Acta Orthop. Belg., 2022, **88**, 11-16

ORIGINAL STUDY

doi.org/ 10.52628/88.1.02

Pilot study: To assess feasibility and tolerability of a minimal invasive implantable PEEK device for prevention of contralateral osteoporotic hip fracture

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A non-comparative multi-centre and international pilot study have been carried on Y-STRUT® (Hyprevention, France), an implantable medical device meant to reinforce the hip to reduce the risk of a contralateral hip fracture. Objectives of the study were to determine the feasibility and tolerance of the procedure. Methods Patients older than 60 years were recruited when presenting at the emergency departments with a low-energy pertrochanteric fracture on one side and with a fracture risk assessed for the contralateral side with BMD, T-Score or other bone quality evaluation tool, FRAX index, or fall risk assessment. Pain and functional ability were assessed at the different follow-up visits using VAS, WOMAC and OHS-12 scores. Results Twelve patients were included and reached a one-year follow-up. Mean age was 82 years old (65 – 91). The average hospital stay was 13 days (3 – 29). The prophylactic surgery did not delay the hospital discharge for any patient. The procedure did not lead to unresolvable serious adverse events. At 3 weeks, all patients were able to walk 6 meters, half of them in less of 30 seconds. Minimal pain was reported all along the follow-up visits, except at 3 years when one patient presented high pain in both hips. WOMAC and OHS-12 scores showed a moderate to mild hip impairment. Conclusion The good short and medium-term outcomes of this pilot study demonstrate the feasibility and the tolerability of the device. Further studies should focus on the efficacy of this immediate and lasting bone reinforcement technique.

Keywords: Hip fracture ; fracture prevention ; prophylactic surgery ; osteoporosis.

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No benefits or funds were received in support of this study.
None of the authors have a conflict of interest.

INTRODUCTION

With the ageing of the population, a significant increase of osteoporotic low energy hip fractures is observed. This presents immense personal challenges and carries a significant socioeconomic burden both for the individual and for society in general.

In Denmark, between 1977 and 2011, the incidence of contralateral hip fracture was estimated in a cohort of 169145 patients followed during 3,8 years after an initial hip fracture. A total of 27834 (16,5%) contralateral femoral neck fractures were reported. The probability to present a contralateral hip fracture was estimated by the Kaplan-Meier method to be 9% at one year and 20 % at five years after the initial hip fracture *(1)*. In this study, mortality after a contralateral hip fracture was higher than after the initial hip fracture (for women: 58% against 41%). Faucett et al. state that a previous hip fracture more than doubles the risk of a contralateral hip fracture *(2)*. Balasubramanian et al. *(3)* state that prior fracture is a strong predictor of subsequent fracture. They performed a retrospective cohort study using administrative claims data and observed a high and early risk of subsequent fracture following a broad array of initial fractures. They conclude that timely management with consideration of pharmacotherapy is warranted in older women following all fracture types evaluated. In a recent study, Sheikh et al. *(4)* found that the patients at highest risk of a second hip fracture were those with dementia, acute inpatient chest infection, urinary tract infection and multiple comorbidities. They conclude that this may be useful in screening for patients at risk.

The search for the holy grail has led to many approaches to solve the problem. Direct protection of the hips by the wearing of ad hoc pads, although a good idea, is not met with adequate results as they are cumbersome *(5, 7)* and lead to a poor compliance *(8)*.

Indirect protection by medically treating osteoporosis is attractive, but the results are only seen after quite a while, and again elderly people are known to have a poor compliance when the taking of pill is concerned. A review of the literature covering subject older than 75 years, has shown that, although bisphosphonates appear effective in the reduction of vertebral fractures, there does not seem to be evidence regarding their efficacy in preventing hip fractures *(9)*.

Finally, surgical solutions have been advanced. Hip nailing is very aggressive as prophylactic fixation. Yet, Faucett shows its cost-effectiveness in future contralateral fragility hip fracture prevention. Giannini et al proposed the insertion of a surgical screw and did a randomised comparative study on 67 patients, 34 of which were instrumented *(10)*. They reported no subsequent fractures in spite of some low energy falls and a good tolerance of the device with no functional impairment caused by it.

Y-STRUT® (Hyprevention, France) is an implantable medical device meant to reinforce the hip to reduce the risk of a contralateral hip fracture. It is inserted in the hip contralateral to the fracture, just after the surgical treatment of the broken hip under the same anaesthesia, or in a delayed surgery in the 3 following months.

Y-STRUT® consists of two perforated PEEK (Poly-Ether-Ether-Ketone) tubes inserted under fluoroscopic control via mini skin incisions. The implants are filled and fixed to the surrounding bone with bone cement. The distribution of cement through the implant perforations also reinforce the surrounding bone.

The principle has been studied with finite element techniques and in vitro biomechanical fall simulations *(11)*. These studies have shown that Y-STRUT® increases the resistance to fracture of the hip with 30-50% compared to non-implanted femurs.

This article presents the final results of the first clinical study carried out with this device. The aim of this non-comparative multi-centre pilot study, conducted in France and Belgium, was to determine the feasibility and tolerance of the procedure.

METHODS

Main inclusion criteria were male and female patients older than 60 years presenting a low-energy pertrochanteric fracture on one side and with a fracture risk assessed for the contralateral side with

BMD, T-Score or other bone quality evaluation tool, FRAX index, or fall risk assessment.

Exclusion criteria were any contra-indication to the surgery, obesity at the level of the pelvis preventing the surgery as the instrumentation would be too short, systemic or local infection around the surgery site, uncontrolled diabetes, fibromyalgia and chronic fatigue, any neoplasm and Paget's disease, osteoarthritis of the hip, any additional lower limb fracture (besides the original hip fracture leading to the hospitalisation), presence of surgical implants in the proximal femur preventing the placement of Y-STRUT®, any allergy or intolerance to PEEK or bone cement, subject already enrolled in another clinical study, severe physical or psychological impairment which could lead to a poor study compliance. It was left to the anaesthesiologist to decide whether the patient would tolerate a possibly lengthened duration of surgery caused by the addition of a Y-SRUT implantation.

Y-STRUT® is an implant inserted in the femoral head by a minimally invasive technique (two small skin incisions) and aiming at reinforcing its biomechanical structure in order to prevent fracture.

The device is composed of two cannulas, or injection chambers, made of polymer PEEK Optima® (Invibio), a well-known biocompatible material (ASTM F2026 - 10 Standard Specification for Poly-ether-ether-ketone (PEEK) Polymers for Surgical Implant Applications). These cannulas form the shape of a 'Y', reinforcing the femoral neck and head, allowing them to resist charges occurring during low energy falls (Figure 1).

Y-STRUT® is combined with cement. The cannulas allow for controlled cement injection. CORTOSS (Orthovita/STRYKER, CE 0344 since 2007), a bioactive cement, was chosen for the study.

The surgical technique is performed under fluoroscopy. Two Kirschner wires are inserted through small skin incisions (2-3 mm) with the aid of a sextant type aiming device. The femoral neck and subtrochanteric tunnel are reamed, and two perforated PEEK implants are inserted and locked into one another in the shape of a 'Y'. There is a variety of implant lengths to accommodate each individual's anatomy.

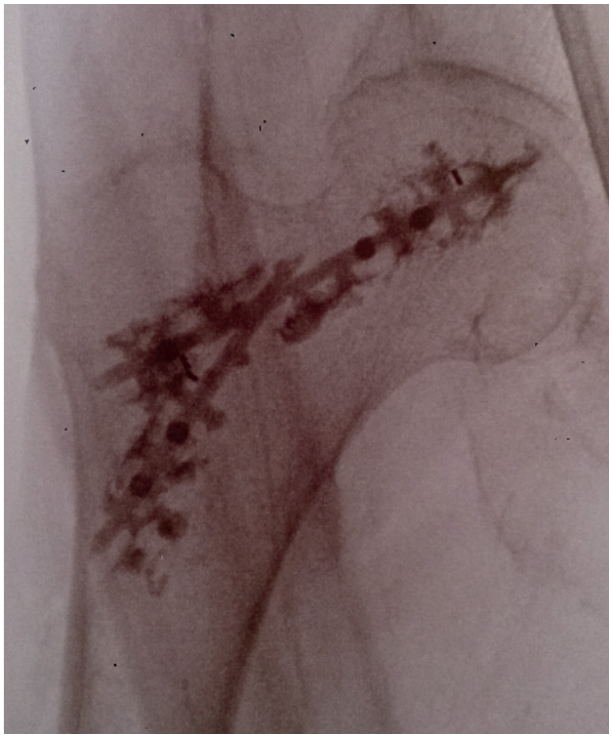

Figure 1. — Y-shape implant combined with bone cement.

Finally, the K-wires are removed, and bone cement injected under controlled pressure until there is a satisfactory filling of the bone around the implant.

The primary objective of the study was to assess the feasibility of the implantation procedure by observing the progression of the surgical technique in the operating theatre and its potential difficulties as well as the time required to perform the procedure.

The secondary objective was related to tolerability.

Short term tolerance was assessed by observing the resumption of walking with or without a walking aid 3 weeks after surgery (6 meter in maximum 30 seconds).

Tolerance was gauged by means of Visual Anolog Scale (VAS) for pain in either hip at each follow-up visits (3 weeks, 3 and 6 months, 1, 2, 3, 4 and 5 years). Pain is considered minimal if it is equal or less than 3 on the side of Y-STRUT® and if this is less than for the initially fractured side.

Also, concomitant treatments specific to pain management during the first 12 months were registered. Function was evaluated by WOMAC pain and function scores *(9)* during the first year

post-treatment and by the Oxford Hip Score (OHS-12) *(13)* at 3 and 6 months, 1, 2, 3, 4 and 5 years.

Adverse events during the surgery and linked to the biomaterials or instrumentation were noted. Adverse events after surgery were recorded, such as fracture, osteolysis or infection. Bone mineral density (BMD) was measured at 3 and 12 months by DEXA bone density scan.

Osseointegration of the implant was assessed by an independent radiologist by analysing X-ray (EOS at 3 and 12 months) and CT-scan.

Finally, the number of postoperative low energy falls was registered.

Data were recorded in electronic case report forms; they were not monitored at the closure of the study.

12 patients were included and reached the one-year follow-up mark.

RESULTS

Of the 12 patients, 10 were female. The average age was 82 years (65 years – 91 years).

According to BMI, 1 patient was overweight and 2 obese, the rest had a normal weight.

The 10-year probability of fracture was on average 24.3% (4.6% - 61%). Fracture risk was high or very high in 5 out of 12 subjects, 2 of which were prone to falls *(14)*.

Unfortunately, a T-score at 3 months was only available for 7 of the 12 subjects. Mean T-score was -2.6 (range -3.8, -1).

Most subjects received CORTOSS (Stryker) as cement, three were injected with PMMA F20 (Teknimed) and one had another PMMA (name non reported), and with on average 9cc (2 cc – 22 cc).

Implantations were performed under general anaesthesia, during the same operative time as the fracture fixation of the opposite side (Figure 2). Surgery duration for Y-STRUT® implantation was on average 54 min (35 min – 90 min) and no adverse events during surgery were reported, except a faulty connection between the two rods in one case with no functional consequences, observed on control RX.

One subject reached the study endpoint at 5 years. Eight subjects were lost to follow-up when the study was closed. One subject sustained a stroke and could not participate any further, one abandoned the study and on died of unrelated causes. Mean follow-up duration was 30 months (19 months – 67 months).

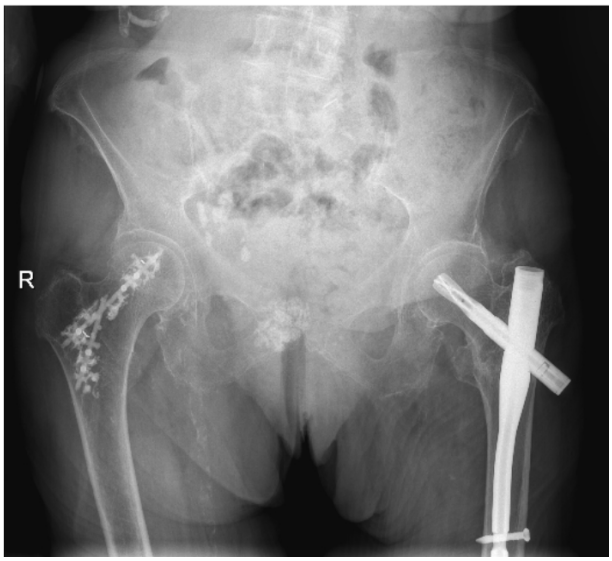

Figure 2. — Y-STRUT® device implanted on the right proximal femur. Nailing of the left (fractured) femur.

The average hospital stay was 13 days (3 days – 29 days). The prophylactic surgery did not delay the hospital discharge for any patient. At 3 weeks, all patients were able to walk 6 meters (n=12), half of them in less of 30 seconds.

Two post-operative adverse events were linked to the procedure or Y-STRUT® itself: two were severe with one subject complaining of excessive pain in the hip and another presenting severe hematomas on both sides (fractured side and Y-Strut side). Both resolved without complication.

Minimal pain was reported all along the follow-up visits, except at 3 years when one patient presented high pain in both hips (Table I).

Main WOMAC pain levels were 5.1 SD 5.2, 2.9 SD 5.1 and 4.9 SD 5.1 out of 20 points, showing a low overall pain.

Similarly, main WOMAC functional difficulties were 23.1 SD 15.9, 12.8 SD 12.8 and 14.9 SD 15.7 out of 60 points at 3, 6 and 12 months respectively.

OHS-12 score slightly varied from 22.7 SD 8.7 at 3 months to 31.2 SD 10.7 at 2 years, that is to say from moderate to mild hip impairment.

Table I. — Pain and function scores

		3 weeks	3 months	6 months	1 year	2 years	3 years	4 years	5 years
VAS	Initial fractured femur	2.4 SD 1.8 (n=12)	3 SD 3.44 (n=10)	1.6 SD 1.8 (n=8)	2.0 SD 2.6 (n=8)	1.1 SD 1.8 (n=8)	3.3 SD 3.4 (n=3)	3.5 SD 1.5 (n=2)	1 (n=1)
	Treated femur	1 SD 1.1 (n=12)	2.1 SD 2.5 (n=10)	2.1 SD 2.7 (n=8)	1.5 SD 2.3 (n=8)	1.0 SD 1.7 (n=8)	3.3 SD 4.7 (n=3)	0 SD 0 (n=2)	0 (n=1)
WOMAC Pain		N/A	5.1 SD 5.2 (n=10)	2.9 SD 5.1 (n=7)	4.9 SD 5.1 (n=8)	N/A	N/A	N/A	N/A
WOMAC Function		N/A	23.1 SD 15.9 (n=10)	12.8 SD 12.8 (n=7)	14.9 SD 15.7 (n=8)	N/A	N/A	N/A	N/A
OHS-12		N/A	22.7 SD 8.7 (n=8)	26.8 SD 7.5 (n=5)	33.9 SD 8.5 (n=9)	31.2 SD 10.7 (n=8)	34 SD 6 (n=2)	38 (n=1)	32 (n=1)

DISCUSSION

As mentioned above, both Balasubramanian et al. and Sheikh et al. propose a timely management with consideration of pharmacotherapy in order to try and prevent a second fracture. Yet, pharmacotherapy has its own drawbacks as pointed in our introduction. Whereas we agree that screening followed by prevention is needed, we would rather propose a definitive minimally invasive surgical solution

Prophylactic surgery with Y-STRUT® appears to be feasible and did not lead to unresolvable serious adverse events. As for each innovative surgery there is a learning curve for the clinician, and this explains why the surgical time varied from 35 to 90 minutes. In fact, once the learning curve is mastered, the procedure can easily be done in about half an hour. For a surgeon used to perform dynamic hip screw surgery for trochanteric fractures, the placement of Y-STRUT® is intuitive.

Y-STRUT® avoids the problem of compliance and is attractive by its minimal invasiveness and its immediate effect. Only two small skin incisions are required, and the instruments and implants are gliding over a Kirschner wire and inside a protective sheath, thus protecting the soft tissues. As the proximal femur in which the Y-STRUT® is embedded is weakened by osteoporosis yet otherwise anatomically intact, there is no interference with any movement or with the hip joint as such. So, no functional impairment was expected, and this was the case as most subjects did not present adverse events linked to the procedure or the implant. In fact, it can be compared with the nailing of the proximal femur as it is done to prevent epiphyseal slipping in Legg-Calvé-Perthes disease since decades.

Interestingly, patients' condition improved when pain and functional scores were compared between 3/6 months and 2 years post-operatively. This tends to show that, even though surgical treatment of osteoporotic fracture is perfectly mastered with high rates of success, the occurrence of a fracture is associated with a decline of the general abilities of these elderly patients during the months following its treatment. Indeed, it is often followed by a radical change in way of life (dependency, nursing home placement, …).

The FRAX® tool has been developed to evaluate fracture risk for patients. It is based on individual patient models that integrate the risks associated with clinical risk factors as well as bone mineral density (BMD) at the femoral neck. In our study, two subjects who were prone to falls had very high fracture risks yet did not break their contralateral hip. We surmise that this was the result of the protection offered by the Y-STRUT®.

The main limitation of this study is its low cohort of patients (only 12 patients) with a relatively short follow-up although one patient reached a follow-up of 5 years. Indeed, it was difficult to get compliance on the follow-up visits for the studied population.

Meaningful results should be obtained with a larger and comparative study. However, even if prophylactic surgery is a topic of interest *(15, 17)* regarding osteoporotic issues, it is still rarely the

object of clinical studies. Only solid results on positive benefit/risk ratios, by demonstrating low risk associated with the procedure and low rates of contralateral fractures, will enable this innovative approach to take its place in clinical practice.

CONCLUSION

The patients studied presenting with a proximal femur fragility fracture and who benefited from a contralateral preventive Y-STRUT® device, resulted in good short-term and medium-term outcomes.

In front of the global burden of fragility fractures, prophylactic surgery appears to be a relevant option to consider and to study. The feasibility of the Y-STRUT® minimal invasive procedure and the tolerance of the device is shown on the cohort. Further studies on a larger cohort should focus on the efficacy of this immediate and lasting bone reinforcement technique.

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