore the original anatomical structure, prevent further collapse, and enhance hand function.

Keywords: Lunate bone; Bone necrosis; Bone cement; Prosthesis; Clinical effect

INTRODUCTION

Lunate bone necrosis, namely Kienböck's disease (KD), once it occurs, and if no timely treatment is available, ischemic necrosis of the lunate bone will induce lunate bone fracture, atrophy and flattening, proximal row carpal collapse, and secondary intercarpal arthritis [1-3]. In cases of lunate osteonecrosis classified as Lichtman stage III A [4], revascularization of the necrotic lunate bone can be achieved through procedures like radial shortening, ulnar lengthening, distal central decompression of the radius, vascularized bone flap transplantation, and free bone flap transplantation [3,5-8]. However, for patients in Lichtman stages III B to IV, irreversible necrosis of the lunate bone occurs along with scaphoid rotation and osteoarthritis [9-11]. Prosthetic replacement therapy has emerged as a crucial treatment method for end-stage lunate osteonecrosis, aiming to prevent severe functional disability and work loss resulting from carpal collapse and osteoarthritis [10,12].

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Bone cement, specifically polymethylmethacrylate (PMMA), is a frequently utilized synthetic biocompatible material known for its mechanical solid stability and long-lasting durability within the body [13-17]. This material can be easily shaped to replicate the contours of the patient's lunate bone, thus preserving the natural articulation with the surrounding carpal bones [13,16]. Based on the anatomic and biomechanical characteristics of the wrist joint, and when combining the physical and chemical properties of bone cement, we independently designed an individualized bone cement prosthesis for implantation to replace necrotic lunate bone. We have achieved promising clinical outcomes, offering a straightforward and viable therapeutic approach for advanced lunate bone necrosis.

This study aims to investigate the clinical efficacy of individualized bone cement prosthetic replacement in managing advanced lunate bone necrosis. We have retrospectively reviewed and analyzed the clinical data of 19 patients with advanced lunate bone necrosis, with the detailed analysis presented herein.

MATERIALS AND METHODS

Study objectives

The Ethics Committee of Hospital approved this study. Before the operation, all patients underwent conventional X-ray, computed tomography (CT), and magnetic resonance imaging (MRI) scans. In addition, they were assessed through clinical examinations, radiological evaluations, and monitoring for any potential complications.

Inclusion criteria: Patients were included in the study if they met the following requirements: (1)They should follow Lichtman stage III b to IV lunate osteonecrosis [18]; (2) no response to conservative treatment for ≥ 6 months (including drug treatment, local blockage, and physical rehabilitation); (3) Aged over 45 years old; and (4) provision of informed consent (where patients were unable to do so, their family members provided informed consent).

Exclusion criteria: Patients were excluded from the study for the following reasons: (1) they were diagnosed with severe medical disorders; (2) they had a wrist joint infection; or (3) the patients and their family members failed to provide informed consent; (4) the follow-up time was less than 12 month.

Surgical procedures

The operation for all included patients was performed by a chief physician with over 15 years of clinical experience and the specific process was listed in the following five steps.

Step 1: Anesthesia and Position

General anesthesia or brachial plexus block was selected according to the patient's physical condition, and the patients were maintained at supine position. Antibiotics were intravenously infused to prevent infection 30 minutes prior to the operation.

Step 2: Approach and Exposure

Following conventional disinfection and draping, a 3-5 cm longitudinal incision was made on the dorsal part of the wrist joint with the lunate bone at the center; the skin, subcutaneous tissues, and dorsal extensor retinaculum of the wrist were dissected layer by layer to expose the articular capsule of the lunate bone. The articular capsule was cut open longitudinally; the ligaments surrounding the lunate bone were cut off to expose the necrotic lunate bone;

Step 3: Pathological Changes and Resection

The pathological changes observed included yellowish discoloration of the lunate, decreased bone mass and fragility, carpal collapse, cystic degeneration, and hyperplasia of the local synovial membrane. Some patients also exhibited lunate volar dislocation and adhesion with surrounding carpal bones. Granulation tissue filled the local lunate gap. Following the removal of necrotic and inflammatory tissues surrounding the lunate bone, saline irrigation was used to clear any remaining fragments (Figure 1A).

Step 4: Individualized bone cement prosthetic replacement

The antibiotic-loaded polymethylmethacrylate (PMMA) bone cement (PALACOS® V; Heraeus Medical GmbH, Hanau, Germany), containing either gentamicin or gentamicin plus vancomycin, was injected into the anatomical position of the lunate bone for implantation and reconstruction of bone defects (Figure 1A); and then make the wrist joint repeatedly subject to ulnar and radial deviation, dorsiflexion and flexion to reached their normal ranges during the bone cement's curing stage, and the bone cement was subsequently shaped. A C-arm perspective was used to confirm whether the bone cement prosthesis matched the original bone (Figure 1 B) and that the prosthesis had not detached during dorsal extension, palmar flexion, ulnar deviation (Figure 1 C), or radial deviation of the wrist joint.

Step 5: Reconstruction

The dorsal articular capsule and the dorsal extensor retinaculum of the wrist joint were sutured layer by layer.

Postoperative Management

Following the operation, a continuous ice compress was applied for 3-5 days; the drainage catheter was removed after 24-48 hours, and the suture was removed at 14 days. The wrist joint was fixed in a functional position with a plaster slab for 2 weeks, and functional exercises promoting finger extension and flexion were encouraged [12,18].

Postoperative examination

Clinical examination: This evaluation was performed at the last visit after the operation. The evaluation indicators for wrist joint function included range of motion (ROM) of the wrist; hand grasp force, which was measured three times for each side using a Jamar meter (the results were averaged); and the degree of wrist joint pain at resting state and after loading. The pain of the wrist joint were evaluated using VAS scores (excellent: 0-2 scores, good: 3-5 scores, average: 6-8 scores, and bad: >8 scores). The Disability of Arm, Shoulder, and Hand (DASH) questionnaire was utilized for evaluating wrist function [19]. This 30-item scale assessed the patient's symptoms, function, and ability to participate in sports. A total score greater than 35 indicates poor wrist function, 15–35 is considered satisfactory, 6–15 is good, and 0–5 is excellent. The Mayo Modified Wrist Score (MMWS) was utilized to assess wrist disability level [12]. This system comprises four key components: pain, functional status (ability to work), range of motion, and grip strength. The scoring scale ranged from 0 to 100 points, with 100 representing the optimal outcome. Scores below 60 were classified as poor, 60-80 as satisfactory, 80-90 as good, and 90-100 as excellent.

Radiological examination: Preoperative and postoperative wrist radiographs were taken in posteroanterior and lateral views with the forearm in a neutral rotation [19]. The radiographs were assessed for carpal height ratio (CHR), ulnar carpal distance ratio (UDR), radio scaphoid angle (RSA), and scaphoid translation ratio (STR). The STR was utilized to quantify the ulnar shift of the scaphoid. Specifically, on a posteroanterior radiograph, the distance between the radial axis passing through the ulnar margin of the scaphoid and the midpoint of the radial sigmoid notch was measured. This distance was then divided by the length of the middle finger metacarpal to calculate the STR (Figure 2). To minimize measurement error, two observers independently took measurements twice, one week apart. The reliability of the measurements was evaluated through intraobserver and interobserver variability.

Assessment of complications: Early complications following surgery included wound infection and poor incision healing, while late complications included bone cement absorption, dislocation, collapse. To evaluate osteoarthritic changes using radiographs, we utilized the grading system developed by Daecke et al [20]. This system was modified into three stages: stage I (mild) indicated focal narrowing of the radioscaphoid joint, stage II (moderate) involved moderate or complete narrowing of the joint, and stage III (severe) denoted loss of joint space accompanied by subchondral sclerosis, cyst, or osteophyte.

Statistical analysis

If the data were normally distributed according to the Shapiro-Wilk test, the data were presented as means with standard deviations (SD); whereas non-parametric data were shown as the median and interquartile range (IQR). Statistical comparisons were performed using paired t-test. $P<0.05$ suggested that a difference was considered as statistically significant.

RESULTS

The general information

There were a total of 19 patients of aseptic lunate bone necrosis (patients' mean age: 51.94 range: 45-67 years), including eight males and 11 females; these patients were followed up for 63.21(range: 34-156) months. There were nine patients of right wrist lunate bone necrosis, ten patients of left wrist lunate bone necrosis, 16 patients of Lichtman stage

Figure 1: A. Complete removal of the lunate bone and the non-curing bone cement was placed into the original anatomical position of lunate bone; B. Determining a good match for the bone cement prosthesis under C-arm radiography; C. Repeated ulnar deviation, radial deviation, dorsal extension, and flexion of the wrist joint during the bone cement's curing period.

Table 1: General information of the patients

Case	Age (Yr)	Gender	Side	Symptom duration (Mo)	Lichtman staging	History	Operation time (Min)	Follow-up (Mo)
1	67	M	L	12	IV	Trauma	43	65
2	45	M	R	7	III b	No	46	156
3	50	M	R	8	III c	Trauma	58	132
4	47	M	L	9	III b	Trauma	51	96
5	51	M	R	24	III c	No	45	86
6	45	F	L	5	III b	Trauma	32	75
7	62	M	R	7	III c	No	48	56
8	59	F	L	8	III b	RA	49	47
9	45	F	R	21	IV	Trauma	51	49
10	47	F	L	6	III b	No	58	47
11	47	F	L	4	IV	No	61	52
12	67	F	L	2	III c	Trauma	57	46
13	55	F	L	8	III c	Trauma	51	38
14	50	F	R	12	III b	No	52	34
15	52	M	R	6	III b	Trauma	48	36
16	50	M	L	12	III c	Trauma	45	45
17	46	M	R	12	III c	RA	44	43
18	56	M	R	14	III b	Trauma	42	46
19	47	M	L	6	III c	No	46	52

Yr, year; M male; F, female; Min, minute; Mo, month; RA, rheumatoid arthropathy; No, no special history.

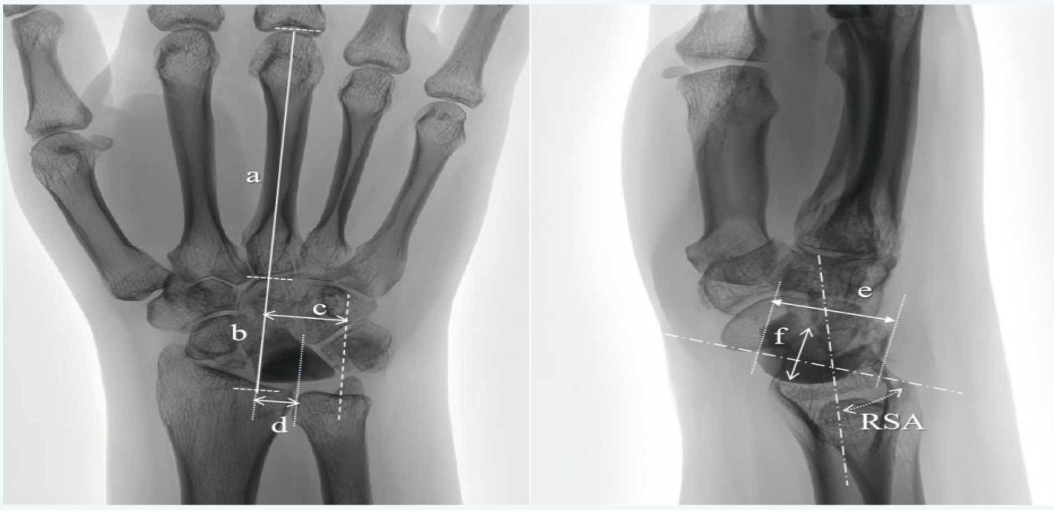

Figure 2: Radiologic indices measured. Carpal height ratio, b/a; ulnar carpal distance ratio, c/a; scaphoid translation ratio, d/a; Stahl index, f/e; RSA, radio scaphoid angle.

III b, and three of Lichtman stage IV. The course of the disease prior to the operation was 9.63 (range: 2-24) months. Ten patients with a history of trauma, two patients with a history of rheumatoid arthropathy, and seven patients with no particular history (Table 1).

The clinical outcomes

The VAS scores of the wrist joint on the affected side showed significant improvement ($P < 0.05$). Out of the total cases, 16 achieved excellent results, 2 showed good results, and 1 had average results. Notably, the VAS value of the affected side was slightly higher than that of the unaffected side ($P < 0.05$); however, this discrepancy did not hinder the patients' daily activities. At the last visit, the patient's wrist joint flexion and extension angle range had significantly improved compared to preoperative measurements ($P < 0.05$) and also compared to postoperative measurements ($P < 0.05$). However, the range of motion was still limited compared to the healthy side, representing 89.47 ± 3.5% of the healthy side. The grasp force, MMWS, and DASH scores showed significant improvement after surgery ($P < 0.05$) and no statistical difference compared to the postoperative results ($P > 0.05$), indicating no further deterioration in wrist joint function, and there was no statistical difference compared to the unaffected side ($P > 0.05$). All working-age patients have successfully returned to their regular work duties without the need to change jobs or leave the company (Table 2).

The radiologic outcomes

The average CHR on the affected side was 0.45 before the operation and increased to 0.50 at the final follow-up visit ($p < 0.05$). Additionally, there was a statistically significant difference between the CHR of the affected and healthy sides ($p < 0.05$). There was no statistically significant difference in postoperative UDR and STR compared to preoperative values ($p > 0.05$), and there was also no statistical difference compared to the healthy side ($p > 0.05$). Due to the impact of bone cement implantation on the measurement of the lunate transverse diameter, the postoperative Stahl index was not assessed. However, the preoperative Stahl index of the affected side was 0.23, notably lower than the unaffected side group with a value of 0.57 ($p < 0.05$). The average radio scaphoid angle on the

Table 2: Comparison of the clinical outcomes

	Affected side				Healthy side	
	Preoperative	Postoperative (1-2years)	At the last visit	p-value (a)	Control	p-value (b)
Pain on VAS	5.56 ± 1.34	1.27 ± 0.57*	1.47 ± 0.47*	<0.001	0.95 ± 0.32	0.001
ROM(°)	90.43 ± 23.45	120.78 ± 20.36*	130.53 ± 21.34*#	<0.001	145.88 ± 21.45	0.037
Grasp force (kg)	22.23 ± 6.46	34.93 ± 7.95*	36.56 ± 8.07*	0.014	40.30 ± 9.54	0.203
MMWS	63.56 ± 8.53	85.42 ± 9.45*	86.56 ± 10.05*	<0.001	90.84 ± 9.64	0.118
DASH score	61.23 ± 9.57	15.73 ± 9.02*	12.34 ± 6.45*	<0.001	8.88 ± 5.56	0.085

* The affected side compared with preoperative, p<0.05; # compared with postoperative, p<0.05; a: Comparison of the clinical outcomes before and after surgery; b:Comparison of the clinical outcomes between the affected side and the healthy side.
VAS, visual analogue scale; ROM, range of motion; MMWS, Mayo modified wrist score; DASH, Disability of Arm, Shoulder, and Hand.

Table 3: Comparison of the radiologic outcomes

	Affected side				Healthy side	
	Preoperative	Postoperative	At the last visit	p-value	Control	p-value
CHR	0.45 ± 0.09	0.51 ± 0.08	0.50 ± 0.06	0.023	0.54 ± 0.03	0.014
UDR	0.31 ± 0.04	0.32 ± 0.04	0.32 ± 0.05	0.504	0.33 ± 0.05	0.542
STR	0.15 ± 0.01	0.16 ± 0.01	0.16 ± 0.05	0.398	0.17 ± 0.04	0.501
Stahl index	0.23 ± 0.03	-	-	-	0.57 ± 0.05	0.001
RSA(°)	70.22 ± 6.33	63.22 ± 6.33*	64.43 ± 6.12	0.006	65.34 ± 7.24	0.678

* Compared with preoperative, p<0.05; CHR, Carpal height ratio, b/a; UDR, ulnar carpal distance ratio, c/a; STR, scaphoid translation ratio, d/a; Stahl index, f/e; RSA, radioscaphoid angle

affected side was 70.22° before the operation and 64.43° at the last visit ($p < 0.05$). There was no statistical difference between the postoperative and last visit angles, suggesting no ongoing instability. However, the difference between the affected and healthy sides was not statistically significant ($p > 0.05$) (Table 3).

The occurrence of complications

Throughout the follow-up period, no patients developed infections. One patient experienced poor wound healing, necessitating frequent dressing changes, but showed improvement after receiving oral antibiotics. Another patient encountered mild bone cement collapse, attributed to the use of a prosthetic bone cement that was too small. Despite this, the patient did not experience any limitations in wrist joint function and continues to be monitored. Notably, no instances of prosthetic dislocation were observed, and typical cases were shown in Figure 3. Changes indicative of radiocarpal joint osteoarthritis were identified in three patients, two in stage I and one in stage II. Two patients showed progression of osteoarthritis, while one patient exhibited new-onset osteoarthritis characterized by the formation of periprosthetic osteophytes and can effectively be managed with oral nonsteroidal analgesics (Table 4).

DISCUSSION

Individualized Bone Cement Prosthetic Replacement was conducted on 19 patients with advanced lunate bone necrosis (Kienböck's Disease) to alleviate wrist pain and enhance movement. Following an average follow-up of 63.21 months, positive clinical outcomes were noted, such as notable pain relief, improved grip strength, and enhanced wrist extension. These outcomes may be attributed to the bone cement's excellent tissue compatibility and comparable strength to bone [16,21]. During surgery, the cement can be customized to match the articular surface and the original lunate bone within the joint space. Additionally, it plays a crucial role in halting the progression of carpal collapse and rearrangement, ultimately leading to improved joint mobility and grip strength.

Many treatments are currently available for aseptic lunate bone necrosis. Simple lunate bone resection can cause carpal bone disarrangement, capitate bone depression, and intractable pain of the wrist joint [1,2,12]. therefore, lunate bone resection and replacement becomes an excellent therapeutic option for lunate bone necrosis [5,10,12]. Many implantable substitutes are available following lunate bone resection, such as capitate bone displacement, lentiform bone displacement, metal ball, tendon ball, and titanium alloy prosthesis [10,22,23]. However, the hard metal ball quickly wears out based on the adjacent carpal bone, while the soft tendon ball and arc transparent cartilage easily result in the instability of the wrist joint after implantation [5,22]. Moreover, a titanium alloy prosthesis is expensive and must be customized in advance; its size is difficult to adjust, and there is difficulty associated with its simulation [10,12].

Conversely, bone cement is characterized by its stable physical and chemical properties; its shape and size can be adjusted during the operation [21,14,17]. Bone cement can be shaped and sized in such a way that it coincides with the patient's original lunate and matches the wrist joint's physiological characteristics [24]. In our study, we observed a significant improvement in the MMWS and DASH scores of the wrist joint, with no statistical difference noted when compared to the unaffected side. These results align with the clinical outcomes of traditional lunate bone replacements and are comparable to those of lunate 3D-printed metal prosthesis replacements [10,12,25,26].

Bone cement demonstrates long-term elasticity retention, effectively preventing deformation, corrosion, and absorption [21,27]. Its favorable tissue compatibility makes it a choice for addressing bone defects [28]. The patient remained symptom-free during the follow-up period, with no signs of infection, rejection, or degradation of the bone cement prosthesis. Imaging analysis showed consistent CHR, UDR, STR, and RSA results between 1 and 2 years post-surgery and at the final follow-up, indicating successful preservation of lunate shape and prevention of collapse. Therefore, the surgical replacement of lunate bone using bone cement prosthesis has the following advantages: (1)one can replace the original necrotic lunate bone with bone cement, which restores the normal anatomy of the wrist joint; (2) this surgery is simple to perform, has a short learning curve, and is cheap so that it can be used in almost all hospitals, especially primary hospitals; (3) once the bone cement is solidified, it becomes stable, allowing for early return to daily activities [17].

Lunate prosthesis dislocation is a significant complication following lunate prosthesis replacement, resulting in wrist pain, restricted function, and potential requirement for additional surgery, with an incidence rate ranging from 6.8-11% [10,12,26]. This study did not observe any cases of dislocation with cemented prostheses. However, one patient experienced mild displacement, possibly due to using a cemented prosthesis that was too small [10,26]. The prosthetic stabilization is predominantly determined by the mutual gomphosis of the prosthetic concave structure, the adjacent bony structure, and the resistance from the adjacent articular capsule and tendons [12,26]. To prevent the detachment of the lunate prosthesis in the early stage, attention shall be paid to the repair

Figure 3: Typical case: A. Preoperative MRI; B. Postoperative X-ray and CT; C. Postoperative MRI. This patient has been followed up on for five years currently. The postoperative X-ray, CT, and MRI examinations showed an excellent position of the lunate bone and no osteoarthritis of the wrist joint and intercarpal joint.

Table 4: The occurrence of complications

iterm	
Infect	0
Poor incision healing	1
Bone cement absorption and collapse	1
Dislocation	0
The occurrence of arthritis	
progress	2
new developments	1

and suturing of the dorsal joint capsule and the dorsal extensor support band of the wrist; after the operation, the plaster immobilization in the functional position shall be performed to avoid the detachment of lunate prosthesis caused by wrist movement and facilitate the repair of the articular capsule and adjacent soft tissues [2,10].

Osteoarthritis is a typical late complication following lunate prosthesis replacement [29-31]. The incidence of this complication varies, with rates such as 17% reported by Minami et al. [32], 22% reported by Meier et al. [33], and 33% reported by Fortin and Louis [34]. Postoperative wrist osteoarthritis is believed to be caused by several factors: ① Inadequate matching of the prosthesis with the bone surface. ② Surgical technique deficiencies, such as improper positioning and unstable fixation [35]. ③ Poor prosthetic material and design. ④ High activity levels in patients [16,30,33]. This study observed changes in radiocarpal joint osteoarthritis in 3 patients, with two patients showing progression of osteoarthritis and one developing new-onset osteoarthritis. During the bone cement curing period, applying wrist radial deviation, maximum range feet backstretch, and buckling to restore bone implants and surrounding anatomical structures may help reduce the risk of osteoarthritis.

LIMITATION

Although our preliminary results are promising, there are several limitations and unanswered questions. One limitation is the small sample size of patients in our study and the absence of extensive data and multi-center studies, which hinders the ability to provide conclusive evidence for clinical application [36]. Furthermore, we should have conducted comparative studies, such as comparing Scaphotrapeziotrapezoid Arthrodesis and 3D-printed lunate prosthesis replacement, thus preventing us from elucidating the potential advantages of bone cement prosthesis implantation in treating advanced lunate osteonecrosis. In addition, the study only included patients over 45 years old due to the permanent nature of bone cement implantation [37]. Further research is needed to better understand the clinical outcomes in younger patients. Lastly, there may be significant errors in postoperative radiographic measurements, even with dual measurement by individuals, due to the impact of the postoperative cemented prosthesis on parameter interpretation.

CONCLUSIONS

Individualized bone cement prosthetic treatment was effective for advanced lunate bone necrosis in middle-aged and elderly individuals. It helped restore the original anatomical structure, prevent further collapse, and enhance hand function.

DECLARATIONS

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Availability Of Data And Materials

All data and materials were in full compliance with the journal's policy.

Ethics Approval And Consent To Participate

Compliance with ethical standards

Consent For Publication

All patients enrolled into the study agreed the use of patients'data for research.

Authors'contributions

Yuan-qiang Li,Wan Chen, Hong-Tao Li and Xin-gang Wang contribute equally to this work, All surgical procedures were carried out by Wan Chen, Cheng-song Yuan, Jing-tong Lv in this study. The Data measurement of specimens was performed by Lin-Ma, Yuan-qiang Li, Rui Li, Xiao-li Gou participated in the patient selection, investigation on the outpatient clinic and radiographic assessments, literature search, and data monitoring. Lin Guo, Yu-ping Yang, and Cheng-Song Yuan completed the statistical analysis and manuscript writing. All authors have read and approved the final manuscript.

AVAILABILITY OF DATA AND MATERIALS

All the data will be available upon motivated request to the corresponding author of the present paper.

DECLARATIONS ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the First Affiliated Hospital of Army Medical University, and all patients provided the written informed consent.

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