ORIGINAL RESEARCH ARTICLE

Mid-term results of revision total hip arthroplasty with an uncemented modular femoral component

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ABSTRACT

Introduction: During revision total hip arthroplasty (THA), the surgeon commonly faces deficient proximal femoral bone. In this situation, distal fixation of the prosthesis is required. The aim of the current retrospective study is to assess the clinical and radiographic mid-term outcome of revision total hip arthroplasty using a modular uncemented, tapered, grit-blasted, distal straight stem system.
Methods: This retrospective study included 70 femoral revisions that were performed in 67 patients using the device of interest. All patients were operated on via an extended trochanteric osteotomy. 60 revisions were performed as 1-stage (12 infected) and 10 as 2-stage (all infected) revisions. At 3 months postoperatively and at final follow-up, patients were assessed radiographically for the presence of osteolysis and for distal integration.
Results: The mean follow-up time was 4.3 (2.0-7.6) years. 4 patients had a removal of at least 1 prosthetic component. Stem survival for any reason was 92% after 5 years (95% confidence interval [CI], 83%-100%). With aseptic loosening of the stem as the endpoint of interest, survival after 5 years was 96% (95% CI, 88%-100%). A postoperative subsidence rate of 14.7% was found. No perioperative femoral fractures were found in the current patient series.
Conclusions: This study showed excellent mid-term survival and good clinical and radiographic outcomes in patients who had undergone revision THA with a modular uncemented, tapered, straight design.

Keywords: Revision, Total hip arthroplasty, Uncemented, Modular

Introduction

The incidence of revision total hip arthroplasty (THA) is projected to increase within the next few decades (1, 2). At present, there are several surgical approaches for the revision of the femoral component of hip prosthesis; all of them aiming to achieve primary stability of the implants. Stability can be achieved with or without bone cement. Survival of cemented revision THA has been described as moderate to poor (3, 4), and has been attributed to the absence of biological reconstruction of the deficient bone stock (3, 5, 6).

Conversely, uncemented modular revision hip arthroplasty offers intraoperative versatility in terms of leg length adjustment, offset reconstruction, anteversion, and fixation. To expound, the importance of modularity is related to the revision hip system's adaptation to various bone configurations. The ability to provide distal fixation is important in the context of deficient proximal femoral bone. During revision surgery, midfemur stability is advantageous because bone stock is often superior. One of the several methods that can be used for fixation includes the uncemented, fluted, tapered, and press-fit implant Revitan® stem (Zimmer Biomet Inc., Warsaw, IN). There are 2 versions of the Revitan stem currently available—a distally curved and a straight version. Until now, there has been a paucity of clinical evidence on the safety and efficacy of this device—particularly for the straight version.

The aim of the present study is to investigate the clinical and radiographic outcomes of the modular distal straight stem system implanted via an extended trochanteric osteotomy (ETO). A detailed radiological analysis that focused on early (first 3 months) and mid-term (final follow-up) subsidence, distal stem integration, and signs of loosening (osteolysis and radiolucencies) over time was performed. We expected that survival rates with the distal straight version would be comparable with the curved version that are documented in published studies.
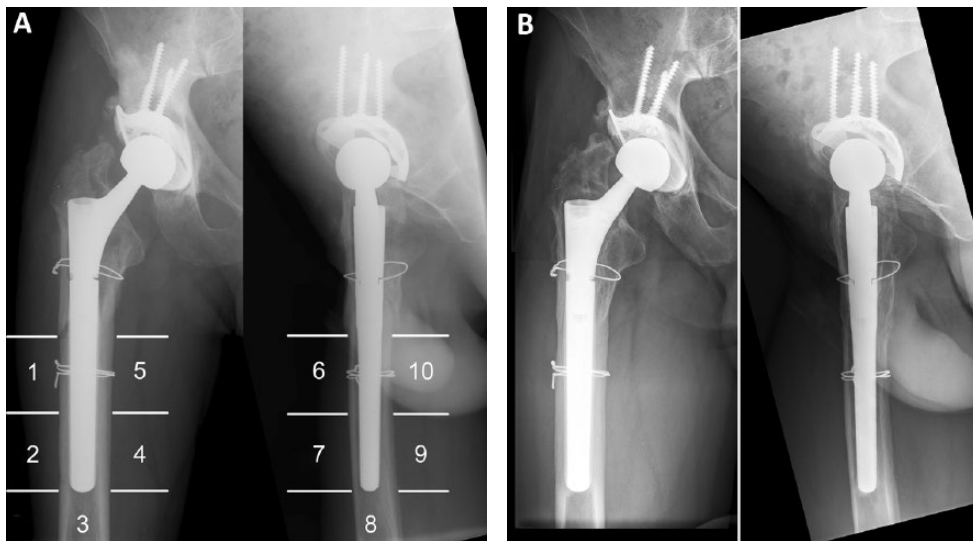
Methods

This was a retrospective, observational, single-centre study in a consecutive series of patients based on prospectively

Fig. 1 - Anteroposterior and lateral radiographs: (**A**) postoperatively; and (**B**) after 5 years in a 58-year-old male patient showing a well-osseointegrated prosthesis and 10 modified Gruen zones.

collected data. All patients who had received the modular Revitan straight stem were included. Its proximal components are offered as either a cylindrical or conical design, with lengths ranging from 55 mm to 105 mm (in 10-mm increments). The conical design was used in this series. The distal component is available with a diameter ranging from 14 mm to 28 mm (in 2-mm increments), and lengths of 140 mm, 200 mm, and 260 mm. The design of both components, which are attached via a connection taper, allows for a secure fit and restoration of the length of the leg. The stem offset is 44 mm. Increased range of motion and decreased risk of impingement are afforded by the slim neck design. A press-fit into the femur is provided via the ribbed stem.

In our centre, the device was utilised in patients with a bone stock sufficient for secure stem anchorage (intact femoral isthmus). Patients with extensive diaphyseal defects accompanied with significant cortical thinning alongside diaphyseal medullary canal widening were also not deemed eligible for this device.

Patients and methods

From January 2006 to December 2011, a total of 70 femoral revisions were conducted in 67 patients using the device of interest. Ethics committee approval was obtained prior to study commencement. The mean age of the study population at the time of surgery was 71.4 years (43.2-85.7 years). 50 (71.4%) patients were female. Indication for revision was aseptic loosening in 41 cases, septic loosening in 22 cases, and periprosthetic femoral fracture in 7 cases. Of the 22 cases that were treated for infection, 12 were performed as 1-stage and 10 as 2-stage procedures (7, 8). Of those hips with loosening, Paprosky femoral defect classification (9) was grade I in 23 hips, grade II in 20 hips, grade IIIA in 9 hips, and grade IIIB in 12 hips. Cases with a periprosthetic fracture were classified as Vancouver type B1 in 2 hips, B2 in 5 hips, and B3 in 1 hip (10). A short contact area between the stem and bone, with a minimum length of 3 cm, was targeted (11). All stems were implanted via an extended trochanteric osteotomy (12) in order to avoid 3-point fixation. The approach involved the creation of a longitudinal bone flap at the anterolateral femur allowing the surrounding musculature to remain attached. The cup was not replaced in 38 cases. In 16 cases, a cemented Müller acetabular roof reinforcement ring (Zimmer Biomet Inc.) was used. In 9 cases, a Burch-Schneider cage (Zimmer Biomet Inc.) was employed, and in 5 cases various other cemented cups were used. In 2 cases, a noncemented Allofit cup (Zimmer Biomet Inc.) was used. Postoperatively, patients were mobilised with partial weight-bearing (15 kg) for 6 weeks using 2 crutches, with unrestricted weight-bearing thereafter.

Prior to study inclusion, patients provided informed consent. At final follow-up, the Harris Hip Score (HHS) was used to assess function, pain, and hip mobility (13). Visual analogue scale (VAS) (14) was used to determine pain at rest, pain at movement, and patient satisfaction. In 20 cases, the HHS score was not correctly collected (i.e., missing values) during clinical follow-up examination. Thus, clinical results are reported only for 50 out of 70 patients in order to avoid reporting bias.

At 3 months postoperatively and at final follow-up, patients were assessed radiographically, in both anteroposterior (AP) and lateral views, for the presence of osteolysis and for distal stem integration. Osteolysis was defined as newly developed endosteal bone loss of at least 3-mm diameter, either with scalloping or with a bead-shaped lucency at the implant–bone interface (15, 16). Progressive radiolucent lines >2 mm at the bone-stem interface were described with respect to their location, using 10 modified Gruen zones in both planes (Fig. 1). Zones were distributed distal to the osteotomy around the stem, with the stem length divided in half in 2 planes. The contact zone of the stem and the prosthesis was measured in millimetres on the anteroposterior (AP) radiograph. The contact zone was defined as the zone in the modified Gruen zones where the stem had direct contact to the cortical bone without the presence of a radiolucent line. Contact zones were measured at 3 months and at latest follow-up. The anchorage distance was defined as the average of the medial and lateral contact zone. A 3-point fixation was deemed to be present in absence of a cross-sectional area of

absolute bone-implant-bone contact in the femur isthmus on the AP radiograph (17). Correction for radiographic magnification was based on the femoral ball head diameter. Proximal bone restoration was assessed according to the method by Böhm (Tab. I) (18). Axial subsidence of the stem was measured as the distance between the cerclage and the most prominent point of the stem at various time points, including immediately postoperatively, at 3 months, and at the time of the latest radiograph. A threshold subsidence of 5 mm was assumed to indicate significance (11, 19, 20). All intraoperative and early postoperative complications were recorded, along with complications occurring up to final follow-up. For patients who experienced a repeat revision, radiographs prior to their repeat revision radiographs were included in the study to avoid attrition bias.

Statistical analysis

Continuous data are presented as mean (range). Categorical data are presented as frequencies (percentages). Kaplan-Meier analysis was used to calculate implant survivorship (21). Patients without any revision were censored at the date of last contact or death. Survival analysis was discontinued when the number of patients in follow-up who were free of the events of interest became less than 25.

Results

1 patient was assessed elsewhere, but it was confirmed that his hip was still in situ. No other patients were lost to follow-up. 2 patients (2 hips) died postoperatively (0.1 and 1.5 years) for causes not related to the revision procedure. Of the remaining 67 hips (64 patients), radiographs were not evaluable in 1 hip. Hence, final radiographic follow-up was carried out on 66 hips (63 patients). The mean follow-up time was 4.3 (2.0-7.6) years. 4 patients had removal of at least 1 prosthetic component. In 1 patient, the stem was revised 5 years postoperatively for aseptic loosening. In 1 patient, an exchange of the proximal stem component was performed 10 months postoperatively due to subsidence of the stem. In 1 patient, the proximal stem component was exchanged to perform a leg length adjustment of 2 cm during cup revision for aseptic loosening elsewhere. 1 female patient had a fracture at the diaphyseal-metaphyseal junction of the modular stem component 6 years after the index procedure. This patient had a normal activity level; at the time of the event her body mass index (BMI) was 25 kg/m^2 and her body weight was 68 kg. She had a distal stem length and diameter of 140 mm and 18 mm, respectively, and a 65 mm proximal stem component. A failure analysis was performed by the manufacturer, but a root cause could not be determined.

Stem survival for any reason was 92% after 5 years (95% confidence interval [CI], 83%100%) (Fig. 2). With aseptic loosening of the stem as endpoint of interest, survival after 5 years was 96% (95% CI, 88%-100%) (Fig. 3).

Complications not leading to stem revision included the following: intraoperatively, among the baseline population of 67 patients (70 hips), a femoral fissure between the intramedullary canal and the cerclage occurred in 1 patient (1.7%), which was treated with an additional cerclage. In
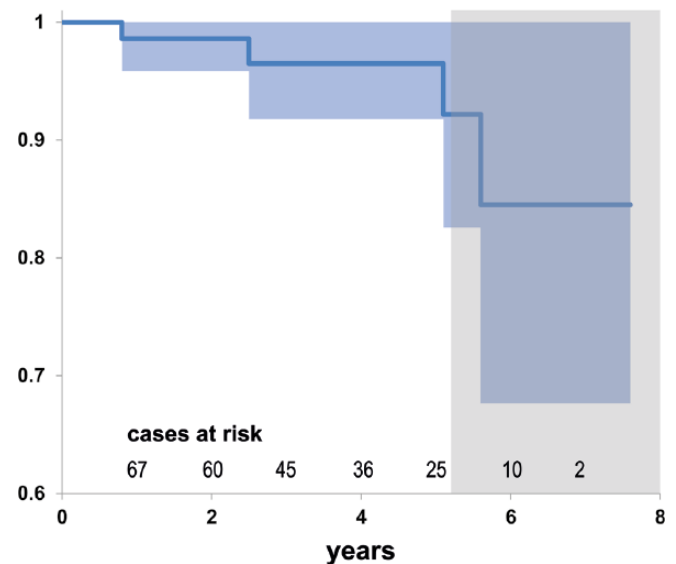

cumulative survival rate

Fig. 2 - Kaplan-Meier survival plot of stem revision for any reason is shown here.

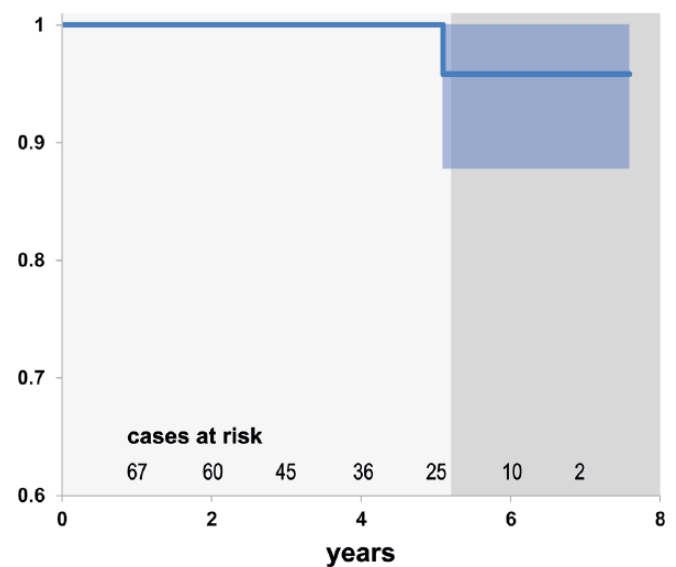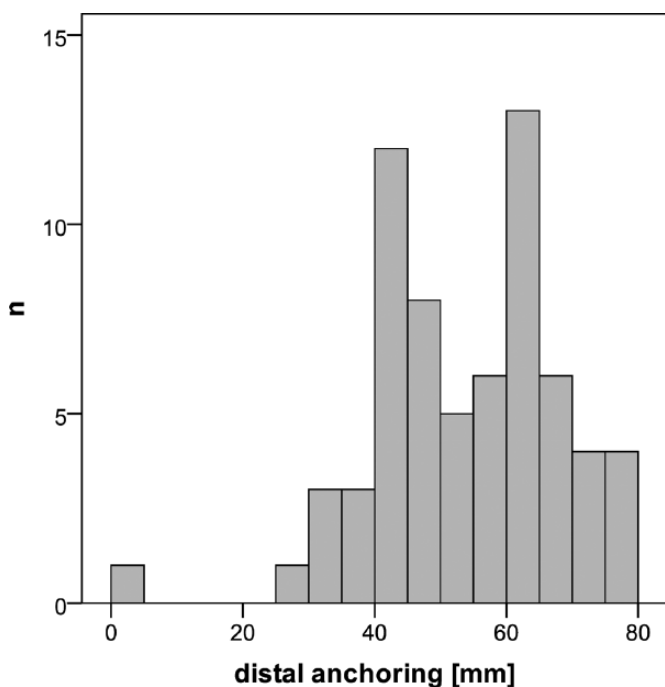**cumulative survival rate**

Fig. 3 - Kaplan-Meier survival plot of stem revision for aseptic loosening is depicted.

another patient, a trochanter fracture occurred, and the trochanter was reattached to the bone with 4 cerclages. In the early postoperative period, 3 patients (4.3%) had a postoperative haematoma that required surgical debridement. 1 patient had a wound healing disturbance postoperatively, but did not require surgical intervention. Postoperatively, 6 hips (8.6%) experienced dislocations and underwent closed reduction. Of those, 1 was attributed to an early subsidence of the stem of 8 mm. 1 patient required surgical debridement for haematogenous infection 2 years postoperatively. In 3 symptomatic patients, arthrocentesis was performed to rule

TABLE I - Bone restoration according to Böhm classification (18)

Class	Description	n (%)
A	Increasing defects	1 (1.5)
B	Constant defects	1 (1.5)
C	Visible bone restoration	3 (4.6)
D	Good bone restoration (complete restoration of the bone tube below the intertrochanteric region)	27 (40.9)
E	Excellent bone restoration (complete restoration of the bone tube including the intertrochanteric region)	34 (51.5)

TABLE II - Overview of radiolucent lines around stem at 3 months and last follow-up

	3 months, n (%)		Final follow-up, n (%)	
	Absent	Present	Absent	Present
Zone 1	68 (100)	0 (0)	65 (98.5)	1 (1.5)
Zone 2	67 (98.5)	1 (1.5)	64 (97.0)	2 (3.0)
Zone 3	67 (98.5)	1 (1.5)	65 (98.5)	1 (1.5)
Zone 4	66 (97.1)	2 (2.9)	64 (97.0)	2 (3.0)
Zone 5	67 (98.5)	1 (1.5)	64 (97.0)	2 (3.0)
Zone 6	68 (100)	0 (0)	65 (98.5)	1 (1.5)
Zone 7	67 (98.5)	1 (1.5)	62 (93.9)	4 (6.1)
Zone 8	68 (100)	0 (0)	64 (97.0)	2 (3.0)
Zone 9	65 (95.6)	3 (4.4)	62 (93.9)	4 (6.1)
Zone 10	64 (94.1)	4 (5.9)	61(92.4)	5 (7.6)

Presented as n (percentage).

Fig. 4 - Histogram of distal anchorage distance of the stem.

out infection, which showed no evidence of infection. Finally, 1 patient required revision surgery 1.5 year after index surgery due to pseudarthrosis of the trochanter.

The mean HHS reported at latest follow-up (n = 50) was 85.6 (31-100). VAS for pain at rest was 0.6 (0-5) and for pain at movement 1.2 (0-8). VAS for satisfaction was 8.8 (3-10).

Healing of the ETO (proximal femoral remodelling) at final follow-up was excellent or good in 61 cases (92%) (Tab. I). The total length of the distal anchoring was 51 mm (25-75 mm) at 3 months and 52 mm (0-76 mm) at final follow-up (Fig. 4). The patient with no distal anchoring was revised. No stem showed a 3-point fixation. At both the 3-month and final follow-up, progressive radiolucency was seen in 6 cases (9%) (Tab. II). Significant subsidence (>5 mm) was seen in 10 hips (14.7%), with an average migration of 16 mm (7-45 mm). 1 stem with 30-mm subsidence at 3 months postoperatively, migrated an additional 25 mm within the first postoperative year and required an exchange of the proximal component. In

1 patient, a stem that experienced a femoral perforation during surgery subsided 20 mm in the first 3 months and 5 mm thereafter. This patient experienced a dislocation. 1 patient with an initial subsidence of 8 mm and 5 mm thereafter, experienced 4 hip dislocations.

Discussion

Revision of integrated uncemented stems, well-cemented stems, and revisions in the presence of extensive osteolytic lesions are typically demanding procedures. Modular stem designs offer versatility in complex femoral revisions in terms of restoration of anatomy and management of bony defects (22, 23). The current study presents mid-term results for the straight Revitan revision stem implanted through an extended trochanteric osteotomy approach, with a focus on survivorship and radiographic outcome. The present findings suggest excellent clinical outcomes with this version of the modular uncemented revision stem.

In this study, implant survival was excellent and comparable to the survival obtained with the curved version of this stem type. Fink et al (11) reported all-cause implant survival at 7.5 years to be 91.4% (95% CI, 86.2%-96.6%). In their cohort of 45 patients (47 hips), Jang et al (24) revised 5 hips for deep infection and 2 hips for dislocation. The 8-year survival rate, with revision for any reason as an event of interest, was 86%.

Good implant survival has also been reported for the straight version of the stem. De Menezes et al (17) found 4% of the baseline population requiring a revision in a population with a mean follow-up of 5 years, but they did not provide a Kaplan-Meier survival rate. The inventors of the Revitan reported no revisions at a mean follow-up time of 6.5 years (25).

The extended trochanteric osteotomy approach is preferred in our clinic for revision of both cemented and uncemented stems, or for periprosthetic fracture in the presence of a loose stem. Various potential complications can impede

successful outcomes. Complications of the endofemoral approach include: iatrogenic fracture; poor positioning of the revision stem; 3-point fixation; and incomplete removal of cement (17). Other potential adverse events of femoral osteotomy include nonunion or proximal migration of the osteotomy fragment (26, 27), and intraoperative split fractures of the dorsal portion (27, 28), which can compromise fixation of the revision stem (26). In the present series, we did not observe significant morbidity related to the femoral osteotomy.

The study implant's stability is provided by its conical geometry, with a distal cone-in-cone fixation. The implant's straight geometry increases ease of implantation, as it is much easier to obtain a straight femur as opposed to a stem with a curvature that exactly corresponds to that of the native femoral bone. Despite the relative ease of implantation with a straight stem, care must be taken to avoid a 3-point support, which can result from the following situations: The surgeon must not provide implantation in the varus position, and a femoral osteotomy is needed when encountering a curved femur. Even though an adequate osteotomy flap length may be obtained with a straight revision stem, care must be taken to avoid a too-long fixation stretch in the femoral diaphysis, which also can result in 3-point fixation. An osteotomy flap of sufficient length with the use of a short stem will provide appropriate press-fit fixation. When the distal extent of the osteotomy is performed close to the femoral isthmus, it will not damage the isthmus.

For the Revitan stem, we believe that a fixation distance of 50 mm is sufficient because the conical stem is implanted in a prepared conical fixation bed in the isthmus of the femur. However, meticulous reaming is a prerequisite for optimal fixation, and underreaming must be avoided. Even then, an initial subsidence was seen in nearly 15% of the patients. It seems that the current femoral stem design requires an initial settling-in period within the host bone to obtain mechanical stability. The present series showed that, for the vast majority of cases, the subsidence only continued to a position of ultimate stability. We reported a postoperative subsidence rate of 14.7%, which is higher than that reported by others (3, 11, 17, 29). Incidences vary between 2% and 71% across the reported series (30), and an incidence of up to 24% has been reported for the Revitan Straight (30). However, different threshold values limit the ability to compare different studies. No perioperative femoral fractures were observed in the current patient series, indicating a good implant fit obtained with the present design. The surgeons' prior experience with the nonmodular, distally tapered, fluted Wagner stem (12, 31) may have contributed to this low fracture rate. High fracture rates have been reported by others with modular femoral stem designs. McInnis et al (32) and Pattyn et al (20) reported 24% and 32% fracture rates, respectively, for stems implanted through an endofemoral approach. Pattyn et al (20) reported an 11% perioperative fracture rate for stems operated on through a transfemoral approach.

In this study, a fracture at the diaphyseal-metaphyseal junction was observed in 1 case. Implant fracture with modular stem types is a rare complication (33, 34). It is likely to be associated with inadequate osseous support of the proximal prosthesis component, which causes a high concentration of stress at the modular junction (11, 19, 34, 35). This may result in micromotion that causes fretting wear and corrosion, and it may eventually lead to a fatigue fracture of the stem (36). Factors associated with an increased risk of fractures are increased BMI, a stem of small diameter, and the use of an extended trochanteric osteotomy for exposure (34). However, in the present case the stem fracture occurred in the absence of any of these risk factors and a comprehensive analysis of the explant by the manufacturer was unable to show a root cause for it.

There are several limitations to this study. The procedures were performed at a single institution. Hence, our study findings are not readily generalisable. Secondly, we did not collect baseline clinical data; hence we were unable to assess improvements in clinical scores. Thirdly, as our clinical data management system was modified during the follow-up period, and clinical outcome data is missing for approximately 1/3 of our patients, our estimates may have been biased. Fourthly, the population was heterogeneous in terms of revision aetiology and bone defects. When a transfemoral approach was performed in femurs with good bone stock (Paprosky type I and II defects), a modular revision stem was used. Several factors influence the length of the distal fixation zone, including the preoperative bone defect, isthmus integrity, and length of the bony flap. As such, in our series, short fixation zones in the isthmus were used, also in femora with good preoperative bone quality.

In conclusion, the survival rate along with clinical and radiographic findings indicate excellent implant performance of the device, which supports the previous findings of those reported for the curved version. However, ongoing surveillance of the device in a large patient series is necessary to confirm our findings and to monitor the rate of implant fractures.

Disclosures

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