Can posterior stand-alone expandable cages safely restore lumbar lordosis? A minimum 5-year follow-up study

Seung-Kook Kim
University Hospital Sharjah
Ogeil Mubarak Elbashier
University Hospital Sharjah
Su-chan Lee
Himchan Hospital
Woo-jin Choi (neurocwj@hanmail.net)
Incheon Sarang Hospital

Research article

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Abstract

Background: Lumbar lordosis (LL) can be restored and screw-related complications may be avoided with the stand-alone expandable cage method. However, the long-term spinopelvic profile changes and safety remain unknown. We aimed to elucidate the long-term radiologic outcomes and safety of this technique.

Methods: Data from a total of 69 patients who underwent multi-level stand-alone expandable cage fusion and 80 patients who underwent screw-assisted fusion between February 2007 and December 2012, with at least 5 years of follow-up, were retrospectively analyzed. Segmental angle and translation, short and whole LL, pelvic incidence, pelvic tilt, sacral slope (SS), sagittal vertical balance, thoracic kyphosis, and presence of subsidence, pseudoarthrosis, retropulsion, cage breakage, proximal junctional kyphosis (PJK), and screw malposition were assessed. The relationship between local and spinopelvic effects was investigated. The implant failure rate was considered a measure of procedure effectiveness and safety.

Results: The stand-alone expandable cage fusion group showed shorter operative times, a lower rate of PJK, and better improvements in segmental angles than the control group, and there was a positive correlation with LL. However, the whole LL was not restored; the SS significantly increased; and subsidence, pseudoarthrosis, and retropulsion rates were significantly higher than those in the control group.

Conclusions: Stand-alone expandable cage fusion can restore local lordosis, however, global sagittal balance was not restored. Furthermore, implant safety still has not been proven.

Background

With the global aging society, degenerative lumbar spine disease is becoming a common health issue. Degenerative lumbar spine disease not only causes spinal stenosis, but it is also related to structural and functional problems. Sagittal imbalance is one such problem and is a crucial contributing factor to a decreased quality of life.[1,2]

Various approaches have been investigated to restore lumbar lordosis (LL) and sagittal balance. Direct decompression and fusion methods, including posterior lumbar interbody fusion and transforaminal lumbar interbody fusion, can achieve both canal decompression and solid fusion; nonetheless, the invasiveness into the bone and musculature is a drawback.[3] With the indirect decompression method, anterior lumbar interbody fusion[4] and lateral lumbar interbody fusion[5] can achieve a greater lordotic curve than that via the posterior approach; however, the possibility of incomplete decompression is a shortcoming.

Stand-alone expandable cages have been designed for restoring LL and correcting sacropelvic imbalance with simultaneous canal decompression. Additionally, these cages help avoid screw-related complications. To the best of our knowledge, the long-term outcomes and safety of this procedure have not been established to date. This study aimed to elucidate the long-term radiologic efficacy of this procedure and evaluate its safety.

Methods

Study Design and Population

This retrospective study reviewed prospective cohort medical data and radiographic findings of patients consecutively treated between February 2007 and December 2012 in a single spine institute. This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and was approved by the institutional review board (XXX IRB 169684-01-201906-04); furthermore, written informed consent was obtained from all patients. This manuscript adheres to the STROBE recommendations for reporting observational studies. Study population selection is shown in Figure 1.

The safety and efficacy of single-level sagittal restoration are controversial[6] and proximal junctional kyphosis (PJK) shows different sagittal and spinopelvic profiles.[7] Among the 1,088 cases of fusion surgery, we applied the following inclusion criteria: 1) degenerative lumbar disease symptoms present for longer than 2 months, 2) spinal instability confirmed on dynamic X-ray but spondylolisthesis grade I or II only, 3) involvement of at least two spinal levels, and 4) availability of at least 5 years' worth of follow-up data. The exclusion criteria were 1) other causes of deformity (e.g., adolescent idiopathic scoliosis), 2) presence of a tumor, 3) infection, or 4) trauma.

Of the 385 remaining cases after the application of the inclusion and exclusion criteria, 235 cases were excluded due to not response to contact. The final patient group (n = 149) was divided into an experimental group (n = 69) who received an expandable cage and a control group (n = 80) who underwent posterior lumbar interbody fusion or transforaminal lumbar interbody fusion.

Operative Technique and In-Hospital Management

In most cases, we applied a facet-preserving technique[8] to support interbody fusion. To preserve sagittal stability before fixed interbody fusion, more than 50% of the facet was preserved. The surgery was performed after spinal or epidural anesthesia. After applying an aseptic operative field dressing with alcohol and betadine, spinal levels were checked with a c-arm before incisions were made. After a midline incision was made based on the operative level, both multifidus muscles were dissected with a monopolar coagulator. Laminectomy was performed with a high-speed air drill and Kerrison punches, and the lower half of the upper laminar, lower half of the spinous process, and upper half of the lower laminar were removed. The ligamentum flavum was removed after the bone and ligament junction were detached with curettes. After meticulous bleeding control in the disc space, total discectomy was performed with a knife, pituitary forceps, and shavers. Rotating type of 8-10 degrees expandable interbody cages were used (Varian™, Medyssey co., Jecheon, Korea) for cage implantation. After fluoroscopic confirmation with the c-arm, muscle and skin were sutured layer by layer. Patients had 3 days of bed rest, and radiography was performed on postoperative day (POD) 3 and POD 15. Patients were fitted with a thoracolumbar sacral orthosis to be used as a brace for 2 months post-surgery.

In the control group, the same laminectomy and discectomy procedures were performed; subsequently, a polyetheretherketone cage was inserted bilaterally, and pedicular screws and lordotic curved rods were applied. Ambulation started on POD 1, and radiography was performed on POD 1 and POD 10. The control group was also fitted with a thoracolumbar sacral orthosis to be used as a brace for 2 months post-surgery.

After the procedure, both groups were prescribed intravenous patient-controlled analgesia, acetaminophen (1000-1500mg/day) and intermittent neuroleptics (pregabalin ,150-300mg/day) and opioids(pethidine 50mg, intramuscular). Blood tests were performed on PODs 3 and 7 to check for inflammation. Follow-up examinations were performed in the outpatient clinic at 2 weeks, 1 month, and 6 months post surgery, and then annually thereafter.

Radiographic Assessment

The radiographic variables used in this study are shown in Table 1. Segmental parameters, such as the segmental angle and translation, were measured[9] to evaluate the local effect (Figure 2a). For the evaluation of LL, the short LL and whole LL were quantified.[10] The following spino-pelvic parameters were calculated: pelvic incidence (PI), pelvic tilt (PT), and sacral slope (SS) (Figure 2b).[11] Global sagittal balance was examined using sagittal vertical balance, and thoracic kyphosis was measured using a compensation mechanism.[11] Implant failures included subsidence,[12] pseudoarthrosis, retropulsion, cage breakage, PJK, and screw malposition.[13] All data were measured by three observers (SKK, OME and WJC) who had all worked as spinal physicians for more than 10 years.

Statistical Analysis and Proficiency Matching

Statistical analyses were performed using R software for Windows version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria). A P-value of less than .05 was considered statistically significant. Continuous variables (age, operative time, hospital stay, and all radiologically measured angles and lengths) were compared using the unpaired Student t-test. Categorical variables (sex, operative type, and preoperative medical grade) were compared using the chi-square test. Proficiency matching between the segmental angle, LL, PI, and sagittal vertical balance was analyzed using the Pearson correlation analysis.

Results

Baseline Demographics

Demographic data are summarized in Table 2. Age, sex, duration of symptoms, follow-up duration, and preoperative medical condition did not significantly differ between the two groups. The majority of surgeries performed involved two spinal levels, as opposed to three levels, in both groups (cage-alone, 95.66%; control, 93.75%; P = .45). The mean operative time was shorter in the cage-alone group than in the control group (58.48 minutes/level versus 81.43 minutes/level; P < .01). Hospital stay was longer in the cage-alone group than in the control group (14.10 days versus 10.12 days; P < .01).

Radiologic Outcomes

Evaluation of the preoperative, short-term, and final radiologic outcomes are summarized in Table 3. With respect to the comparison of local and lumbar factors, the segmental angle was significantly corrected (P < .01) (Figure 3a). The segmental angle and short LL were greatly corrected in short-term results, and the correction angle decreased in both groups. The segmental angle and LL showed a significant positive correlation in the Pearson correlation analysis (Figure 3b) (r = 0.223, P = .0063). However, this segmental lordosis correction did not restore LL (P = .5049) (Figure 3c). Although SS significantly increased (P = .0027) (Figure 3d), PT decreased; as a result, PI was not significantly changed. Overall, global sagittal balance did not significantly change in either group.

SS also showed a positive correlation with segmental angle correction (Figure 3e); however, this segmental angle correction did not show a significant positive correlation with PI (Figure 3f).

Implant Failures

Implant problems, including cage- and screw-related complications, are summarized in Table 4. Subsidence (Figure 4a), pseudoarthrosis (Figure 4b), cage breakage (Figure 4c), and retropulsion (Figure 4d) rates were significantly higher in the cage-alone group than in the control group (P < .01, P = .02, P = .02, and P = .02, respectively). However, the rates of PJK and screw malposition were significantly higher in the control group than in the cage-alone group (P = .03 and P = .02, respectively).

Discussion

To our knowledge, this study is the first to report the long-term outcomes of posterior stand-alone expandable cage fusion surgery. In this study, insertion of an expandable cage alone not only increased the segmental angle but also correlated positively with LL. However, LL was not corrected, and the SS increased. High implant failure rates, weak support of the posterior element, and compensatory mechanisms are possible factors affecting these results. Based on our results, we have drafted a relationship chart of these factors (Figure 5).

Are There Any Advantages to the Posterior Stand-Alone Expandable Cage Approach?

Screw placement at the pedicle has been regarded as the standard posterior stabilization procedure since 1969, and it was first introduced by Harrington and Tullos.[14] The efficacy and superior support of this technique compared with other techniques, particularly the superior biomechanical strength[15] and presence of three columns, which provide more support than other techniques,[16,17] have been reported.

However, this technique needs wide exposure for screw insertion and anatomic landmark confirmation. Furthermore, the reported rate of screw malposition ranges from 0 to 42%.[18,19] Because we skipped the process of screw placement in this study, operative time was saved, the paraspinal and posterior facet complex was preserved with a small incision, and radiation exposure was reduced. Compared with the anterior lumbar interbody fusion and lateral lumbar interbody fusion procedures, simultaneous direct decompression can be performed and abdominal organs or hypogastric nerve injury can be avoided.[20,21] Our results show that both the cage-alone and screw fixation groups had decreased segmental angles in the long-term, with expandable cages achieving a greater angle change. This shows that expandable cages have the effect of local angle correction. In addition, we found that the rate of PJK was significantly lower in the cage-alone group when compared to the control group. As PJK is induced by overloading the junctional disc space,[22] our facet-preserving technique might result in less junctional disc space overload than the firmly fixed screw technique.

Is Interbody Fusion Without Screw Fixation Safe?

Compared with other fusion procedures, the possible complications of interbody fusion without screw fixation are different. In posterior fusion with a cage, owing to the wide exposure and screw placement, dural tear, rod fracture, PJK, and root damage are common complications.[23] With a stand-alone anterior or oblique approach, insufficient decompression means that additional decompression is required, and psoas muscle weakness and abdominal and vessel injuries[24] are common complications. During the short-term period, patients who received a posterior expandable cage-alone reported minor complications, such as posterior leg pain, infection, and wound problems.[25] However, long-term complications included implant issues, especially subsidence, pseudoarthrosis, retropulsion, and cage breakage. High subsidence rate and cage breakage can be caused by an excessive restoration of the local angle.[26] The lack of screw during the initial period decreases support, which subsequently leads to higher rates of pseudoartrosis[27] and retropulsion. Even though our series showed implant failure did not need revision and replacement, it could be the reason for postoperative pain and disability during recovery.

Why Is It That an Expandable Cage Cannot Restore Sagittal Balance?

The manufacturers have designed the expandable cages to be able to increase the lordosis by up to 9 degrees; however, our measured mean segmental correction was only 4.66 degrees. Subsidence[26] and pseudoarthrosis[27] are known factors that can reduce the lordotic angle. Cage breakage and retropulsion are possible debilitating events that can decrease LL. This may be the reason why the segmental angle did not correct LL, even though both parameters showed a significant positive relationship. Furthermore, weak posterior fixation can change the sacropelvic profile. In the normal aging process, PT and thoracic kyphosis increase. However, because PI is a consistent parameter,[28] SS increases as a compensatory mechanism. However, our results in the cage-alone group were different. Initially, the SS increased more in the cage-alone group than in the control group because of the lack of posterior support. Consequently, the PT was compensated for; hence, PI was preserved. Posterior screw fixation played a role in maintaining the SS in the control group, and the whole spinopelvic profile was better preserved in the control group than in the cage-alone group.

How to Solve Issues and Gain Better Outcomes

Three issues should be resolved to achieve better outcomes with this technique. First, we need to use more stable and advanced materials for interbody fusion. The use of enhanced titanium or bioactive glass ceramics can reduce the rate of pseudoarthrosis.[29] Second, we need to preserve posterior support. Motion-preserving total disc replacement surgery showed more stable outcomes than the currently evaluated method[30] because of complete preservation of the posterior facet complex. Due to the fact that it is impossible to decompress the posterior canal, modified minimally invasive techniques, such as unilateral approaches, should be considered. Third, we need to increase bone density. The use of teriparatide in femoral fractures showed efficient prevention of bony subsidence[31]; thus, the use of hormones or medication may play a role in achieving better outcomes.

Limitations of the Study and Future Scope

This study has limitations that need to be overcome in further studies. First, because of the retrospective study design, many patients were lost during follow-up, and many confounding factors were present. Despite our strict patient inclusion criteria, the possibility of selection bias could not be eliminated. Second, there may have been major advancements in medications that support bone formation and advancements in the quality of cage materials since the patients in this study were treated. Therefore, it is essential for future studies to address the effects of better bone-forming agents and the application of stronger cage materials. Future studies should also have a multicenter prospective study design.

Conclusions

We reported the long-term outcomes of posterior expandable cage fusion surgery. Stand-alone expandable cage fusion can only restore local lordosis, as global sagittal balance was not restored. Furthermore, long-term implant safety has not been proven. This method needs further investigation in today’s current medical environment of advancements in cage materials and improved medications for bone support.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and was approved by the institutional review board (Himchan IRB 169684-01-201906-04); furthermore, written informed consent was obtained from all patients.

Consent for publication

Not applicable.

Availability of data and materials

We attached our all raw data as a supplementary file.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

SKK designed study, performed all data analysis. WME drafted the manuscript. WJC carried out operation and radiologic evaluation. SCL carried out statistical analysis and supervised all process. All authors read and approved the final manuscript.

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None

Authors' information

Woo-jin Choi MD, PhD is a consultant neurosurgeon in Korea. Seung-kook Kim MD, PhD is a consultant spine surgeon in the United Arab Emirates and Korea. Ogeil Mubarak Elbashier MD is an orthopedic senior specialist in the United Arab Emirates and Malaysia. Su-Chan Lee is a consultant orthopedic surgeon in Korea.

Abbreviations

LL, lumbar lordosis

PJK, proximal junctional kyphosis

POD, postoperative day

PI, pelvic incidence

PT, pelvic tilt

SS, sacral slope

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Tables

Table 1. Descriptions of the measurements and implant failure

Category	Parameter	Definition
Local factor	Segmental angle[32]	Angle between the perpendicular line of the lower endplate of the upper vertebra and upper endplate of the lower vertebra
	Segmental translation[32]	Forward or backward slippage on a lateral radiograph
Lumbar factor	Short lumbar lordosis[5]	Cobb angle between the upper endplate of the fused vertebra and lower endplate of the fused vertebra
	Whole lumbar lordosis[5]	Cobb angle between the upper endplate of L1 and the lower endplate of L5
Spinopelvic factor	Pelvic incidence[23]	Angle between the perpendicular line to the mid-point of the upper sacral endplate and mid-point of both femoral heads
	Pelvic tilt[23]	Angle between the vertical line from the femoral head and center of the sacral endplate
	Sacral slope[23]	Angle between the vertical line and superior sacral endplate
Global sagittal balance	Thoracic kyphosis[23]	Angle between the T4 upper endplate and T12 lower endplate
	Sagittal vertical axis[23]	Distance from the vertical line of the C7 body to the inferior lateral corner of the L5 body
	Sagittal balance[23]	Sagittal vertical axis line located within 5 cm
Implant	Subsidence[22]	Greater or equal to 2 mm loss of height

failure	Pseudoarthrosis[6]	Bony non-union between two vertebrae
	Proximal junctional kyphosis[6]	Proximal junction Cobb angle of at least 10° greater than the preoperative angle
	Screw malposition[6]	Perforated pedicular screw

Table 2. Baseline characteristics of participants

Factor	Total (n = 149)	Stand-alone expandable cage fusion (n = 69)	Screw-assisted fusion (n = 80)	*P*-value
Age (years), mean (SD)	63.25 (8.37)	61.78 (8.05)	64.51 (8.50)	.15[a]
Sex (%) Male Female	38 (25.5) 111 (74.5)	M: 19 (27.54) F: 50 (72.46)	M: 19 (23.75) F: 61 (76.25)	.36[b]
Symptom duration (months), mean (SD)	9.52 (10.40)	10.86 (12.74)	8.36 (7.75)	.14[a]
Follow-up duration (months), mean (SD)	72.91 (17.53)	75.23 (14.23)	70.91 (11.62)	.10[a]
ASA-PS grade, %, mean (SD) 1 2 3	13 (8.72) 144 (87.92) 5 (3.36)	4 (10.14) 67 (86.96) 69 (2.9)	6 (75) 77 (88.75) 1 (3.75)	.82[b]
No. of involved levels, %, mean (SD) 2 3	141 (94.63) 8 (5.37)	66 (95.65) 3 (4.35)	75 (93.75) 5 (6.25)	.45[b]
Operative time/level, min,	70.80	58.48 (11.10)	81.43 (13.75)	<.01[a]*

mean (SD)	(17.01)			
Hospital stay, days, mean (SD)	11.96 (2.85)	14.10 (1.97)	10.12 (2.10)	<.01[a]*

[a]Independent Student t-test

[b]χ-square test

*P < .05

ASA-PS, American Society of Anesthesiologists physical status; F, female; M, male; No., number; SD, standard deviation

Table 3. Comparison of the pre-surgery and final follow-up radiologic parameters in each group

	Stand-alone expandable cage fusion (n = 69)			Screw-assisted fusion (n = 80)			*P*-value
	Pre-op	Final	Δ parameter	Pre-op	Final	Δ parameter	
Segmental angle, degree, mean (SD)	0.54 (3.50)	4.31 (3.97)	4.66 (3.76)	0.88 (3.21)	4.29 (3.52)	2.03 (1.16)	<.01[a]*
Translation, mm, mean (SD)	3.62 (1.88)	1.60 (1.37)	2.02 (1.57)	3.05 (1.59)	0.95 (1.10)	1.66 (1.39)	.95[a]
Short lumbar lordosis, degree, mean (SD)	14.03 (10.17)	16.76 (12.74)	2.73 (9.82)	16.66 (12.87)	17.71 (9.99)	1.05 (9.26)	.28[a]
Whole lumbar lordosis, degree, mean (SD)	28.50 (16.17)	29.02 (17.04)	0.52 (13.79)	31.43 (16.94)	33.40 (14.62)	1.97 (12.55)	.50[a]
Pelvic incidence, degree, mean (SD)	54.73 (10.02)	55.44 (9.08)	-0.68 (11.21)	55.83 (8.96)	55.97 (10.26)	-0.13 (8.08)	.72[a]
Pelvic tilt, degree, mean (SD)	30.80 (9370)	29.50 (10.41)	-1.30 (10.79)	28.04 (9.34)	27.20 (9.16)	-0.83 (9.20)	.77[a]
Sacral slope, degree, mean (SD)	24.01 (8.20)	28.84 (8.00)	4.48 (14.24)	28.04 (8.73)	28.84 (8.75)	-1.51 (13.58)	<.01[a]*
Thoracic kyphosis, degree, mean (SD)	4.69 (3.69)	7.99 (3.89)	3.29 (2.18)	4.53 (3.26)	8.24 (3.71)	3.70 (2.64)	.06[a]
Sagittal vertical axis, cm, mean (SD)	4.10 (1.93)	4.11 (2.26)	0.01 (2.57)	4.14 (2.33)	4.13 (2.33)	0.50 (2.10)	.07[a]

[a]Independent Student’s t-test

*P < .05

SD, standard deviation

Table 4. Comparison of the implant failure rate in each group

Implant failure	Stand-alone expandable cage fusion (n = 69)	Screw-assisted fusion (n = 80)	P-value
Subsidence, no. (%)	18 (26.09)	7 (8.75)	<.01[a]*
Pseudoarthrosis, no. (%)	10 (14.46)	3 (3.75)	.02[a]*
Proximal junctional kyphosis, no. (%)	7 (10.1)	18 (22.5)	.03[a]*
Cage breakage, no. (%)	8 (11.59)	0 (0)	.02[a]*
Cage retropulsion, no. (%)	5 (7.25)	0 (0)	.02[a]*
Screw malposition, no. (%)	0 (0)	6 (6.25)	.02[a]*

[a]Independent Student’s t-test

*P < .05

No., number

Figures

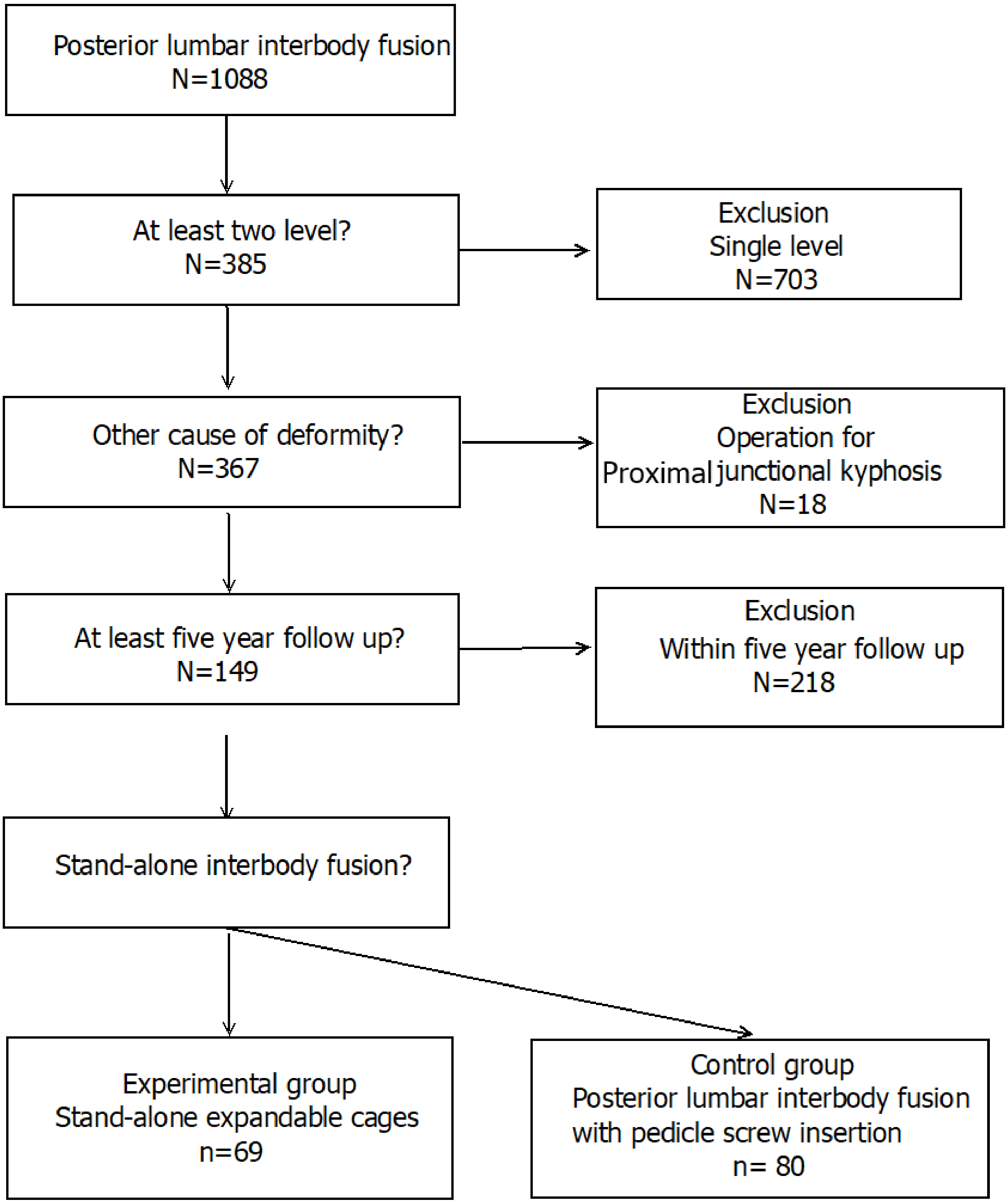

Figure 1

Study population selection

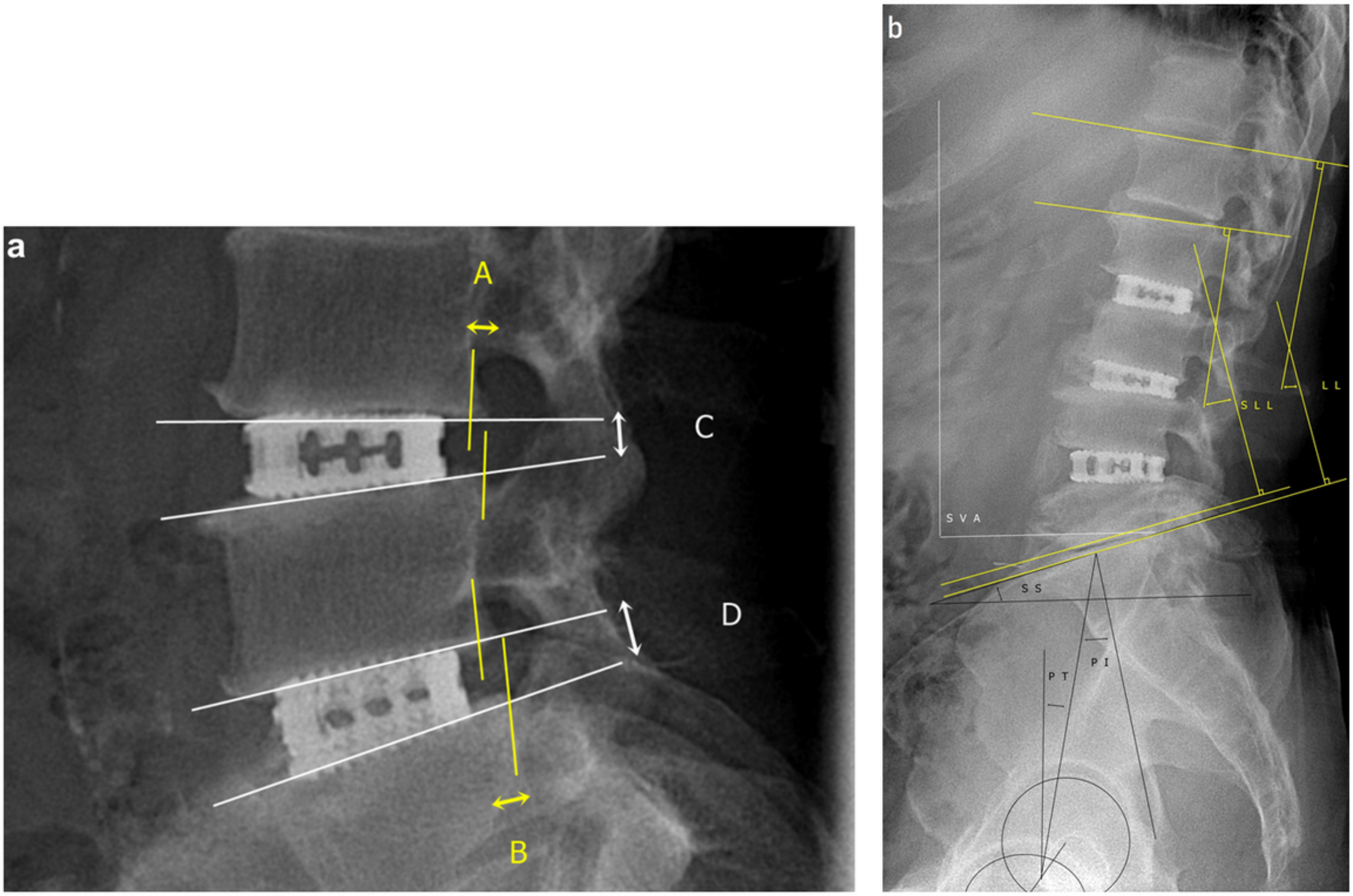

Figure 2

Radiologic parameters (a) Local factors. Translation is calculated as the mean of the diameters of translation (yellow characters). Segmental angle is calculated as the mean of the Cobb angles (white characters). (b) Lumbar factors. Lumbar lordosis (yellow characters) and spinopelvic profile (white characters). PI, pelvic incidence; PT, pelvic tilt; SLL, segmental lumbar lordosis; SS, sacral slope; SVA, sagittal vertical angle; WLL, whole lumbar lordosis

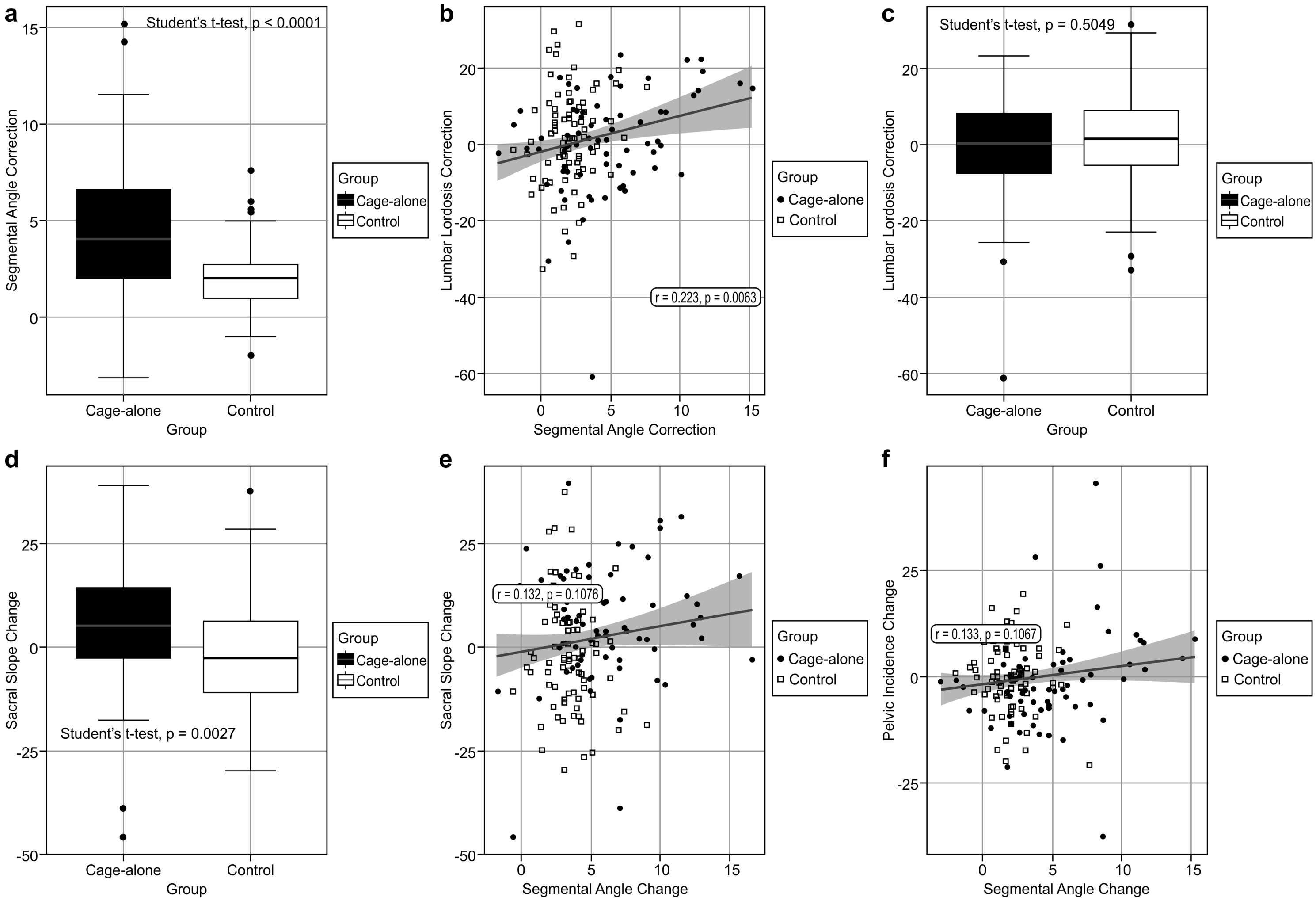

Figure 3

Relationship between sacropelvic profiles (a) Comparison of the mean segmental corrections. (b) Correlation between the segmental angle change and lumbar lordosis. (c) Comparison of the mean lumbar lordosis corrections. (d) Comparison of the mean sacral slope changes. (e) Correlation between the segmental angle change and sacral slope change. (f) Correlation between the segmental angle change and pelvic incidence change.

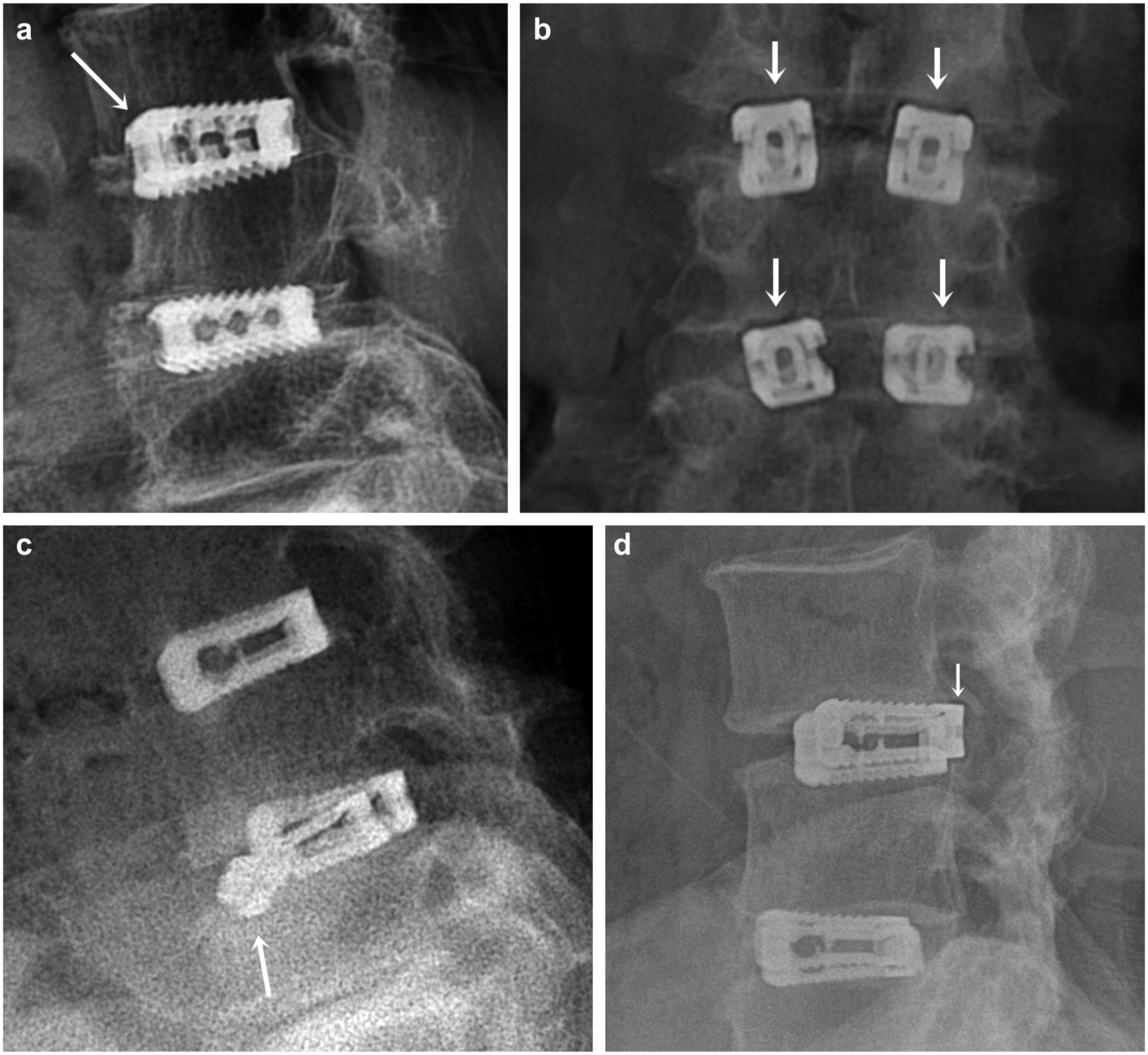

Figure 4

Implant failures after follow-up (a) Lateral radiograph showing subsidence. (b) Anterior-posterior radiograph showing pseudoarthrosis. (c) Lateral radiograph showing cage breakage. (d) Lateral radiograph showing retropulsion.

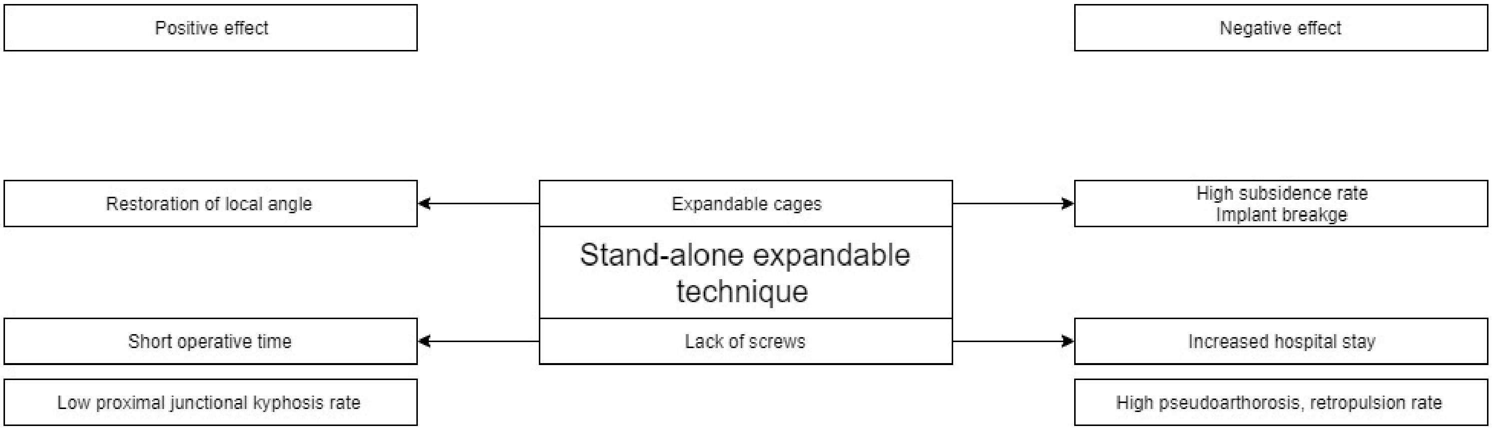

Figure 5

Relationship map of the implant factors, patient factors, and sacropelvic profile

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- STROBEchecklist.doc