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*Original Article*

# Efficacy of calcium sulfate particles combined with allogeneic bone grafting on bone defects after surgery for benign bone tumors of the extremities

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**Abstract:** Background: Benign extremity bone tumors significantly impact patients' quality of life. While autologous bone grafting increases surgical trauma and donor-site complications, allogeneic bone grafting carries risks of infection and rejection. Objective: To evaluate the efficacy of calcium sulfate (CS) particles combined with allogeneic bone grafting for bone defects following benign extremity bone tumor surgery. Methods: This retrospective analysis included 121 patients treated at Honghui Hospital (Jan 2018-Dec 2020). The control group (CG, n=60) received CS artificial bone grafts, while the research group (RG, n=61) received CS combined with allogeneic bone grafts. Outcomes included treatment efficacy, drainage volume, soft tissue swelling resolution time, bone healing time, particle absorption time, residual bone defect rate, complications, limb function at 18 months postoperatively, Pain scores (VPS) of the two groups before and after treatment and quality of life at 6, 12, and 18 months postoperatively. Results: The RG demonstrated a significantly higher total effective rate compared to the CG. Postoperative drainage volume and soft tissue swelling disappearance time were notably reduced in the RG. Additionally, the RG showed shorter bone healing time and particle complete absorption time, lower residual bone defect rate after artificial bone absorption, and decreased incidence of wound infection and delayed healing. The VAS score of patients in the RG group improved more significantly than that of the CG. Limb function at 18 months and quality of life at 6 and 12 months were significantly better in the RG. Conclusions: CS particles combined with allogeneic bone grafting effectively reduces postoperative bone defects, promotes recovery, and improves quality of life in patients with benign extremity bone tumors, warranting clinical promotion.

**Keywords:** Calcium sulfate particles, bone allograft, benign bone tumor of extremities, bone defects

## Introduction

Benign bone tumors of the extremities are believed to damage the patient's normal tissues and the external cortex [1]. At present, the disease is mainly treated by excision of the diseased site. Due to the common occurrence of bone defects formed after the excision of benign tumors, bone graft reconstruction has become an essential part of surgical treatment [2]. For benign bone tumors which require surgical intervention, the surgical indications usually include continuous tumor enlargement, that causes pain symptoms and increases the risk of pathological fractures, or that causes adjacent joint dysfunction and neurovascular compression [1, 2]. Autologous bone transplantation not only aggravates surgical trauma, but it also contributes to complications in the donor site. While allogeneic bone grafting may lead to both infection and rejection, which is detrimental to the surgical outcome and patients' prognostic life quality. Therefore, artificial bones made of calcium carbonate are often adopted in clinical practice [3, 4].

Calcium sulfate (CS) can induce osteocyte growth and neovascularization, promote osteocyte adhesion, and prohibit the ingrowth of soft tissues [5]. The most important feature of CS particle artificial bone is that it can control the absorption rate of CS particles by controlling the size and shape of hemihydrate crystals, thereby maintaining the absorption rate in a stable state, which can be accurately determined by clinical imaging examination [6, 7].

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Artificial bones are considered to mitigate the risk of infection and rejection, and it is a preferred bone graft material for use in the future [8]. In recent years, its application in bone tumor surgery has been increasing, often used to fill the cavities left after scraping benign bone tumors to restore local bone mass [9]. However, researchers have argued that CS artificial bone will be completely absorbed in the body within 6 to 12 weeks, and if the bone growth cannot keep up with the rate of degradation, the artificial bone will lose its scaffolding function in the later stage of recovery. Thus without sufficient supporting strength, the patient will experience fractures [10, 11].

To provide more reference solutions for the clinical treatment of benign bone tumors, this research used CS artificial bone combined with allogeneic bone in the treatment of patients with benign bone tumors of the extremities, and compared its efficacy with that of artificial bone implantation alone, with related details reported as follows.

## Materials and methods

### *Clinical information*

This study retrospectively analyzed the clinical data of 121 patients with benign bone tumors of the extremities treated in Honghui Hospital, Xi'an Jiaotong University from January 2018 to December 2020. Among them, 60 patients treated with CS artificial bone were taken as the control group (CG). On that basis, 61 additional patients treated with allogeneic bone grafting were selected as the research group (RG).

Surgical plan selection: All patients underwent preoperative imaging evaluation to determine tumor size, location, and extent of bone defects. To reduce selection bias and ensure the balance of baseline data between the two groups, this study selected patients with similar lesion scope, anatomical location, and degree of bone destruction for analysis. For patients who meet the inclusion criteria, based on the observed bone defect morphology during surgery and the surgeon's habits, simple CS artificial bone implantation (control group) or CS artificial bone combined with allogeneic bone implantation (research group) were used for bone defect reconstruction. Combined allogeneic bone transplantation is mainly suitable for cases with large bone defects or those located in the main weight-bearing area (such as the lower end of the femur, tibial plateau, etc.) to enhance the initial stability and long-term support capacity of the structure. After surgery, the bone healing time, incidence of complications, and functional recovery of the two groups of patients were compared through imaging and functional scoring.

Inclusion criteria: (1) Preoperative imaging and postoperative pathological examination confirmed benign bone tumors in the limbs, including giant cell tumors, chondroblastomas, osteoblasts, osteoid bone tumors, etc; (2) All patients underwent lesion scraping or resection surgery, and bone defects requiring bone grafting reconstruction were left during the operation; (3) OSTEOSE calcium sulfate (CS) particle artificial bone of the same brand and model was used for bone defect filling; (4) The clinical and imaging follow-up data are complete. This experiment has been approved by the Honghui Hospital, Xi'an Jiaotong University Ethics Committee and complies with the Helsinki Declaration.

Exclusion criteria: (1) Pathological diagnosis of primary malignant tumors or metastatic bone tumors in the limbs; (2) Individuals with combined blood system diseases, acute or chronic infections, or immune system diseases; (3) Patients with severe dysfunction of important organs such as the heart, liver, brain, and kidneys or mental disorders, who cannot tolerate surgery and follow-up; (4) Combined pathological fractures that requires internal fixation treatment, which may interfere with the evaluation of bone healing process; (5) Incomplete clinical or imaging follow-up data, or loss to follow-up.

### *Treatment regimes*

(1) First, curettage was performed on the lesion site of both groups of patients, and the cortical bone was fenestrated, with the fenestration range slightly larger than that of the tumor lesion. An appropriate amount of tissue was collected for intraoperative pathological examination; the tumor tissue was be completely removed if the tumor was pathologically determined to be benign, and the inner wall of the medullary cavity was polished with an air drill and cauterized with an electric knife. Then

the surgical field was rinsed with sterile water for injection and hydrogen peroxide solution. The medullary cavity was inactivated with absolute ethanol, followed by bone grafting.

(2) CG patients received simple artificial bone grafting: OSTEOSE CS artificial bone was selected to fill the medullary cavity.

(3) RG patients were treated with CS artificial bone combined with allogeneic bone grafting: according to the extent of the lesions, allogeneic bone particles were implanted close to the inner wall of the medullary cavity, and were compacted with the bone graft rod. After about 1/3 of the cavity defect was filled, the medullary cavity was filled with a mixture of OSTEOSE CS artificial bone and allogeneic bone particles (ratio 4:1), and then covered with fenestrated cortical bone or allogeneic particles not infiltrated by the tumor. If the cortical bone at the fenestration was not infiltrated by tumor tissue, it was backfilled to cover the bone graft. Plates were selected for protective internal fixation according to the condition, and drainage tubes were routinely placed. Finally, the incision was sutured layer by layer.

*Postoperative management and follow-up*

Prophylactic antibiotics were applied until postoperative day 2. The wound healing was observed during the postoperative wound dressing change, and patients were guided to gradually perform functional exercises on the bed. All drainage tubes were removed within 72 hours after surgery, followed by review of the bone graft site by X-ray films. The affected limbs of patients were temporarily non weight-bearing after the operation. Patients were followed up in the outpatient clinic at the first and third months after the operation, and the functional exercise was guided according to the follow-up results. Thereafter, the outpatient follow-up was carried out every 1 to 3 months according to the recovery situation, and every 6 months or 1 year if the recovery was good. During the outpatient follow-up, X-ray examination of the bone graft site was performed to record the time of complete resorption of the artificial bone and the presence (if any) of bone defects after artificial bone resorption.

*Observation indicators*

(1) First, the therapeutic efficacy of the two groups was evaluated and compared. Patients were evaluated as markedly effective (no recurrence of symptoms after surgery, fully recovered limb function with no physical impairment, and the ability to perform non-contact exercise), effective (no obvious recurrence of disease symptoms, no pain, mild limb limitation, and no obvious disability symptoms), and ineffective (no significant change after surgery versus before surgery, or condition worsening with local necrosis, amputation, etc.); the total effective rate of treatment = (markedly effective + effective)/total number × 100%. (2) The incision drainage volume and the disappearance time of soft tissue swelling of patients after treatment were recorded and compared. (3) The bone healing time and postoperative particle complete absorption time of both groups were observed and compared. The bone healing time is defined as the time after surgery until the transplanted bone and host bone reach the imaging healing standard. Two senior radiologists used a double-blind method to evaluate the X-ray or CT images of regular postoperative follow-up examinations. The bone healing standard refers to the modified Neer grading standard: if the interface between the transplanted bone and the host bone was blurred or disappears, the bone trabeculae pass through the transplant area, and the cortical bone connection is continuous, it was considered to have achieved bone healing. The complete absorption time of postoperative particles is defined as the time from the day of surgery to the complete disappearance of CS artificial bone particle shadows or complete replacement by new bone tissue on imaging. (4) The residual bone defect rate after complete absorption of artificial bone was recorded and compared. At the last follow-up after surgery, CT three-dimensional reconstruction examination was performed to measure the residual cavity volume (V_residual) in the bone defect area without obtaining bone filling using multi plane reconstruction technology, and compared with the original bone defect volume (V_initial) measured immediately after surgery. The calculation formula for residual bone defect rate was: residual bone defect rate = (V_residual/V_initial) × 100%. The measurement work is completed by radiologists in the medical imaging workstation, and all patients use the same window width, window level, and measurement conditions to ensure data comparability. (5) The incidence of adverse events such as postoperative incision infection and

delayed incision healing was recorded and compared. The occurrence of incision infection and deep infection events in two groups of patients was recorded within 30 days after surgery and during follow-up. Incision infection was defined as the appearance of redness, swelling, exudation, and suppuration in the local area of the incision, with or without positive pathogen culture; Deep infection refers to the appearance of infection in the surrounding tissues or bone marrow cavity of the transplant, which needs to be confirmed by imaging or pathogen examination. The formula for calculating infection rate was: Infection rate = (number of infected cases/total number of cases in the group) × 100%. The incision infection rate and deep infection rate were calculated for each group separately and compared for difference in total infection rate between the two groups. (6) Enneking bone and soft tissue tumor postoperative functional scoring criteria were used to evaluate the limb function of patients 18 months after surgery [12]. This scale is recommended by the International Society for Limb Protection (ISOLS) and comprehensively evaluates six dimensions: pain, functional activity, emotional acceptance, brace use, walking ability, and gait changes. Each dimension is divided into six levels ranging from 0-5 points, with a maximum score of 30 points. According to the total score, the recovery of limb function is divided into three levels: excellent (23-30 points), indicating that the patient has no pain, basic functional activities are not restricted, no braces are needed, and the gait is normal; Good (15-22 points), indicating that the patient has mild pain or functional limitations, requires partial restriction of movement, occasionally requires support, and has mild gait abnormalities; Poor (<15 points) indicates significant pain and severe functional limitations in the patient, requiring continuous use of braces and significant gait abnormalities. Excellent rate = (excellent + good) cases/total cases × 100%. (7) The pain scores (VAS) of the two groups before treatment and 1 month after treatment were evaluated and compared. (8) The Karnofsky Functional Status (KPS) score was used to evaluate the quality of life of patients at 6, 12, and 18 months after surgery [13]. This scale quantifies the functional status of patients on a percentage scale and is comprehensively evaluated by assessors based on the patient's ability to engage in normal activities, severity of the condition, and self-care ability. The rating range is 0-100 points, with each 10 points being a level. Among them, 100 points indicate that the body is normal, without any discomfort or illness; A score of 80 or above indicates normal activity with only mild symptoms; A score of 50-70 indicates partial self-care, but requires medical assistance; A score below 50 indicates the need for care from others in daily life, and the condition may rapidly deteriorate. By comparing the mean KPS scores of the two groups of patients at each follow-up time point, the impact of different bone grafting methods on the long-term quality of life of patients after surgery was determined.

*Statistical methods*

SPSS18.0 (IBM) software was used for data analysis and GraphPad Prism 8 software for illustrating figures. The Chi-square test was adopted to analyze enumeration data. For measurement data, the Student's t test and paired t test were used for inter-group comparison and comparison before and after treatment, respectively. A statistical difference was present when $P<0.05$.

## Results

*General information comparison*

Subjects in the two groups were comparable due to insignificant differences in gender, age and smoking history ($P>0.05$, **Table 1**).

*Comparison of therapeutic efficacy*

The number of markedly effective, effective and ineffective patients in the RG were 30, 28, and 3, respectively, and corresponding data in the CG were 20, 26, and 14, respectively, suggesting that the RG has higher therapeutic efficacy than the CG (95.08% vs. 76.67%, **Table 2**).

*Comparison of postoperative incision drainage volume and soft tissue swelling disappearance time*

The incision drainage volume and soft tissue swelling disappearance time of RG patients were (263.09±9.14) ml and (6.39±1) d, re-

**Table 1.** General information [n (%)]

| Factors | Research Group n=61 | Control Group n=60 | $\chi^2$ | P |
|---|---|---|---|---|
| Gender | | | 0.069 | 0.792 |
| Male | 35 (57.38) | 33 (55.00) | | |
| Female | 26 (42.62) | 27 (45.00) | | |
| Age (years) | | | 0.075 | 0.785 |
| ≤34 | 31 (50.82) | 29 (48.33) | | |
| >34 | 30 (49.18) | 31 (51.67) | | |
| BMI ($kg/m^2$) | | | 0.007 | 0.933 |
| ≤23 | 28 (45.90) | 28 (46.67) | | |
| >23 | 33 (54.10) | 32 (53.33) | | |
| smoking history | | | 0.066 | 0.797 |
| Yes | 41 (67.21) | 39 (65.00) | | |
| No | 20 (32.79) | 21 (35.00) | | |
| Tumor Site | | | 0.008 | 0.928 |
| Upper Limbs | 30 (49.18) | 30 (50.00) | | |
| Lower Limbs | 31 (50.82) | 30 (50.00) | | |
| Tumor Volume | | | 0.008 | 0.931 |
| <20 $cm^3$ | 29 (47.54) | 29 (48.33) | | |
| ≥20 $cm^3$ | 32 (52.46) | 31 (51.67) | | |
| Internal Fixation | | | 0.066 | 0.797 |
| Yes | 20 (32.79) | 21 (35.00) | | |
| No | 41 (67.21) | 39 (65.00) | | |

**Table 2.** Comparison of curative effects [n (%)]

| Curative Effect | Research Group n=61 | Control Group n=60 | $\chi^2$ | P |
|---|---|---|---|---|
| Markedly Effective | 30 (49.18) | 20 (33.33) | 3.133 | 0.077 |
| Effective | 28 (45.90) | 26 (43.33) | 0.081 | 0.776 |
| Ineffective | 3 (4.92) | 14 (23.33) | 8.495 | 0.004 |
| Total Effective Rate | 58 (95.08) | 46 (76.67) | 8.495 | 0.004 |

**Table 3.** Comparison of postoperative incision drainage volume and soft tissue swelling disappearance time

| Items | Research Group n=61 | Control Group n=60 | t | P |
|---|---|---|---|---|
| Incision Drainage Volume (ml) | 263.09±9.14 | 314.08±10.51 | 28.49 | <0.001 |
| Soft Tissue Swelling Disappearance Time (d) | 6.39±1 | 9.73±1.21 | 16.56 | <0.001 |

spectively, which were evidently lower compared with CG patients ([314.08±10.51] ml, [9.73±1.21]) d (P<0.05, **Table 3**).

*Comparison of bone healing time and postoperative particle complete absorption time*

The bone healing time and postoperative particle complete absorption time of patients in the RG were (8.75±0.98) months and (2.13±0.34) months, respectively, and those in the CG were (13.98±1.2) months and (5.62±0.52) months, respectively, suggesting that the RG needed much less time in terms of these two indicators than the CG did (P<0.05, **Table 4**).

*Comparison of residual bone defect rate after complete absorption of artificial bone*

As mentioned earlier, the two groups had no evident differences in baseline data other than treatment methods, so we analyzed the residual bone defect rate after complete absorption of artificial bone in the two groups to further

**Table 4.** Comparison of bone healing time and postoperative particle complete absorption time

| Items | Research Group n=61 | Control Group n=60 | t | P |
|---|---|---|---|---|
| Bone healing time (months) | 8.75±0.98 | 13.98±1.2 | 26.28 | <0.001 |
| Postoperative particle complete absorption time (months) | 2.13±0.34 | 5.62±0.52 | 44.83 | <0.001 |

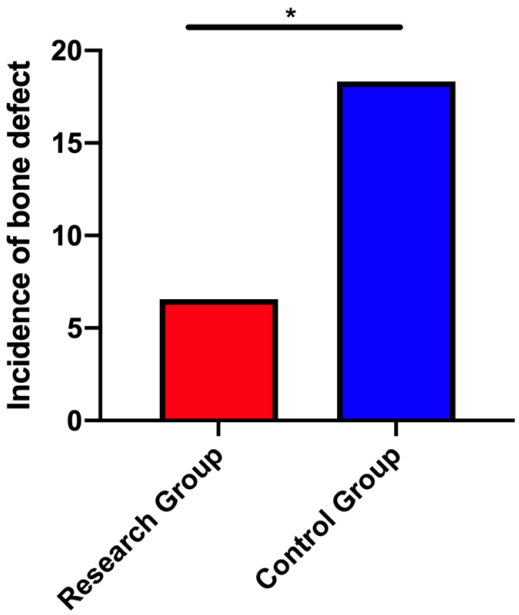


**Figure 1.** Comparison of residual bone defect rate after complete absorption of artificial bone. Note: * means P<0.05.

evaluate the therapeutic efficacy. The results showed that the residual bone defect rate after complete absorption of artificial bone was 6.56% (4/61) in the RG and 18.33% (11/60) in the CG, suggesting a lower rate of residual bone defects in the RG after complete absorption of artificial bone (P<0.05, **Figure 1**).

*Comparison of the incidence of postoperative incision infection and delayed incision healing*

The incidence of postoperative incision infection and delayed incision healing in the RG was 1.64% and 3.28%, and those in the CG were 10.00% and 13.33%, respectively, showing better performance in these two indicators in the RG compared with the CG (P<0.05, **Table 5**).

*Comparison of limb function in the two groups of patients at 18 months after operation*

At 18 months after operation, the number of patients in the RG with limb function evaluated as excellent, good and poor were 34, 23, and 4, respectively, and those in the CG were 23, 21, and 16, respectively. The data revealed a markedly higher excellent and good rate of limb function in the RG versus the CG (P<0.05, 93.44% vs. 73.33%, **Table 6**).

*Comparison of VAS scores between the two groups before and after treatment*

Before treatment, there was no significant difference in the VAS score between the two groups (P>0.05). After treatment, the VAS score of the two groups was significantly improved compared with that before treatment, but the improvement of the VAS score of the RG group was more significant than that of the CG, and the difference was statistically significant (P< 0.05) (**Figure 2**). Comparison of postoperative quality of life.

The postoperative KPS score of both groups increased evidently (P<0.05), with higher scores in the RG at 6 and 12 months postoperatively (P<0.05). No evident difference was observed in the KPS score between the two groups at 18 months postoperatively (P>0.05). Details are shown in **Figure 3**.

## Discussion

Existing evidence suggests that an ideal bone graft substitute should have the following characteristics: a slightly acidic biological environment locally, good biocompatibility, favorable for osteoblasts and blood vessel ingrowth, biodegradation time of about 2 months, and osteoconductivity, osteogenesis and osteoinduction properties [14, 15]. Autologous bone and allogeneic bone are the most commonly used bioreconstruction materials in clinical practice, of which the former has good bone conductivity and induction, which is an ideal reconstruction material in clinical practice; however, with limited sources, the autologous bone is prone to complications at the donor site [16]. The other one, allogeneic bone, is used in virtue of partial induction and osteoconductivity, but it can in-

**Table 5.** Comparison of the incidence of postoperative incision infection and delayed incision healing

| Items | Research Group n=61 | Control Group n=60 | $\chi^2$ | P |
|---|---|---|---|---|
| Postoperative wound infection rate | 1 (1.64) | 6 (10.00) | 3.879 | 0.049 |
| Incidence of delayed wound healing | 2 (3.28) | 8 (13.33) | 4.033 | 0.045 |

**Table 6.** Comparison of limb function between the two groups at 18 months after surgery [n (%)]

| Assessment | Research Group n=61 | Control Group n=60 | $\chi^2$ | P |
|---|---|---|---|---|
| Excellent | 34 (55.74) | 23 (38.33) | - | - |
| Good | 23 (37.70) | 21 (35.00) | - | - |
| Poor | 4 (6.56) | 16 (26.67) | - | - |
| Excellent and good rate | 57 (93.44) | 44 (73.33) | 8.866 | 0.003 |

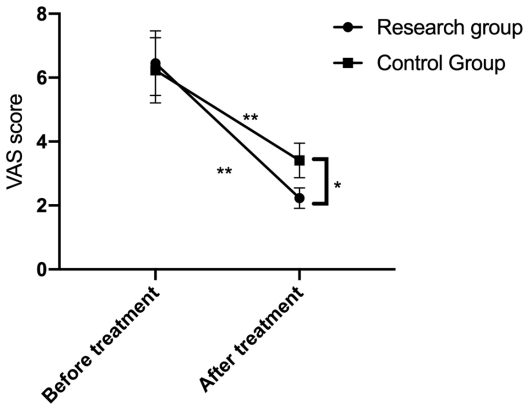


**Figure 2.** Comparison of VAS scores between the two groups before and after treatment. * Indicates P<0.05, ** indicates P<0.001.

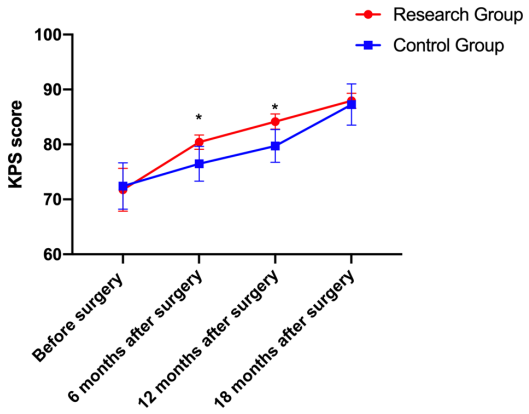


**Figure 3.** Comparison of life quality between groups 2 years after surgery. Note: * means P<0.05.

crease the risk of adverse events, including infection, fracture and nonunion [17]. Therefore, finding a new type of artificial bone substitute material has become the focus of current clinical research.

Studies have shown that CS can cause osteoblast adhesion, induce bone growth, promote angiogenesis and ingrowth, and prevent soft tissue ingrowth [18]. CS has osteoinductive properties different from phosphate, and is mainly used to reconstruct bone defects after tumor resection. After degradation in vivo, it can form a slightly acid and high calcium environment, which facilitates the formation of new bone and promotes the proliferation and differentiation of osteoblasts [19, 20]. In addition, it has the effect of local decalcification of host bone, thus stimulating the release of osteogenic-inducing factors [21]. OSTEOSE CS particles are a new type of artificial bone substitute with high-purity α crystal structure, which has good histocompatibility and fast degradation rate, similar to the formation of new bone [22, 23]. In this study, we adopted CS artificial bone combined with allogeneic bone to treat patients with benign bone tumors of the lower extremities for bone grafting, and compared its therapeutic efficacy with that of artificial bone implantation alone. The results showed evidently lower incidence rates of postoperative incision infection and delayed incision healing in the RG compared with the CG (P<0.05), suggesting that the combination of allogeneic bone and artificial bone did not increase the incidence of incision-related adverse events. After the artificial bone was completely absorbed, the residual bone defect rate of RG patients was lower (P<0.05), suggesting that the use of allogeneic bone combined with bone grafting could induce bone growth and reduce the dosage of CS artificial bone and the risk of residual bone defects. This discovery is consistent with previous research results. A case study by Korean scholars [24] confirmed that decalcified

allogeneic bone matrix and calcium sulfate complex have good osteogenic effects. Histological examination showed that the proportion of new bone formation was 16.7%-41.7%, and the material was slowly absorbed over time without any inflammatory cell infiltration or granuloma reaction. Previous studies [25] have suggested that compared with pure artificial bone, CS artificial bone combined with allogeneic bone grafting could notably reduce the incidence of incision-related adverse events and the risk of artificial bone defects in patients with lower extremity benign bone tumors. Moreover, it further demonstrates that the adoption of CS particles combined with allogeneic bone can effectively avoid autologous bone transplantation-induced infections and CS particle degradation, improve the absorption rate of patients, and induce bone growth. The combined use of the two could greatly improve the safety of treatment while bringing about significant efficacy. Subsequently, we also compared the VAS scores of the two groups before and after treatment, and the results showed that the pain degree of the two groups was significantly relieved, but the patients in the RG group improved more significantly. This suggests that compared with the single artificial bone treatment, the combined treatment of allogeneic bone and artificial bone has a more obvious effect on improving the pain of patients.

To further analyze the influence of the two bone implant schemes on the long-term prognosis of patients, we evaluated and compared the limb function of patients at 18 months postoperative and the life quality of the two groups 6 months, 12 months and 18 months after surgery. The excellent and good rate of limb function was determined to be evidently higher in the RG than in the CG 18 months after operation; the RG had better performance in terms of life quality at 6 months and 12 months after operation, but there was no marked difference in life quality at 18 months postoperatively. This suggests that the combination of allogeneic bone and artificial bone therapy can validly promote patients' postoperative recovery and improve their quality of life compared with mono-therapy of artificial bone. Previous studies [26] have also pointed out that allogeneic bone combined with artificial bone could effectively promote postoperative recovery of patients, similar to our findings.

## Conclusion

To sum up, without increasing the incidence of incision-related adverse events, the combined use of CS artificial bone and allogeneic bone grafting for benign bone tumors of the extremities can effectively improve the treatment efficiency, reduce the risk of residual bone defects, and promote patients' postoperative recovery and life quality, which is worthy of clinical promotion. However, there are still some shortcomings in this study. On the one hand, due to the small sample size, the results need further validation. On the other hand, this study only analyzes the efficacy of CS particles combined with allogeneic bone grafting. In fact, the field of bone tissue biomaterials is developing rapidly, and it is necessary to further explore appropriate treatment options with updated materials to bring more benefits to patients.

## Disclosure of conflict of interest

None.

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