SIGN HIP CONSTRUCT: ACHIEVING HIP FRACTURE FIXATION WITHOUT USING AN IMAGE INTENSIFIER

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ABSTRACT

Objective: The aim of this study was to assess outcomes of using the SIGN Hip Construct (SHC) to achieve hip fracture fixation without the use of an image intensifier.
Design: Prospective case series.
Setting: Muhimbili Orthopaedic Institute, Dar es Salaam, Tanzania.
Outcome measures: Radiographic union, callus formation, infection, fracture angulation, weight bearing status
Results: A total of 68 patients with trochanteric fractures were operated using the SHC of whom 41 patients came for follow up at 6 weeks. Clinical signs of fracture union were seen at 6 weeks among all patients; all but one had radiographic signs of callus formation. The majority (76%) of patients were ambulatory within 3 days after the surgery. At the 6 week follow-up, there was 1 (1.5%) case of infection and 8 (11.8%) cases of varus collapse.
Conclusion: Using the SIGN Hip Construct, hip fracture fixation can be achieved safely without an image intensifier. This implant may be a good alternative in developing countries where access to fluoroscopy is limited or non-existent.

INTRODUCTION

Hip fractures in the orthopaedic literature are typically characterized as a problem of High-Income Countries (HICs). However, the largest growth in incidence is predicted to occur in developing countries in Asia, Africa, and Latin America due to the aging population and the increasing prevalence of osteoporosis in these countries (2).

Intertrochanteric fractures are defined as any fracture from the extra capsular part of the neck of the femur to a point 5cm distal to the lesser trochanter (3). Although these fractures unite almost invariably with conservative treatment, the high rate of complications associated with prolonged immobilization in the elderly has made stable reduction and internal fixation the preferred treatment. Internal fixation of trochanteric fractures allows early mobilization, which may be lifesaving in the elderly population (4). Various classification systems have been proposed, but none have gained widespread clinical use (5). However, Evans (6) and Kyle *et al* (7) have presented a simple classification which is based on degree of fracture stability.

Implants used for fixation of these fractures include pin-plate assemblies (e.g. S-P nail plate), adjustable angle device (e.g. McKee and McLaughlin nail plates), fixed angle devices (e.g. Jewet nail plate, blade plate), sliding compression screw assemblies (e.g. DHS, DCS), and intramedullary nails (e.g. Ender nails, intramedullary hip screws). In HICs, the sliding hip screw and cephallomedullary nail have become the most commonly used implants. However, their cost is prohibitive in many resource limited settings such as Tanzania. Furthermore, fluoroscopy is required to safely implant these devices, which may not be available in many hospitals.

To overcome these challenges, SIGN Fracture Care International developed the SIGN Hip Construct (SHC). The SHC is intended for use in developing countries as it is provided at low-cost to hospitals and can be used without C-arm fluoroscopy guidance. However, few studies to date have looked at the outcomes of treatment of intertrochanteric fractures with the SHC in the absence of fluoroscopy. In this study, we aim to report short-term outcomes of the SHC for treatment of intertrochanteric fractures of the femur without use of an image intensifier.

MATERIALS AND METHODS

A prospective case series of patients with intertrochanteric fractures treated with the SHC between 2009 and 2011 was conducted at Muhimbili Orthopaedic Institute (MOI), Dar es Salaam. The SHC was selected to treat hip fracture patients as it is a suitable solution for our study centre because it can be used without an image intensifier. Ethical clearance

was obtained from Muhimbili University of Health and Allied Sciences Institutional Review Board.

All patients were provided a standard regiment of third-generation cephalosporins preoperatively which was continued postoperatively for 3 days. Clinical data for all patients was collected prospectively using the SIGN database. Plain radiographs were performed preoperatively, postoperatively, and at the 6-week follow-up visit. Fractures were sub-classified as stable or unstable based on the presence of posteromedial comminution involving the lesser trochanter. Patients were invited for a follow-up visit at 6 weeks postoperatively. Outcomes measured during follow-up included rate of infection, varus collapse, and weight-bearing status.

Surgical technique

Prior to surgery, the SHC template and preop X-rays were used to approximate the required length of compression screws as well as the angle of placement. The same was performed for the single interlocking screw required. General or spinal anaesthesia induction was performed and the patient was placed in the lateral decubitus position.

A direct lateral approach to the proximal femur was performed. The fasciae latae was incised from the tip of the trochanter distal to the vastus ridge. The vastus lateralis was divided inferior to the vastus ridge to expose the lateral aspect of the femur. The fractures were reduced by traction and manipulation with palpation of the fracture site to assess the quality of reduction. All patients were treated by two surgeons who were trained by the SIGN organization on how to use the SHC.

Implants were introduced following standard techniques. The SHC uses a 10x280mm intramedullary nail inserted through a trochanteric entry point. Proximal fixation is achieved by a single interlocking screw and 2 compression screws that pass alongside, but not through, the nail. Compression screws were inserted after creating a hand-drilled pilot hole. Proper positioning of the pilot holes was achieved by the use of a blunt hand drill ("pilot drill"). The angle was determined using a combination of the Z-angle finder (coronal plane) and palpation of the anterior neck of the femur (axial plane). Distal fixation is accomplished using a single distal interlocking screw placed with assistance of a jig.

Movement of the operated limb and partial weight bearing with axillary crutches were permitted beginning on the first postoperative day. Full weight bearing was allowed only when radiographs showed evidence of union.

RESULTS

A total of 68 patients with trochanteric fractures were operated using the SHC and followed for a minimum of six weeks. There were 53 (78%) male and 15 (22%) female patients (Table 1).

Table 1
Patient demographics

Age group (years)	No.	(%)
15-30	8	11.8
31-46	9	13.2
47-52	4	5.9
53-68	16	23.5
69-84	26	38.2
>85	5	7.4
Total	68	100

Patients presented to the hospital within 24 hours of injury in 30 (44.1%) cases. There were 31 cases who presented within 2 to 10 days (n = 31, 45.6%) of injury and 7 who presented more than 10 days after. Those that presented earlier generally lived within the region of the study centre while those who had delayed presentation lived in other regions in Tanzania. The most common mechanism of injury was fall from standing height which was seen in 33 (48.5%) cases. There were 7 (10.3%) patients who fell from greater than standing height. Road traffic injury was the second most common cause and was seen in 25 (37%) cases. Among the road traffic injuries, 10 were drivers, 7 were passengers, and 8 were pedestrians. Three (4.4%) patients sustained injury due to assault.

Out of 68 patients, 27 (40%) had osteoporosis of grade I, II, or III by Singh Index (Table 2) (8). A strong statistical relationship was found between age and degree of osteoporosis ($p<0.01$).

Table 2
Degree of osteoporosis by Singh Index

Age (years)	Singh Index Grade						
	I No. (%)	II No. (%)	III No. (%)	IV No. (%)	V No. (%)	VI No. (%)	Total No. (%)
15-30	0 (0)	0 (0)	11 (2.5)	0 (0)	0 (0)	7 (87.5)	8 (100)
31-46	0 (0)	0 (0)	0 (0)	0 (0)	3 (33.3)	6 (66.7)	9 (100)
47-52	0 (0)	0 (0)	0 (0)	3 (75.0)	1 (25.0)	0 (0)	4 (100)
53-68	0 (0)	1 (6.3)	2 (12.5)	8 (50.0)	4 (25.0)	1 (6.3)	16 (100)
69-84	0 (0)	7 (26.9)	11 (42.3)	8 (30.8)	0 (0)	0 (0)	26 (100)
>85	1 (20)	0 (0)	4 (80.0)	0 (0)	0 (0)	0 (0)	5 (100)
Total	1 (1.5)	8 (11.8)	18 (26.5)	19 (27.9)	8 (11.8)	14 (20.6)	68 (100)

The majority (n=39, 57.4%) of patients sustained a stable intertrochanteric fracture. Stable fractures more commonly resulted from falls, while unstable fractures resulted from higher energy mechanisms (Table 3).

The majority of cases (54.4%) had a delay of 10 days or more from the time of presentation to the date of surgery. This was often times due to a lack of operating space since cases are performed in the order that they arrived at the hospital. Some of the delays of surgery were due to medical co-morbidities like diabetes mellitus and hypertension.

The six week follow up rate was 60% (41/68). There were 12 patients who were lost to follow-up that could be reached by telephone; among these patients, inability to obtain transport (n=9) and death due to unrelated cause (n=3) were the reasons cited for missing the follow-up clinics. The remaining 15 patients who were lost to follow-up could not be reached. The patients who were unable to attend the clinic for transportation reasons lived far away from the study centre.

The majority (76%) of patients were ambulatory within 3 days after the surgery. Among the three patients who had delayed mobilization greater than 2 weeks postoperatively, 1 had severe postoperative anaemia, 1 had concomitant spine injury, and another had widespread metastatic disease. The remaining patients all achieved ambulation within 5 days after surgery. At the six week follow-up, there was 1 case of infection (1.5%) and 8 cases of varus collapse (11.8%) (Table 4).

Table 3
Stable versus unstable fracture and mechanism of injury

Type of fracture	MTA No. (%)	Fall (Height) No. (%)	Fall (Standing) No. (%)	Assault No. (%)	Total No. (%)
Stable	12 (30.8)	5 (12.8)	20 (51.3)	2 (5.1)	39 (100)
Unstable	13 (44.8)	2 (6.9)	13 (44.8)	1 (3.4)	29 (100)
Total	25 (36.8)	7 (10.3)	33 (48.5)	3 (4.4)	68 (100)

Table 4
Time of injury to surgery in relation to complication after six week

Time of injury to surgery (Days)	Complication beyond 6 weeks				
	Change of angle No. (%)	Infection No. (%)	None No. (%)	Lost follow-up No. (%)	Total No. (%)
<7	0 (0)	1 (5.9)	8 (47.1)	8 (47.1)	17 (100)
8-14	3 (17.6)	0 (0)	9 (52.9)	5 (29.4)	17 (100)
>15	5 (14.7)	0 (0)	15 (44.1)	14 (41.2)	34 (100)
Total	8 (11.8)	1 (1.5)	32 (47.1)	27 (39.7)	68 (100)

DISCUSSION

In this study, we provide short-term outcomes of the SIGN Hip Construct for the treatment of intertrochanteric fractures without fluoroscopic image guidance. We found that the SHC allowed for mobilization within a reasonable timeframe postoperatively in nearly all cases. This was achieved with a relatively low rate of infection (1.5%). Varus collapse was not uncommon (11.5%). However, there were no cases of femoral head cut-out with violation of the hip joint, which is a major concern in these patients.

Postoperative infection of the surgical site continues to be a major concern in any surgery conducted in a low resource setting, particularly given the routine use of open reduction techniques. Notably, the infection rate we measured in our patient population is similar to that which has been reported by other studies, including those from HICs. For instance, Edwards *et al*. (10) conducted a similar study in the United Kingdom and found a deep wound and superficial wound infection rate of 1.2%. Currently, no study has been conducted which directly compares infection rates between the SHC and other types of hip implants.

One limitation of this study was the small sample size. However, this will nonetheless be the largest published report on this implant. We were also limited by a short duration of follow-up and high rate of loss to follow-up. Though this limits our ability to comment on long-term clinical outcomes, the study does support the safety of the device for more widespread use in developing settings.

Another major limitation was the lack of a comparison group, which limits inferences that can be made. However, there are no other implants that can be used in a similar setting that do not require a C-arm, making such a study difficult to perform. Lastly, no data was collected on functional outcomes or patient-centred outcomes, such as health-related quality of life.

Nevertheless, our preliminary results provide the first report of the safety and feasibility of the SIGN Hip Construct in a developing country. Most importantly, the SHC is a viable alternative to non-operative treatment which has been shown to be associated with significant morbidity and mortality (11). While future work needs to be done to assess long-term clinical and radiographic outcomes of the SHC, this study supports the continued use and evaluation of the device.

CONCLUSION

The SIGN Hip Construct appears to be a safe option for the surgical treatment of intertrochanteric fractures in developing settings without the use of intraoperative image guidance.

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