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Effects of prior shelf procedure on subsequent conversion total hip arthroplasty

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Abstract

Background It is unclear if shelf acetabuloplasty provides adequate bone coverage when conversion total hip arthroplasty (THA) is required in patients with developmental dysplasia of the hip (DDH). We aimed to investigate the short-term results of conversion THA after shelf acetabuloplasty.

Methods Forty-six patients requiring conversion THAs after a prior shelf acetabuloplasty were matched to THAs for osteoarthritis secondary to Crowe I DDH in a 1:1 ratio. Surgical factors, clinical scores, cup placement, and bone coverage of the cup were evaluated.

Results The preoperative Japanese Orthopaedic Association (JOA) score and flexion range of motion (ROM) were lesser in the shelf group (JOA: 49.2 ± 22.4 vs. 60.1 ± 14.5, $p < 0.01$, flexion ROM: 69 ± 22.4 vs. 82.1 ± 17.5, $p < 0.01$). There were no significant differences in JOA (88.7 ± 8.7 vs. 92.1 ± 8.0,$p = 0.053$) and flexion ROM (93.5 ± 17.3° vs. 99.5 ± 8.0, $p = 0.08$) after the index THA.All cups in both groups were placed at the anatomical hip centre. The cup centre edge angle (cup CE) was significantly lower in the shelf group (21.3°vs. 28.4, $p = 0.0011$), and ratio of cup coverage over the cup was lower in the shelf group (77.0% vs. 86.9%, $p < 0.0001$). There was no significant difference in the number of cases where acetabular bone grafting was performed (87.0% vs. 80.4%, $p = 0.46$). The operative time tended to be longer in the shelf group (117 ± 30.3 min vs. 106.6 ± 25.3 min, $p = 0.06$), and there was no significant difference in intraoperative blood loss (294.3 ± 33.8 vs. 313.3 ± 25.9, $p = 0.50$).

Conclusion Conversion THA after prior shelf acetabuloplasty provided encouraging short-term results with no major complications. Prior shelf acetabuloplasty did not complicate subsequent THA. Bone coverage of the acetabular component was inadequate in total hip arthroplasty, even with prior shelf acetabuloplasty.

Keywords Shelf acetabuloplasty, Conversion total hip arthroplasty, Acetabular osteotomy, Developmental dysplasia of the hip

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Background

In patients with developmental dysplasia of the hip (DDH) without proper treatment, hip osteoarthritis often progresses to the point that requires a hip replacement, also known as total hip arthroplasty (THA).

In the early stages of DDH, some patients undergo acetabular osteotomy to increase coverage over the femoral head to slow down the progression of osteoarthritis. In recent years, rotational acetabular osteotomies (RAO), Chiari osteotomy, and periacetabular osteotomy (PAO) are increasingly performed to rotate the acetabular bone [1, 2]. Shelf acetabuloplasty was originally introduced by Franz König (1891) and has been performed successfully for many years [3]. Shelf acetabuloplasty is a procedure in which a bone graft is taken from the pelvis and grafted to the acetabulum to stabilize the hip joint.

Several reports have showed satisfactory long-term results after shelf acetabuloplasty [2, 4–6]. However, some patients require conversion to THA due to progression of hip osteoarthritis after shelf acetabuloplasty [7, 8].

There are several reports of satisfactory outcomes for conversion THA after shelf acetabuloplasty [7, 9]. Tamaki et al. reported that there were no significant differences in operative time, blood loss, or bone grafting required for THA after shelf acetabuloplasty compared with THA without PO [9].

Although it is expected that there would be a larger acetabular bone stock after shelf acetabuloplasty compared with DDH left untreated, there have been no reports on whether prior shelf acetabuloplasty increases bone coverage over the acetabular component when subsequent THA is performed. Moreover, there have been major limitations in the comparative studies between conversion THA after previous preservation surgery and THA without previous hip surgery, such as the small number and heterogeneity of subjects.

The purposes of this study were: (1) to examine whether patients undergoing THA after previous shelf acetabuloplasty had better clinical outcomes compared to the matched control group (THA without previous surgery) and (2) to examine whether prior shelf acetabuloplasty increases bone coverage over the acetabular component at conversion THA.

Patients and methods

This retrospective study included patients who underwent conversion THA for osteoarthritis progression after the shelf operation performed for DDH at our institute from 1997 to 2020, with a follow-up of more than 1 year after THA. In total, 47 hips (40 patients) were included in the shelf group. The control group consisted of 1,527 patients who underwent primary THA for secondary osteoarthritis due to DDH from 2006 to 2020. Among them, 416 patients (455 hips) with Crowe group I hips, without a history of previous hip surgery were included in the analysis. All patients provided informed consent and the study protocol was approved by the Institutional Review Board of our hospital.

Surgical techniques

All conversion THAs in the shelf group and primary THAs in the matched control group were performed using the lateral or anterolateral approach (Table 1).

The acetabular component was placed at the anatomical hip centre set at a target angle of inclination of 40° and an anteversion angle of 20°.

The choice of cemented or cement-less acetabular components was based on the surgeon's preference. A cemented cup tended to be used when a large bone graft was necessary, while a cement-less cup was used when the bone volume seemed to be sufficient to cover the acetabular component. Autologous bone grafting was

Table 1 Baseline characteristics of propensity-matched Shelf group and matched control group

Variable		Shelf ($n = 46$)	Matched control ($n = 46$)	P value	SMD
Age		56.6 ± 9.1	56.4 ± 9.4	0.91	0.02
Sex (female)		40(87.0%)	39(84.8%)	0.76	0.03
BMI (kg/m^2)		22.6 ± 3.6	23.3 ± 3.9	0.35	0.18
Type of THA				0.82	
	Cemented	15(32.6%)	13(28.3%)		0.14
	Cementless	10(21.7%)	9(19.6%)		0.1
	Hybrid	21(45.7%)	24(52.2%)		0.13
	Reverse Hybrid	0(0%)	0(0%)		
Approach to hip				0.03	
	Anterolateral	26	36		
	Lateral	20	10		
Year THA performed		1997~2020	2006~2020		
Time to conversion THA (year)		29.3 ± 12.3(9~50)	NA		

Values are given as mean ± standard deviation, or number(%)

BMI: body mass index, THA: total hip arthroplasty, SMD: Standardized mean difference

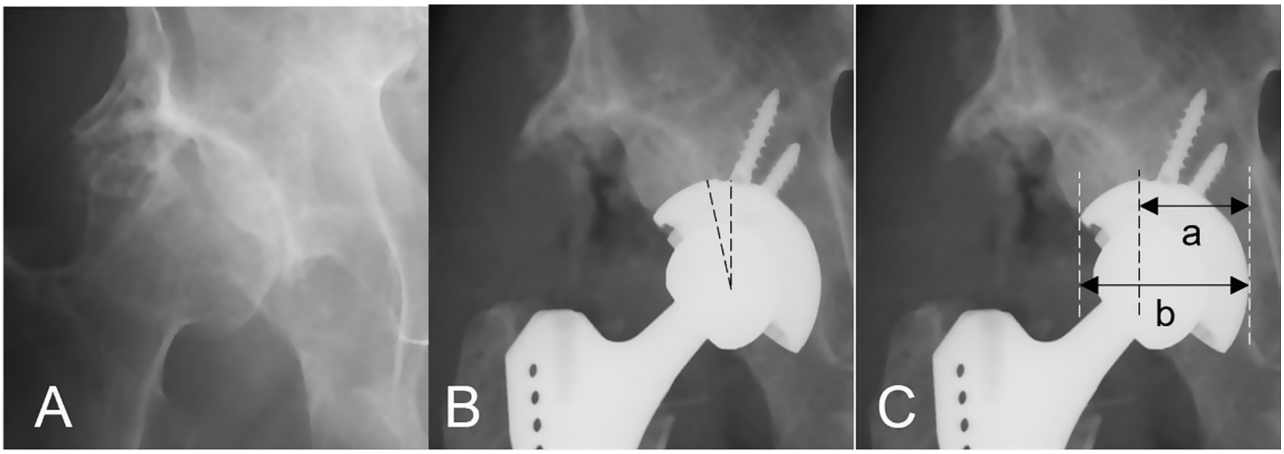

Fig. 1 Radiographic parameters of host bone coverage of acetabular cups are shown. (**B**) The angle is the Cup CE angle.(**C**)The bone coverage index is a/b×100(%)

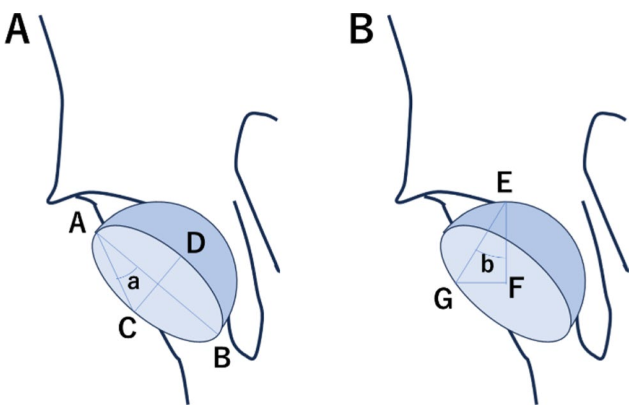

Fig. 2 A diagram illustrates the measurements utilized in the AP radiograph. We created a line connecting points **A** and **B**, identifying point **C** as the midpoint of the lower curve of the ellipse. Following this, we drew a line from **A** to **C**. The angle a is represented by the intersection of Line **AB** and Line **AC**. In (**B**), to assess true anteversion on the AP radiograph, we extended a line from point **E** (the highest point of the semicircle) to point **F** (the center of the ellipse). We then determined point **G** at the intersection of the horizontal line that passes through point F and subsequently drew a line from **E** to **G**. The angle b is defined by Lines **EF** and **EG**

performed when a defect was present between the cup and the acetabulum. Most of the bone grafting is performed by impacting bone chips into the defect between the cup and the acetabulum; however, in cases of larger defects, bulk grafts are secured with screws. This decision is made at the surgeon's discretion.

Evaluation method

Surgery-related factors including the duration of surgery and intraoperative blood loss were compared between the groups. Haemoglobin (Hgb) levels before surgery and at one week after the index THA were compared to evaluate perioperative blood loss.

Radiographic analysis was performed using serial anteroposterior radiographs of the pelvis. We determined the location of the femoral head centre preoperatively and postoperatively, with reference to a line drawn through the teardrops. The vertical height of the centre of the femoral head, perpendicular to this reference line, was measured. The horizontal distance between the lowest point of the teardrop and the centre of the femoral head was measured. Limb lengthening was defined as the reduced distance of the prominent point of the lesser trochanter. This was obtained by comparing the postoperative and preoperative radiographs and corrected according to magnification 10. At the final follow-up, the location of the acetabular component, inclination and anteversion angles, limb length discrepancy (LLD), cup centre-edge (cup-CE) angle, and cup bone coverage index (BCI %), which indicated the lateral bone coverage (excluding the coverage obtained by bone grafting) on the cups 11were measured (Fig. 1).

The cup anteversion angle was evaluated using the Liaw measurement method on plain AP radiographs obtained in the supine position 12(Fig. 2).

For cup placement, the percentage of bone graft to the acetabulum and the percentage of bone graft that required screw fixation were calculated.

JOA hip score and hip range of motion (ROM) were used to evaluate hip function before and 1 year after the index THA. The JOA hip score consists of four components: pain (40 points), ROM (20 points), walking (20 points), and activities of daily living (ADL) (20 points).

Complications (revision surgery, infection, aseptic loosening, and dislocation) during the follow-up period were also assessed. Radiological aseptic loosening was defined as the appearance of a continuous line around the circumference of the acetabular component and its migration (Hodgkinson criteria type 3 and 4) [13, 14].

Statistical analyses

Differences in proportions between the shelf and matched control groups were calculated using Pearson's chi-square test. Differences in means were calculated using Student's t-test. Statistical significance was set at $p<0.05$. The matched control and shelf groups were constructed through 1:1 propensity score matching. Logistic regression analysis was used to compute the propensity for prior shelf acetabuloplasty. Patients' demographic factors (age, sex, BMI, and type of THA [cemented, cementless, hybrid, and reverse hybrid]) were used as covariates in the propensity score. Patients with prior shelf acetabuloplasty were matched to those without any previous hip surgery using calipers with a width equal to 0.2 of the standard deviation of the logit of the propensity score. A 1:1 ratio was used for the matching. Standardized mean differences (SMDs) for all covariates were estimated before and after matching, and balance was considered achieved when the SMD was <0.2. Whether the matching was successful was judged based on the proportion of matched patients and the balance of covariates after matching.

All statistical analyses were performed using JMP Pro 15 software (SAS Institute, Cary, NC, USA).

Results

Of the 47 hips in the shelf group, 46 were successfully matched in a 1:1 ratio with the control group. There were no statistically significant differences between the groups for any of the baseline variables, and the matching was relatively good with SMD<0.2 (Table 1).

Surgical outcomes are presented in Table 2.

The duration of surgery tended to be longer in the shelf group than in the matched control, although the difference was not statistically significant ($p=0.06$).

There was no significant difference in intraoperative blood loss or perioperative Hgb level between the shelf and matched control groups.

Table 2 Operative data and cinical evaluation

Variable	Shelf (*n*=46)	Matched control (*n*=46)	*P* value
Laterality (right)	26(56.5%)	20(44.4%)	0.25
Follow up (year)	9.2±6.6	6.0±3.7	0.005
Duration of surgery (min)	117.6±30.3	106.6±25.3	0.06
Intraoperative blood loss (ml)	294.3±33.8	313.3±25.9	0.5
Hb change (g/dl)	2.07±1.8	2.27±1.2	0.65
Autologous bone grafting	40(87.0%)	37(80.4%)	0.46
Screw fixation for bone graft	13(28%)	10(21.7%)	0.47
Revision	0(0%)	0(0%)	
Infection	0(0%)	0(0%)	
Dislocation	0(0%)	0(0%)	

Values are given as mean±standard deviation, or number(%)

Bone grafting for coverage of the acetabular component was performed in 40 hips (87%) in the shelf group and 37 hips (80.4%) in the matched control group ($p=0.46$). Screw fixation of the graft bone was performed in 13 hips (28.3%) in the shelf group and in 10 hips (21.7%) in the matched control group, with no significant difference ($p=0.47$).

No cases of postoperative infection or dislocation were observed. No revision surgery was performed in the shelf or matched control groups.

The operative functional outcome scores are shown in Table 3.

The flexion range of motion before the index THA was 69.2 ° in the shelf group, which was significantly smaller than that in the matched control group (82.1 °, $p=0.0029$). At one year after THA, the flexion ROM still tended to be smaller; however, the difference was not significant (93.5 ±±±17.3°vs 99.5±12.8, $p=0.053$).

The mean JOA score before THA was 49.2 in the shelf group and 60.1 in the matched control group ($p<0.01$). There were significant differences in the pain, ROM, and walking components. At 1 year after the THA, the mean total JOA score for the shelf group was smaller than that of the matched control group, but the difference was not significant (88.7±8.7 vs. 92.1±8.0, $p=0.053$). A representative case is shown in Fig. 3.

Radiographic outcomes

The radiographic outcomes are shown in Table 4.

The centre of femoral head before THA was higher in the shelf group than in the matched control group (34.4 mm vs. 30.6 mm, $p=0.01$). In contrast, there was no significant difference in the height of the femoral head centre after THA (25.1 mm vs. 24.1 mm, $p=0.34$). All acetabular components in both groups were within the region of the anatomical hip centre, that is, they had a superior displacement of <15 mm from the approximate femoral head centre [15] and a superior displacement of <35 mm from the inter-teardrop line [16].

No aseptic loosening of the cups or stems was observed at the last follow-up. The average of length of radiographic follow-up was 6.0±3.7 in the shelf group and 9.2±6.6 in the matched control group.

In the postoperative radiographic analysis, the cup CE angle was significantly lower in the shelf group than in the matched control group (21.3°vs. 28.4, $p<0.01$). The BCI percentage was also significantly lower in the shelf group than in the matched control group (77% vs. 86.9%, $p<0.01$), indicating that the postoperative bone coverage over the cup in the AP radiograph was smaller in the shelf group.

There were no significant differences in the horizontal distance of the postoperative centre of the femoral

Table 3 Pre and post operative functional outcome scores

	Pre Operation	Shelf (*n* = 46)	missing	Matched control (*n* = 46)	missing	*P* value
ROM	flexion	69.2 ± 22.4		82.1 ± 17.5		0.0029
	extension	2.1 ± 4.5	5	2.4 ± 6.8	3	0.78
	abduction	15.6 ± 8.5		15.3 ± 9.0		0.86
	adduction	10.0 ± 5.9		9.2 ± 6.0		0.54
	external rotation	19.2 ± 16.7		20.9 ± 14.6	2	0.62
	internal rotation	9.9 ± 13.7		7.9 ± 11.1	2	0.46
JOA score	total	49.2 ± 12.4	1	60.1 ± 14.5		0.0002
	Pain	15.1 ± 7.9	1	18.9 ± 8.4		0.03
	ROM	11.6 ± 3.5	1	13.1 ± 3.1		0.03
	Walking	8.1 ± 4.2	1	14.2 ± 5.0		< 0.0001
	ADL	14.2 ± 3.3	1	13.9 ± 3.0		0.593
	Post Operation	**Shelf (*n* = 46)**	**missing**	**Matched control (*n* = 46)**	**missing**	***P* value**
ROM	flexion	93.5 ± 17.3		99.5 ± 12.8		0.08
	extension	4.9 ± 6.8	11	5.0 ± 4.9	5	0.93
	Abduction	26.5 ± 6.5		27.6 ± 5.5		0.39
	adduction	15.2 ± 4.3	9	13.8 ± 4.6	4	0.2
	external rotation	40.8 ± 11.6	9	39.6 ± 17.2	6	0.73
	internal rotation	20.8 ± 11.8	10	22.4 ± 9.0	6	0.42
JOA score	total	88.7 ± 8.7		92.1 ± 8.0		0.053
	Pain	37.9 ± 2.7		38.3 ± 3.5		0.62
	ROM	16.5 ± 2.9		17.1 ± 2.1		0.25
	Walking	16.7 ± 4.5		18.3 ± 2.9		0.052
	ADL	17.5 ± 2.3		18.4 ± 2.2		0.053

Values are given as mean ± standard deviation

ROM: range of motion

JOA: Japan Orthopaedic Association

ADL: activity of daily living

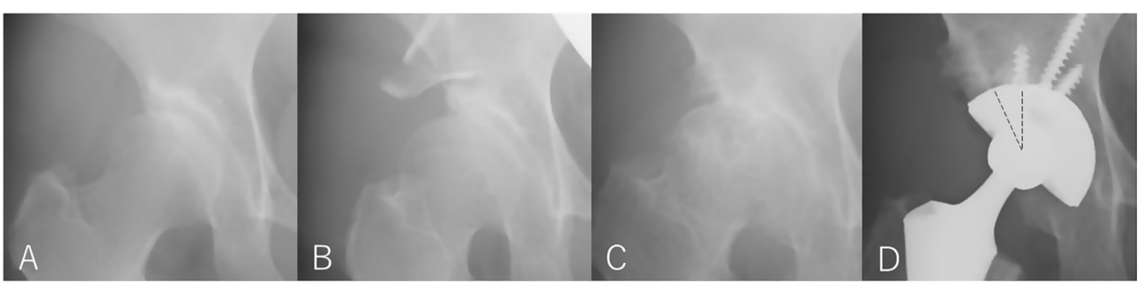

Fig. 3 (**A**)(**B**) 52 year-old women who underwent shelf procedure on right hip. (**C**)(**D**) 9 years after the surgery, she underwent conversion THA due to sereve osteoarthritis on the right hip. Cup CE angle was 17°,and the clinical result was excellent with JOA score of 94

head, cup inclination, cup anteversion, or limb length discrepancy.

Discussion

Shelf acetabuloplasty is performed in adolescents and young adults with developmental dysplasia. This procedure has been associated with good long-term results. While there are many reports on conversion to THA after periacetabular osteotomy, there have only been a few reports on conversion to THA after shelf acetabuloplasty. To the best of our knowledge, this is the first study to examine the clinical and radiographic outcomes of conversion to THA after shelf acetabuloplasty in comparison with a matched control group with a relatively large number of cases (46 hips).

In the present study, the mean interval between THA conversion and shelf acetabuloplasty was 29.3 years and the longest interval was 50 years. Shelf acetabuloplasty still plays a role in preservation surgery for hip dysplasia to prevent osteoarthritis progression. Tanaka et al. reported that the survival rate after shelf acetabuloplasty with THA as the endpoint was very high, with a 25-year survival rate of 91% and 35-year survival rate of 72% [17]. In contrast, Migaud et al. reported a 20-year survival rate of 35%; however, many patients had severe osteoarthritis before surgery. Severe dysplasia (CE angle < 0 °) and

Table 4 Pre and post operative Radiographic outcomes

Variable		Shelf ($n=46$)	missing	Matched control ($n=46$)	missing	*P* value
Preoperative	LLD	-9.9 ± 15.9	3	-9.0 ± 9.5		0.71
	Height of head center	34.4 ± 7.3	3	30.6 ± 6.3		0.010
	Horizontal distance of head center	47.6 ± 9.2	3	46.5 ± 7.6		0.54
Postoperative	Cup CE	21.3 ± 10.0		28.4 ± 10.1		0.0011
	BCI(%)	77.0 ± 10.6		86.9 ± 10.6		< 0.0001
	Cup inclination	43.3 ± 4.9		43.4 ± 6.1		0.96
	Cup anteversion	12.6 ± 6.5		14.1 ± 6.1		0.25
	Height of femoral head center	25.1 ± 4.6		24.1 ± 4.7		0.34
	Horizontal distance of femoral head	33.1 ± 8.3		32.3 ± 4.9		0.59
	LLD	1.6 ± 9.4		1.0 ± 8.2		0.73

Values are given as mean ± standard deviation

LLD: limb length discrepancy, CE: center edge, BCI: bone coverage index

severe osteoarthritis were reported to be poor outcome factors [2].

Initially, we thought that shelf acetabuloplasty would increase acetabular bone coverage over the femoral head, leading to increased coverage of the acetabular component when conversion to THA was required. This could also decrease the necessity for bone grafting on the acetabulum. Fawzy et al. reported that shelf acetabuloplasty improves acetabular bone stock and facilitates the placement of the acetabular component [6]. Tamaki et al. also reported that acetabular bone grafting was not necessary for conversion to THA after shelf acetabuloplasty [9]. However, in the present study, bone grafting was performed in 87.0% of the cases. This percentage was similar to the incidence of bone grafting in the matched control group (80.4%, $p=0.46$). The cup CE after THA was smaller in the shelf group than in the matched control group (21.3° vs. 28.4°, $p=0.011$). These findings indicate that prior shelf acetabuloplasty does not necessarily provide better mechanical support during THA conversion. Although all patients in the matched control group were matched to have a dislocation degree of Crowe group I, the preoperative femoral head centers in the Shelf group were approximately 3 mm higher. Postoperatively, there were no differences in femoral head height between the groups, suggesting that this slight preoperative difference in head position may have contributed to the observed differences in bone coverage rate. Even within the same category of Crowe I, it can be stated that patients in the Shelf group tend to have more difficulty achieving bone coverage. If surgeons allow a high hip centre, they might not feel the necessity of a bone graft and would have a higher cup CE. At our institute, conversion THA is performed with the aim of placing the acetabular component at the anatomical centre. The potential difference in the strategy for placement of the acetabular component may be the reason for the difference in the results between the previous study [9] and the current one.

The results of this study showed that shelf acetabuloplasty did not increase the bone coverage for the acetabular component and did not reduce the need for bone grafting. In contrast, Tamaki et al. reported that in THA after shelf osteotomy, no bone graft was required because of increased acetabular bone mass [6, 9]. However, since bone grafting on the shelf is extra-articular, we believe that bone grafting may have been required for anatomic cup placement as well as for acetabular dysplasia, even though the bone volume appeared to be sufficient radiographically.

In the present study, the operative time tended to be longer in the shelf group; however, there was no significant difference, nor was there a significant difference in blood loss. In conversion THA after PAO, extensive release of soft tissue is necessary owing to adhesions and sometimes contractures, which occur after the prior procedure [18]. However, Tamaki et al. reported that in conversion, THA after shelf acetabuloplasty was easier than that after RAO because the shelf tended to cause less postoperative fibrous tissues. The conversion to THA after the shelf was associated with less operative time and blood loss, and improved acetabular bone stock compared with THA after RAO [9]. This finding is consistent with the results of the present study.

In this study, the JOA hip score was used for clinical evaluation. The preoperative JOA score was significantly lower in the shelf group for the ROM, pain, and walking components than in the matched control group. Flexion ROM before THA was significantly smaller in the shelf group than in the matched control, but the difference between the groups was not significant after THA ($p=0.08$). The increased bone stock on the anterior and lateral parts of the acetabulum might have led to the decreased ROM. However, there have been many reports suggesting that there are no differences in clinical score and range of motion in flexion between THAs with and without prior PO and that THA after PO provides significant pain relief and improved function [19–21] .

Regarding complications, there were no cases of infection, dislocation, or revision in either the shelf or control group in the present study. Shapira et al. reported that the major complication rate of THA after PO was 8.8% in a shelf acetabuloplasty group and 4.5% in a control group. The most common complication was dislocation (2.8%) followed by implant failure (1.4%) [22].

There were no significant differences in the angle and position of implant placement, and the limb length discrepancy observed preoperatively improved. In previous studies, it has been reported that cup inclination did not change significantly after PO, although cup anteversion tended to be lower in the conversion groups than in control groups [19, 21, 23]. Furthermore, Osawa et al. reported that the percentage of cup placed in Lewineck's safe zone was lower in the conversion THA group after PO, and care should be taken in cup placement due to the potential anatomical changes caused by the prior surgery. The reason for the similar anteversion between groups in this study is that acetabular anteversion was not modified in shelf acetabuloplasty, while it was often modified in PO.

For the limb length difference, there were no significant differences in limb length between the groups before THA or at the final follow-up. Previous studies have reported that mean LLD was the same or higher for THA after PO [18, 23]. This may be due to anatomical anomaly that resulted in higher cup installation.

This study had several limitations. First, this was a retrospective cohort study with a limited number of cases. However, compared with previous studies on similar topics, the number of cases in this study was relatively large. The comparison with a matched control group is the strength of this study. Second, we were unable to compare the CE angles before and after the shelf. It is possible that the cup CE angle in the shelf group was lower because the patients in the shelf group originally had a very low CE angle before shelf acetabuloplasty and this may have affected the bone grafting rate and the bone coverage index of the shelf group. Finally, only short-term follow-up data were analysed. Further studies are needed to determine the long-term clinical and radiographic outcomes of THA after shelf acetabuloplasty.

In conclusion, conversion THA after prior shelf acetabuloplasty provided encouraging short-term results with no major complications. However, bone coverage of the acetabular component was inadequate in total hip arthroplasty, even with prior shelf acetabuloplasty.

Conclusions

Conversion THA after prior shelf acetabuloplasty provided encouraging short-term results with no major complications. Prior shelf acetabuloplasty did not complicate subsequent THA. No aseptic loosening of acetabular component was observed in both groups. Bone coverage of the acetabular component was inadequate in total hip arthroplasty, even with prior shelf acetabuloplasty.

Abbreviations

THA	total hip arthroplasty
JOA	Japanese Orthopaedic Association
ROM	range of motion
cup CE	cup centre edge angle
DDH	developmental dysplasia of the hip
RAO	rotational acetabular osteotomy
PAO	periacetabular osteotomy
PO	pelvic osteotomy
Hgb	haemoglobin
LLD	limb length discrepancy
cup CE	cup centre-edge
BCI%	bone coverage index
ADL	activities of daily living
SMDs	Absolute standardised differences

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None.

Author contributions

All authors contributed to the study conception and design. Data collection was done by TI. Material preparation and analysis were performed by TI and KT. The first draft of the manuscript was written by TI, KI. Software, YK and SM. Manuscript revise, KG. Statistics, YO. All authors commented on previous versions of the manuscript. The final manuscript was written by TI and KT. All authors read and approved the final manuscript.

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Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Kyoto University Graduate School and Faculty of Medicine, Ethic Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by Kyoto University Graduate School and Faculty of Medicine, Ethic Committee.

Consent for publication

Not Applicable.

Competing interests

The authors declare no competing interests.

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