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Abstract

Objective: To compare the clinical efficacy of one stage posterior debridement with iliac bone graft, titanium mesh bone graft or granular bone graft in the surgical treatment of single segment lumbar tuberculosis.

Methods: Ninety-eight patients who underwent one stage posterior debridement, bone graft and internal fixation for single segment lumbar tuberculosis from 2015 to 2018 were involved in this study, involving 32 case in iliac bone graft group, 32 case in titanium mesh bone graft group and 34 cases in granular bone graft group. The primary outcomes involved operative time, operative blood loss, postoperative hospital stay, visual analogue scale (VAS) score, erythrocyte sedimentation rate (ESR), C reactive protein (CRP), ASIA grade and postoperative complications. The secondary outcomes were Cobb angle correction and loss, and bone graft fusion time. All the outcomes were recorded and analyzed.

Results: Compared with iliac bone graft and titanium mesh bone graft group, granular bone graft had shorter operative time (P=0.003), less operative blood loss (P=0.010) and shorter bone graft fusion time (P<0.001). With the follow-up of 14-36 months, the VAS score, ESR, CRP and neurological function in the three groups were all

significantly improved (P<0.05). The bone graft fusion time of the granular bone graft group was significantly shorter than iliac bone graft group and titanium mesh bone graft (P<0.05), but no significant differences were found in the correction and loss of Cobb angle, and the incidence of complications among the three groups (n.s.).

Conclusion: Granular bone graft has less surgical trauma and shorter bone graft fusion time compared with iliac bone graft and titanium mesh bone graft in the surgical treatment of single segment lumbar tuberculosis. The three methods may achieve comparable clinical efficacy in alleviating symptoms, correcting kyphosis and improving neurological function for appropriate cases.

Keywords:

Lumbar tuberculosis; Posterior debridement; Internal fixation; Bone graft

1. Introduction

Spinal tuberculosis (STB) is a common extra-pulmonary TB, accounting for about 50% of osteoarticular TB [1]. Delayed treatment of STB may cause vertebral bone destruction, collapse, kyphosis and even paralysis due to the compression of spinal cord or nerve [2, 3]. Currently, combination treatment of anti-TB chemotherapy and surgery is considered the gold standard treatment of STB [4]. Surgical treatment is required for patients with severe kyphosis, impaired neurological function and spinal instability [5].

Debridement is the key to a STB surgery, because it is beneficial to control STB lesions, improve the effect of anti-TB drugs, promote bone graft fusion, and reduce the risk of STB recurrence [6]. Debridement will result in vertebral defect and further damage to spinal stability, so bone graft is very important to repair vertebral defect, promote spinal fusion and reduce postoperative STB recurrence [7]. At present, the most commonly used bone graft methods in STB surgery are iliac bone graft and titanium mesh bone graft. Both of the two methods were reported with high bone graft fusion rate and good ability of correcting spinal kyphosis [8], but the concerns about surgical trauma, deterioration of spinal biomechanical stability, donor site complications and displacement or subsidence of the grafted iliac bone mass or titanium mesh were no rarely reported and got more and more attention [9, 10]. In recent years, granular bone graft was reported with satisfactory clinical efficacy in the surgical treatment of STB. Our previous study found that granular bone graft has less surgical trauma and shorter bone fusion time compared with structural bone graft in the

surgical treatment of single segment thoracic tuberculosis, the two methods may achieve comparable clinical efficacy in alleviating symptoms, correcting kyphosis and improving neurological function for appropriate cases [11]. However, more and more surgeons wondered whether this positive results may or may not be extrapolated to the lumbar spinal tuberculosis surgery population because of the high loading force in lumbar level.

Liu et al reported 21 cases of lumbosacral TB treated with one stage posterior debridement, granular bone graft and internal fixation, and all patients got bone graft fusion within 6 months [12]. Xu et al included 32 cases of single segmental lumbar TB undergoing single-stage posterior debridement, compact bone graft and internal fixation, and all patients achieved bone fusion within 3-9 months. But neither of the two studies compared the clinical efficacy of granular bone graft with other bone graft methods in lumbar STB surgery [13]. Liu et al compared the clinical efficacy of one-stage posterior debridement with granular autogenous bone graft versus anterior debridement, structural bone graft combined with posterior instrumentation in lumbar tuberculosis and the results showed that granular bone graft had a significantly shorter operation time, lower blood loss, shorter hospital stay and less hospitalization cost, but no difference in the bone graft fusion time was found [14]. However, this conclusion may be biased because the surgical approaches used in the two groups were quite different. Thus, the difference in clinical efficacy among granular bone graft, iliac bone graft and titanium mesh bone graft in surgical treatment of lumbar spinal tuberculosis remains unclear.

Therefore, we conducted this retrospective singer center cohort study to compare the clinical efficacy of granular bone graft, iliac bone graft and titanium mesh bone graft in the treatment of single segment lumbar tuberculosis.

2. Materials and methods

All of the participants provided their written informed consent to participate in this study before their data were stored in the hospital database and used for research purposes. The work has been reported in line with the STROCSS criteria [15].

2.1 Patients selection

Medical records of hospitalized patients diagnosed with lumbar STB in our department from 2015 to 2017 were retrospective analyzed.

Inclusion criteria: (1) Preoperative diagnosis of lumbar spinal tuberculosis (L1/2-L5/S1) and confirmed by postoperative pathological examination. (2) Adult single segment lumbar spinal tuberculosis (age>18 years). (3) Surgical method was one-stage posterior debridement, bone graft fusion and internal fixation.(4) The methods of bone graft were iliac bone graft, titanium mesh bone graft or autologous granular bone graft. (5) The follow-up time was more than 12 months. (6) The clinical and imaging data during the follow-up were complete.

Exclusion criteria: (1) Suspected spinal tuberculosis patients without pathological examination. (2) Multi-segmental spinal tuberculosis, cervical or thoracic spine

tuberculosis, etc. (3) Patients with previous history of spinal surgery. (4) Spinal tuberculosis with active pulmonary tuberculosis or malignant tumor, etc.

2.2 Preoperative management

All patients underwent X-ray, CT and MRI examination, to evaluate the destruction degree of vertebral body, narrowing of intervertebral space, cold abscess formation or not and spinal cord compression. Preoperative sagittal Cobb angle was also measured on lateral X-ray. These evaluations help us to making the preoperative diagnosis and developing the surgical strategies. All patients were treated with regular anti-TB chemotherapy before the surgery (rifampicin 450mg/d, isoniazid 300mg/d, pyrazinamide 1500mg/d and ethambutol 750mg/d) for 2 to 4 weeks. Surgery was taken when the symptoms of tuberculosis poisoning were relieved and the basic diseases such as diabetes, coronary heart disease, hypertension were under control.

2.3 Surgical methods

The choice of bone graft method was mainly based on the following principles: (1) Iliac bone graft and titanium mesh bone graft were mainly used for: (a) bony destruction exceeding 50% of the height of the vertebrae with serious bone cortical destruction, or (b) neither side of the affected vertebral body could be implanted with pedicle screws. Iliac bone graft was used for young patients with less basic diseases and good operative tolerance and titanium mesh bone graft was used for middle-aged or elderly patients with more basic diseases and poor operative tolerance. (2) Granular

bone graft was mainly used for: (a) bony destruction not exceeding 50% of the height of the vertebrae, or (b) bony destruction exceeding 50% of the height of the vertebrae, but with no serious bone cortical destruction and at least one side of the affected vertebra could be implanted with pedicle screws.

The patients were placed in prone position after general anesthesia, and C arm X ray was used to confirm the lesion segment. Subperiosteal detachment of the bilateral paraspinal muscles was performed via a posterior median approach (if the lesion was unilateral, an intermuscular approach was applied to the contralateral side). Expose the spinous process, lamina, articular process and transverse process of the lesion segment, and the upper and lower adjacent normal vertebrae. Then pedicle screws were inserted into the one or two normal vertebrae above and below the lesion segment, pedicle screws were inserted on both sides of the lesion segments (pedicle screws were just inserted on the contralateral side when vertebrae was severely destroyed), and then lock the titanium rod temporarily. Resect bilateral vertebral plate of lesion segments, protect the dural sac, nerve root and decompress the spinal canal. When necessary, pedicle of the lesion segment could also be removed. Appropriately distract the vertebral body, use different types of curette to strike off caseous necrosis, intervertebral disc, dead bone, etc, and keep the relatively healthy bone tissue till bone surface bleeding. The posterior screw system was properly pressurized to correct kyphosis and C-arm X-ray was used to confirm the kyphosis correction.

The bone graft bed was designed and bone graft was performed with different methods: (1) Iliac bone graft group: Harvest an iliac bone with three sides of cortex,

prune the size suitable and implant it into the vertebral body. (2) Titanium mesh bone graft group: The crushed bone block was mixed with 1.0 g streptomycin and filled into a suitable titanium mesh, and then implanted into the vertebral body. (3) Granular bone graft group: The vertebral plate and spinous process that harvested during surgery were made into 3 ~ 5 mm granular bone and then implanted into the vertebral body and tamped down. The posterior margin was covered with a gelatin sponge containing isoniazid to prevent bone graft particles from entering the spinal canal. Streptomycin 1.0 g and isoniazid 0.3 g were placed in the lesion, two drainage tubes were placed in the incision and then the incision was closed layer by layer.

2.4 Postoperative management

Prophylactic use of antibiotics for the first 3 days after surgery. Incision drainage was removed when drainage volume less than 40 ml/d, and a X-ray examination was checked after extubation. Patients were asked to continue the anti-TB chemotherapy for 18~24 months after operation. After one week, patients could get out of bed wearing braces and the brace was applied for postoperative 3~6 months. X ray, ERS, CRP, hepatic and renal function, CT and MRI (if necessary) were followed up to 1,3,6,12 months postoperatively. The postoperative and follow-up sagittal Cobb angle were measured on lateral X-ray.

2.5 Outcome indexes

Clinical outcomes: (1) Operative time, operative blood loss and postoperative hospital stay. (2) Visual analogue scale (VAS) score, erythrocyte sedimentation rate (ESR) and C reactive protein (CRP) were recorded preoperatively and at the last follow-up. (3) Neurologic function: ASIA grade was evaluated preoperative and at the last follow-up. (4) Complications were recorded during the follow-up.

Imaging outcomes: (1) Cobb angle: the angle between the upper endplate of the upper vertebral body and the inferior endplate of the inferior vertebral body is defined as Cobb angle. The Cobb angle of preoperative, postoperative and last follow-up were all measured on the lateral X-ray respectively. (2) Bone graft fusion time: according to the CT scan during the follow-up, the criterion of bone graft fusion reported by Bridwell et al was used to evaluate whether bone fusion has been achieved. Bridwell et al. divided the graft fusion into four levels [16]. Grade I: Fused with remodeling and trabeculae. Grade II: Graft intact, not fully remodeled and incorporated though; no lucencies. Grade III: Graft intact, but a definite lucency at the top or bottom of the graft. Grade IV: Definitely not fused with resorption of bone graft and with collapse. Grade I and Grade II are defined as bone graft fusion in this study.

2.6 Statistical analysis

SPSS 19.0 software was used for statistical analysis. Quantitative data were expressed in mean±standard deviation. ANOVA analysis and paired t-test were used for inter-group and intra-group comparison of quantitative data, respectively.

Inter-group comparison of disordered qualitative data was performed by the X^2 test. Wilcoxon rank sum test and Mann-Whitney rank sum test were used for intra-group and inter-group comparison of ordered qualitative data, respectively. $P<0.05$ was considered to be a significant difference.

3. Results

A total of 98 patients were included, including 32 cases in iliac bone graft group, 32 cases in titanium mesh bone graft group and 34 cases in granular bone graft group. No significant differences were found in age ($P=0.456$), gender ($P=0.886$), cold abscess ($P=0.634$), body mass index (BMI) ($P=0.239$), ASA grade ($P=0.951$) and preoperative comorbidities ($P=0.956$) among the three groups. **(Table 1)**

The surgical time of granular bone graft group was significantly shorter than iliac bone graft group and titanium mesh bone graft group ($P=0.003$). Granular bone graft group had less surgical blood loss compared with iliac bone graft group and titanium mesh bone graft group ($P=0.018$). No significant difference was found in postoperative hospital stay among the three groups ($P=0.473$). There were no significant differences in preoperative and last follow-up VAS score, ESR and CRP among iliac bone graft group, titanium mesh bone graft group and granular bone graft group (preoperative: $P=0.217$, 0.853 and 0.159, respectively; last follow-up: $P=0.168$, 0.608 and 0.641, respectively). At the last follow-up, VAS score, ESR and CRP were all significantly improved compared with those preoperatively ($P<0.001$ for all the three outcomes). **(Fig. 1)**

No significant differences were found in preoperative, postoperative and last follow-up Cobb angle among iliac bone graft group, titanium mesh bone graft group and granular bone graft group (P=0.823, 0.642 and 0.493, respectively). Postoperative Cobb angle was significantly corrected in the three groups compared with those preoperatively (P<0.001 for all the three groups), and all had a certain degree of Cobb angle loss during the follow-up (P<0.001 for all the three groups). There were no significant differences in Cobb angle correction and loss among the three groups (P=0.220 and 0.300, respectively). The follow-up time of the three groups were 28.2±8.4 months, 27.8±9.6 months and 27.5±8.9 months respectively, and no significant difference was found (P=0.953). The bone graft fusion time of the granular bone graft group (8.0±2.9 months) was significantly shorter than iliac bone graft group (8.6±5.6 months) and titanium mesh bone graft group (5.2±1.1 months) (P<0.001). **(Fig. 2)**

There were no significant differences in preoperative and last follow-up ASIA grade among the iliac bone graft group, titanium mesh bone graft group and granular bone graft group (P=0.968 and 0.233, respectively). Compared with preoperative ASIA grade, all patients in the three groups achieved significant improvements at the last follow-up (P=0.004, 0.003 and 0.004, respectively) (**Table 2).** The postoperative complications of the three groups were showed in **Table 3**. No significant difference was found in complications rate among the three groups (P=0.850) and all cases were cured after active treatment.

Typical Cases

Typical cases were shown in **Fig. 3, 4, 5**.

Discussion

Our study found that iliac bone graft and titanium mesh bone graft had longer operative time and more blood loss than granular bone graft group, which may be owing to the following reasons: (1) the complex bone graft bed preparation, implanting difficulties of large iliac bone mass and titanium mesh [17]. (2) granular bone is easy to prepare and convenient to implant [13]. At the last follow-up, VAS score, ESR, CRP and neurological function were all significantly improved in the three groups, this may be due to the effective anti-TB chemotherapy and decompression of the spinal canal [18]. No significant difference was found in postoperative complications among the three groups and all complications were cured after active treatment, this also indicated the safety of the three bone graft methods in the lumbar STB surgery.

Potential concerns about granular bone graft used in lumbar STB surgery such as insufficient supporting force and poor ability of correcting kyphosis were also reported because of its loose structure [14]. But in our study, no differences in Cobb angel correction and loss were found among the three groups. The possible reasons were as follows: (1) The Cobb angle correction depends mainly on the compression of the posterior internal fixation, instead of the supporting force of iliac bone mass, titanium mesh or granular bone to the anterior column [19]. (2) The ischemic necrosis, collapse and displacement of the iliac bone mass or the subsidence of the titanium mesh may

also cause Cobb angel loss [20, 21]. (3) Iliac bone graft and titanium mesh bone graft require high quality of bone graft bed and too much local bone tissue is removed during surgery, this may also affect spinal stability and cause Cobb angle loss [22]. (4) The bone graft fusion time in the granular bone graft group is shorter than the iliac bone graft group and titanium mesh bone graft group, and we previously reported that once bone graft fusion is achieved, Cobb angle loss is minimal [23]. (5) The difference in the length of posterior fixation segment may also affect local stability and the Cobb angle correction and loss [22].

During the follow up, granular bone graft group showed the shorter bone fusion time, and this may be associated with the following reasons: (1) Granular bone is small in volume and has a large contact area with the vertebral body, which is conducive to the infiltration of nutrients and the growth of new blood vessels [24]. (2) Granular bone compacts with each other and the micro-deformation can induce the local production of bone morphogenetic protein to facilitate the bone fusion [18, 25]. (3) Central ischemia of iliac bone mass causes absorption, collapse or displacement, which may affect the bone graft fusion [20]. (4) Titanium mesh subsidence, especially in osteoporosis patients or too much osteogenic endplate removed during surgery[21].

We consider that the indications of one stage posterior debridement, granular bone graft and internal fixation for the surgical treatment of single segment lumbar STB were as follows: (1) Severe back pain with poor responds to regular conservative treatment. (2) Progressive aggravation of neurological impairment or paralysis. (3) Progressive exacerbation of local instability or kyphosis. (4) Single segmental lumbar

tuberculosis with: (a) bony destruction not exceeding 50% of the height of the vertebrae, or (b) bony destruction exceeding 50% of the height of the vertebrae, but with no serious bone cortical destruction and at least one side of the affected vertebra could be implanted with pedicle screws. (5) The tuberculosis lesion is mainly in the former column and the posterior column was not involved.

This study has some limitations. Firstly, this study is a non-randomized controlled study. Secondly, the sample size of this study is small and follow-up time is short. Thirdly, surgeons may have different experiences in the three bone graft methods.

In conclusion, the three bone graft methods including iliac bone graft, titanium mesh bone graft and granular bone graft can achieve similar clinical efficacy in correcting kyphosis, alleviating clinical symptoms and improving neurological function in the surgical treatment of single segment lumbar STB via one stage posterior debridement, bone graft and internal fixation, but granular bone graft can result in less surgical trauma and faster bone graft fusion.

Competing financial interests

The author(s) declare no competing financial interests.

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Figure legends

Fig. 1. Comparison of operative time (a), operative blood loss (b), postoperative hospital stay (c), VAS score (d), ESR (e) and CRP (f) among the three groups. (# Inter-group comparison, $P<0.05$; * Intra-group comparison, compared with preoperative, $P<0.05$)

Fig. 2. Comparison of preoperative, postoperative and last follow-up Cobb angle (a), Cobb angle correction and loss (b), follow-up time and bone fusion time (c) among the three groups. (# Inter-group comparison, $P<0.05$; * Intra-group comparison, compared with preoperative, $P<0.05$; & Intra-group comparison, compared with postoperative, $P<0.05$).

Fig. 3. A 28-year-old male with L4-5 STB in iliac bone graft group. (a~d) Preoperative MRI and CT showed that L4 and L5 vertebra body and the intervertebral disc were destroyed. (e, f) Postoperative X-ray. (g~j) CT at 8 months postoperative showed bone fusion between L4 and L5. (k, l) X-ray at 29 months postoperative showed good location of posterior instrument.

Fig. 4. A 23-year-old male with L4-5 STB in titanium mesh bone graft group. (a~d) Preoperative CT and MRI showed that L4 and L5 vertebra body and the intervertebral disc were destroyed, and lumbar instability was formed. (e, f) Postoperative X-ray. (g~j) CT at 10 months postoperative showed bone fusion between L4 and L5. (k, l) X-ray at 28 months postoperative showed good location of titanium mesh and posterior instrument and normal lumbar lordosis.

Fig. 5. A 36-year-old male with L4-5 STB in granular bone graft group. (a~d) Preoperative CT showed that L5 vertebra body and the L4/5 intervertebral disc were destroyed, but with no serious bone cortical destruction. (e, f) Postoperative X-ray. (g~j) CT at 5 months postoperative showed bone fusion between L4 and L5. (k, l) X-ray at 24 months postoperative showed good location of posterior instrument.

Tables

Table 1. Comparison of general data of the three groups.

Table 2. Comparison of ASIA grade of the three groups.

Table 3. Comparison of postoperative complications of the three groups.

Table 1. Comparison of general data of the three groups.

Items	Iliac bone graft (n=32)	Titanium mesh bone graft (n=32)	Granular bone graft (n=34)	P-value
Age (year), mean±SD	43.3±15.8	38.9±13.1	39.7±15.7	0.456
Gender (Male / Female)	16 / 16	17 / 15	16 / 18	0.886
Cold abscess (Yes / No)	20 / 12	18 / 14	23 / 11	0.634
BMI (kg/m^2), mean±SD	22.2±2.1	21.5±2.0	21.3±2.1	0.239
ASA grade (n)				
□	21	19	22	0.951
□	9	11	9	
□	2	2	3	
Comorbidities (n)				0.956
Hypertension	3	5	6	
Diabetes	4	3	3	
Cardiovascular diseases	3	2	3	
Lung diseases	1	2	2	

Table 2. Comparison of ASIA grade of the three groups.

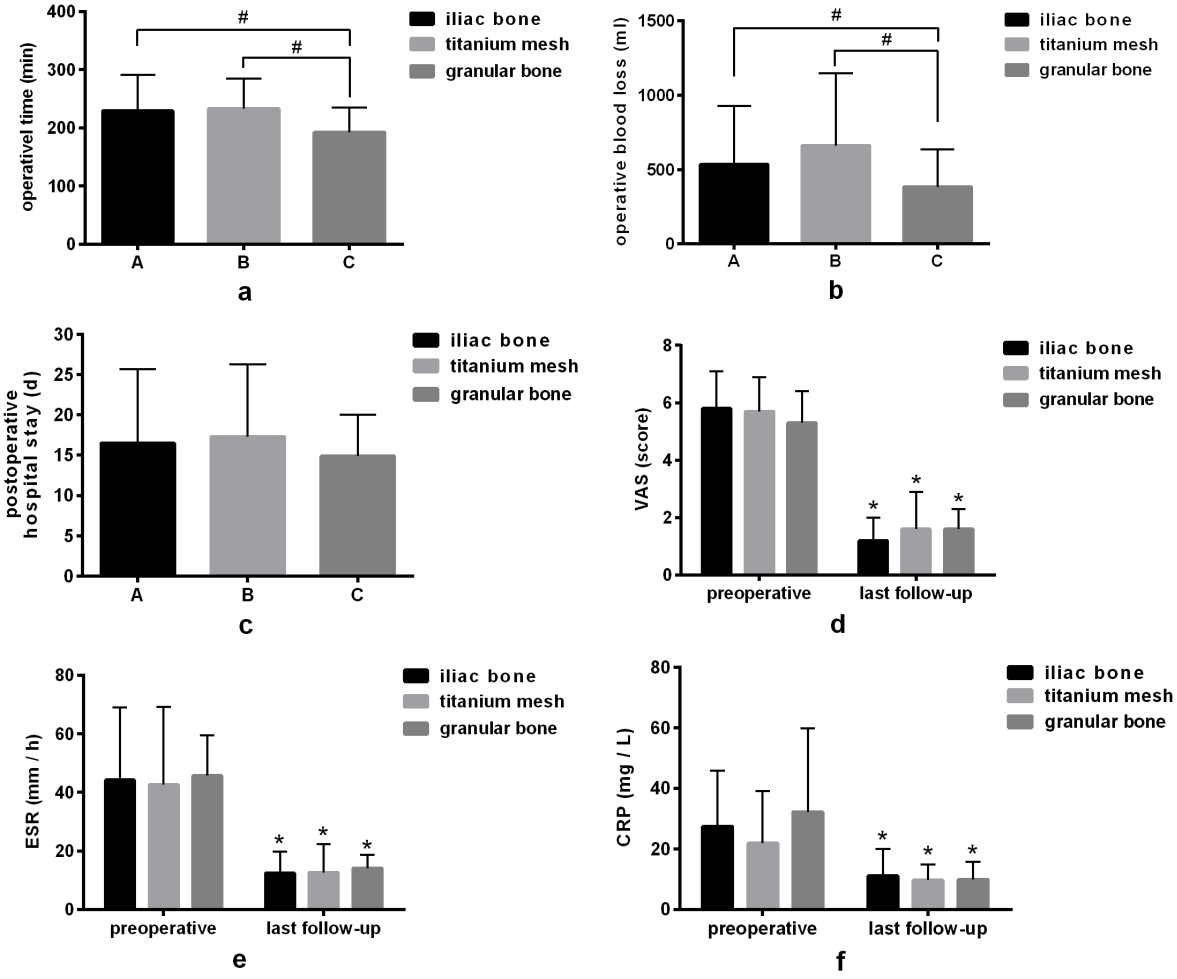
ASIA grade	Iliac bone graft (n=32)	Titanium mesh bone graft (n=32)	Granular bone graft (n=34)	P-value
Preoperative ASIA grade				0.968
A	0	0	1	
B	0	0	0	
C	1	1	4	
D	9	8	4	
E	22	23	25	
Last follow-up ASIA grade *				0.233
A	0	0	0	
B	0	0	1	
C	0	0	0	
D	1	1	3	
E	31	31	30	

* Compared with preoperative, P-values of the three groups were 0.004, 0.003 and 0.004, respectively.

Table 3. Comparison of postoperative complications of the three groups.

Complications	Iliac bone graft (n=32)	Titanium mesh bone graft (n=32)	Granular bone graft (n=34)
Cerebrospinal fluid keakage	0	1	0
Hepatic dysfunction	2	3	2
Renal dysfunction	1	2	3
Sinus formation	3	2	3
Pulmonary infection	2	2	3
Urinary tract infection	2	1	1
Deep vein thrombosis	1	1	2
In total [#]	11	12	14

[#] Compared among the three groups, P=0.547.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iliac bone
titanium mesh
granular bone
operative blood loss (ml)
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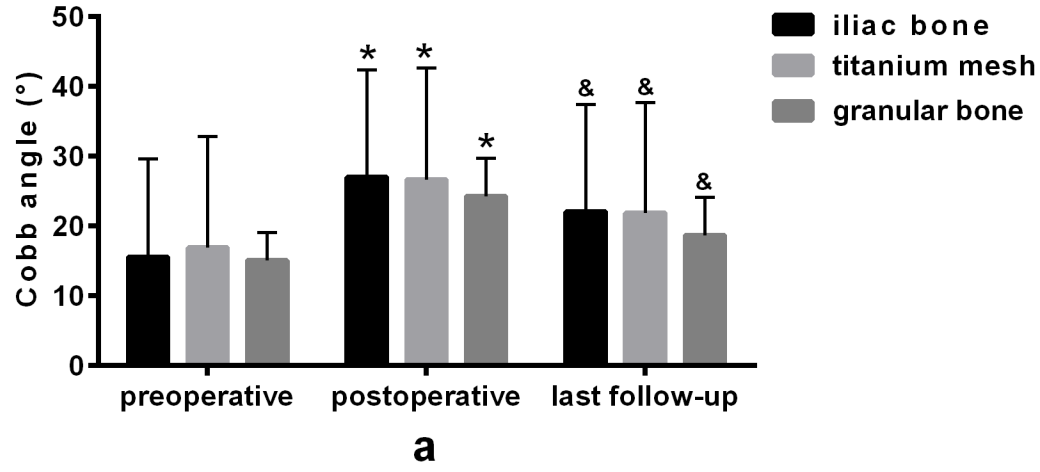
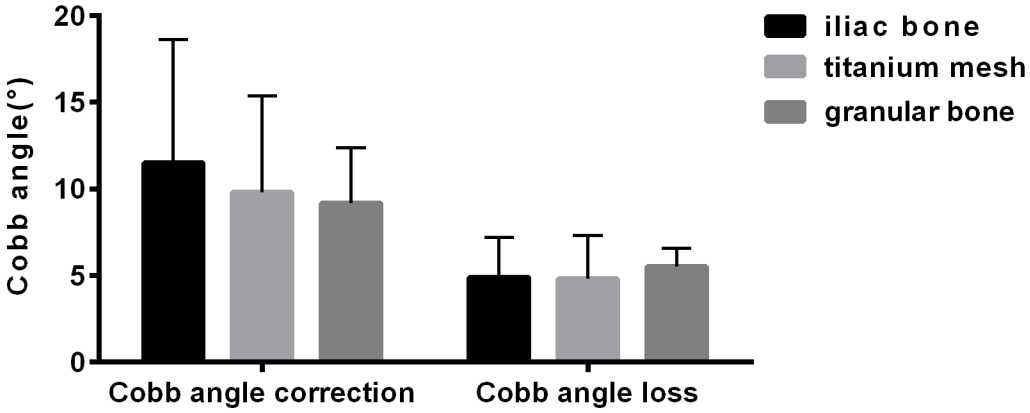
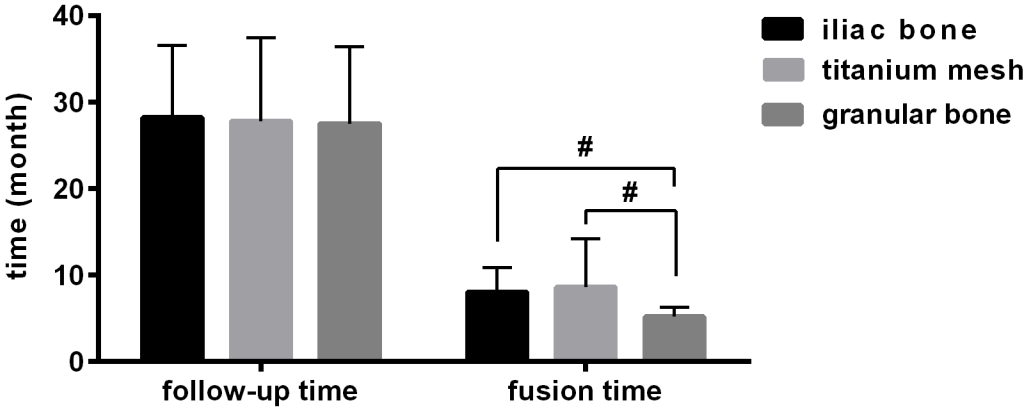
1000
500
0
#
#
A
B
C
b
iliac bone
titanium mesh
granular bone
postoperative hospital stay (d)
30
25
20
15
10
5
0
A
B
C
c
iliac bone
titanium mesh
granular bone
VAS (score)
8
6
4
2
0
*
*
*
preoperative
last follow-up
d
iliac bone
titanium mesh
granular bone
ESR (mm / h)
80
60
40
20
0
*
*
*
preoperative
last follow-up
e
iliac bone
titanium mesh
granular bone
CRP (mg / L)
80
60
40
20
0
*
*
*
preoperative
last follow-up
f
iliac bone
titanium mesh
granular bone


Cobb angle (°)
50
40
30
20
10
0
*
*
*
&
&
&
preoperative
postoperative
last follow-up
iliac bone
titanium mesh
granular bone

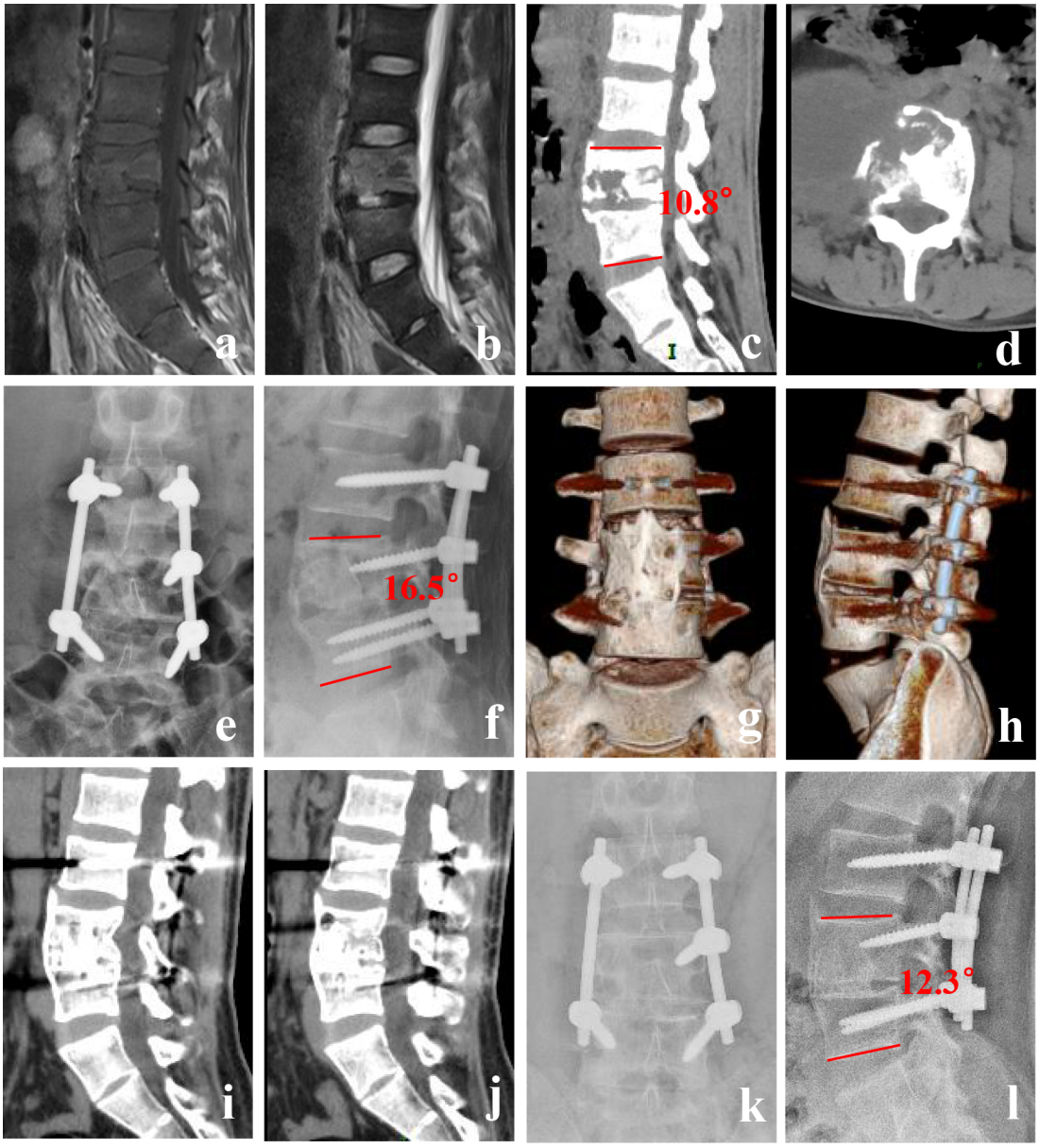
a

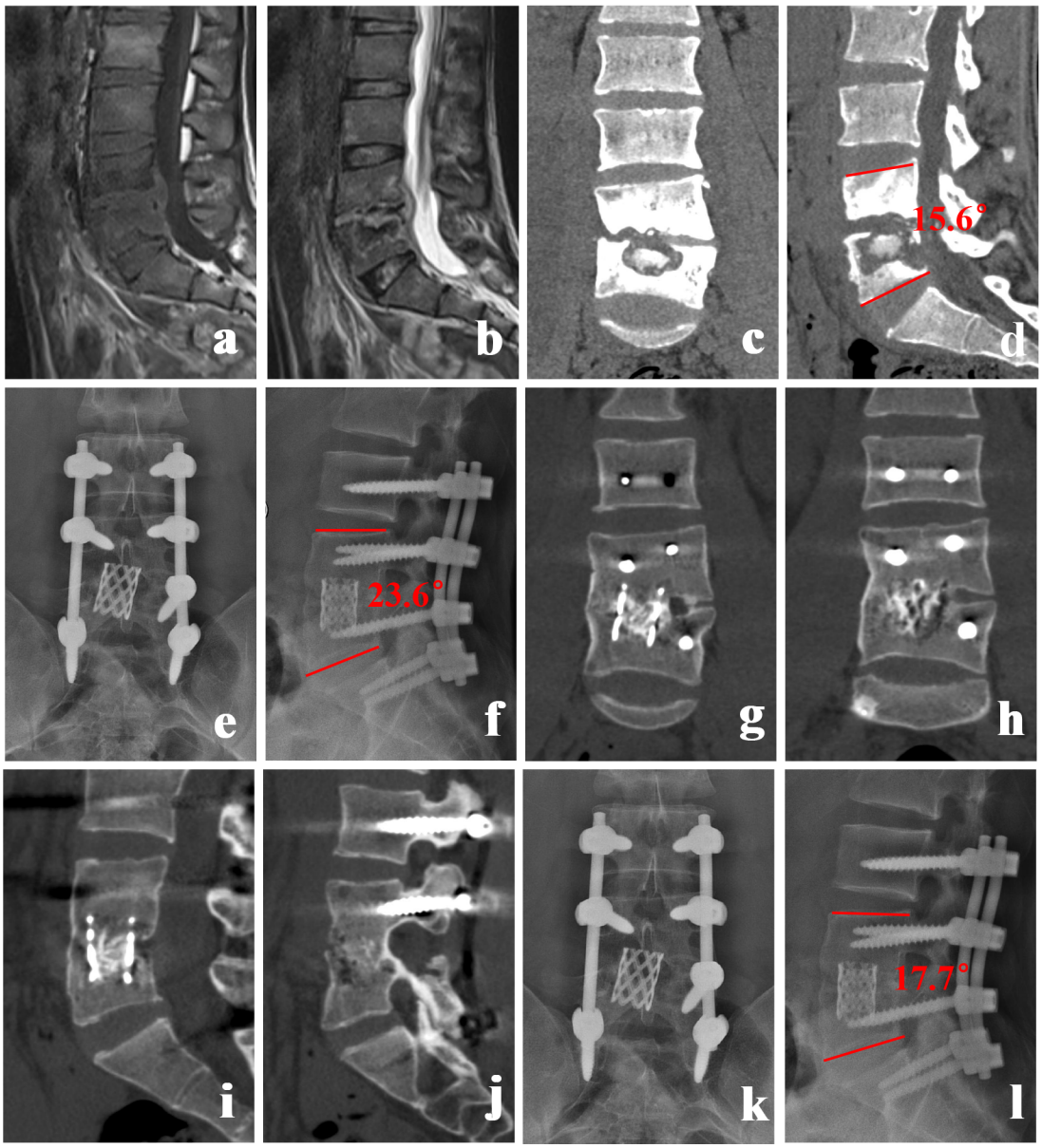

Cobb angle(°)
20
15
10
5
0
Cobb angle correction
Cobb angle loss
iliac bone
titanium mesh
granular bone

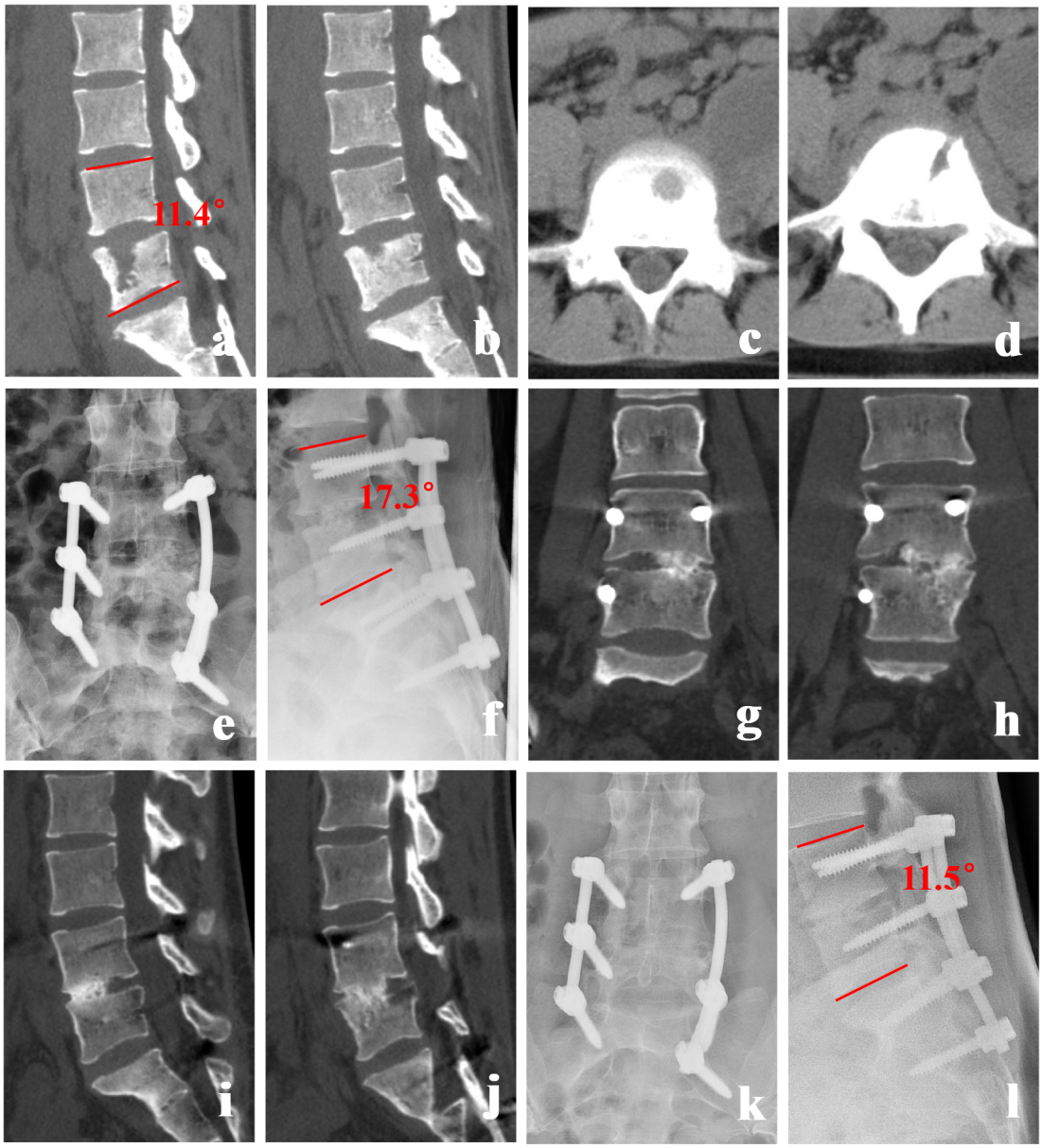
b


time (month)
40
30
20
10
0
#
#
follow-up time
fusion time
iliac bone
titanium mesh
granular bone

c


a
b
10.8°
c
d
e
16.5°
f
g
h
i
j
k
12.3°
l


a
b
c
d
15.6°
e
f
23.6°
g
h
i
j
k
l
17.7°


11.4°
a
b
c
d
e
17.3°
f
g
h
i
j
k
11.5°
l

Data Statement

I wish to give a statement explaining why I am not linking to or uploading my research data. Data will be made available on request.

Highlights

- Retrospective comparison of iliac bone graft, titanium mesh bone graft and granular bone graft in single segment lumbar tuberculosis surgery.
- Iliac bone graft, titanium mesh bone graft and granular bone graft can achieve similar VAS score, ESR, CRP, kyphosis correction, neurological function and complications.
- Granular bone graft has shorter operative time, less operative blood loss and shorter bone graft fusion time compared with iliac bone graft and titanium mesh bone graft.

The STROCSS 2019 Guideline		
Item no.	**Item description**	**Page**
TITLE		
1	Title: - The word cohort or cross-sectional or case-controlled is included - The area of focus is described (e.g. disease, exposure/intervention, outcome) - Key elements of study design are stated (e.g. retrospective or prospective)	1
ABSTRACT		
2a	Introduction: the following points are briefly described - Background - Scientific Rationale for this study	1
2b	Methods: the following areas are briefly described - Study design (cohort, retro-/prospective, single/multi-centred) - Patient populations and/or groups, including control group, if applicable - Interventions (type, operators, recipients, timeframes) - Outcome measures	1
2c	Results: the following areas are briefly described - Summary data (with statistical relevance) with qualitative descriptions, where appropriate	1-2
2d	Conclusion: the following areas are briefly described - Key conclusions - Implications to practice - Direction of and need for future research	2
INTRODUCTION		
3	Introduction: the following areas are described in full - Relevant background and scientific rationale - Aims and objectives - Research question and hypotheses, where appropriate	3-5
METHODS		
4a	Registration and ethics - Research Registry number is stated, in accordance with the declaration of Helsinki* - All studies (including retrospective) should be registered before submission *"*Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject*" (this can be obtained from: ResearchRegistry.com or ClinicalTrials.gov or ISRCTN)	5
4b	Ethical Approval: the following areas are described in full - Necessity for ethical approval - Ethical approval, with relevant judgement reference from ethics committees - Where ethics was unnecessary, reasons are provided	5
4c	Protocol: the following areas are described comprehensively - Protocol (*a priori* or otherwise) details, with access directions - If published, journal mentioned with the reference provided	N/A

4d	Patient Involvement in Research - Describe how, if at all, patients were involved in study design e.g. were they involved on the study steering committee, did they provide input on outcome selection, etc.	5
5a	Study Design: the following areas are described comprehensively - 'Cohort' study is mentioned - Design (e.g. retro-/prospective, single/multi-centred)	5
5b	Setting: the following areas are described comprehensively - Geographical location - Nature of institution (e.g. academic/community, public/private) - Dates (recruitment, exposure, follow-up, data collection)	5
5c	Cohort Groups: the following areas are described in full - Number of groups - Division of intervention between groups	5
5d	Subgroup Analysis: the following areas are described comprehensively - Planned subgroup analyses - Methods used to examine subgroups and their interactions	N/A
6a	Participants: the following areas are described comprehensively - Eligibility criteria - Recruitment sources - Length and methods of follow-up	5-6
6b	Recruitment: the following areas are described comprehensively - Methods of recruitment to each patient group - Period of recruitment	5-6
6c	Sample Size: the following areas are described comprehensively - Margin of error calculation - Analysis to determine study population - Power calculations, where appropriate	5-6
INTERVENTION AND CONSIDERATIONS		
7a	Pre-intervention Considerations: the following areas are described comprehensively - Patient optimisation (pre-surgical measures) - Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications)	6
7b	Intervention: the following areas are described comprehensively - Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) - Aim of intervention (preventative/therapeutic) - Concurrent treatments (antibiotics, analgaesia, anti-emetics, NBM, VTE prophylaxis) - Manufacturer and model details where applicable	6-8
7c	Intra-Intervention Considerations: the following areas are described comprehensively - Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time) - Pharmacological therapies include formulation, dosages, routes and durations - Figures and other media are used to illustrate	6-8

7d	Operator Details: the following areas are described comprehensively - Training needed - Learning curve for technique - Specialisation and relevant training	7-8
7e	Quality Control: the following areas are described comprehensively - Measures taken to reduce variation - Measures taken to ensure quality and consistency in intervention delivery	7-8
7f	Post-Intervention Considerations: the following areas are described comprehensively - Post-operative instructions and care - Follow-up measures - Future surveillance requirements (e.g. imaging, blood tests)	8
8	Outcomes: the following areas are described comprehensively - Primary outcomes, including validation, where applicable - Definitions of outcomes - Secondary outcomes, where appropriate - Follow-up period for outcome assessment, divided by group	8-9
9	Statistics: the following areas are described comprehensively - Statistical tests, packages/software used, and interpretation of significance - Confounders and their control, if known - Analysis approach (e.g. intention to treat/per protocol) - Sub-group analysis, if any	9
RESULTS		
10a	Participants: the following areas are described comprehensively - Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons) - Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences)	10
10b	Participant Comparison: the following areas are described comprehensively - Table comparing demographics included - Differences, with statistical relevance - Any group matching, with methods	10
10c	Intervention: the following areas are described comprehensively - Changes to interventions, with rationale and diagram, if appropriate - Learning required for interventions - Degree of novelty for intervention	10
11a	Outcomes: the following areas are described comprehensively - Clinician-assessed and patient-reported outcomes for each group - Relevant photographs and imaging are desirable - Confounders to outcomes and which are adjusted	10-11
11b	Tolerance: the following areas are described comprehensively - Assessment of tolerance - Loss to follow up, with reasons (percentage and fraction) - Cross-over with explanation	11
11c	Complications: the following areas are described comprehensively - Adverse events described - Classified according to Clavien-Dindo classification* - Mitigation for adverse events (blood loss, wound care, revision surgery	11

	should be specified) *Dindo D, Demartines N, Clavien P-A. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. 2004; 240(2): 205-213	
12	Key Results: the following areas are described comprehensively - Key results, including relevant raw data - Statistical analyses with significance	10-11
DISCUSSION		
13	Discussion: the following areas are described comprehensively - Conclusions and rationale - Reference to relevant literature - Implications to clinical practice - Comparison to current gold standard of care - Relevant hypothesis generation	11-13
14	Strengths and Limitations: the following areas are described comprehensively - Strengths of the study - Limitations and potential impact on results - Assessment of bias and management	13-14
15	Implications and Relevance: the following areas are described comprehensively - Relevance of findings and potential implications to clinical practice are detailed - Future research that is needed is described, with study designs detailed	14
CONCLUSION		
16	Conclusions: - Key conclusions are summarised - Key directions for future research are summarised	14
DECLARATIONS		
17a	Conflicts of interest - Conflicts of interest, if any, are described	14
17b	Funding - Sources of funding (e.g. grant details), if any, are clearly stated	14