MINI-INVASIVE NAIL VERSUS DHS TO FIX PERTROCHANTERIC FRACTURES: A CASE-CONTROL STUDY

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Summary

Background: Fixation devices to treat trochanteric fractures belong to two general categories: dynamic hip screw (DHS) type and intramedullary type implants. In spite of possible pitfalls, both are considered valid options. Comparing a sliding screw-plate system (DHS) along a mini-invasive nailing device (BCM™ nail) with primary insertion of the cephalic screw, sheds light on the debated management of trochanteric fractures.

Hypothesis: Due to its design, the BCM™ nailing system allows a stable internal fixation and promotes enhanced postoperative functional recovery.

Objectives: To test this hypothesis in a comparative prospective case-control study using the DHS screw-plate as a reference.

Materials and methods: Two groups of 30 patients, older than 60 years old, with trochanteric fractures were included in this study. The screw-plates were placed according to the standard method. Regarding the nailing system, the cephalic screw was positioned first, then the nail was inserted through the screw via a mini-invasive approach and locked distally using a bicortical screw. Comparison between the two groups was based on (1) operative data: operating time, intra- and postoperative blood loss; (2) immediate postoperative course: complications, length of hospital stay, delay to sitting in a wheelchair; (3) the postdischarge evolution: weight-bearing, readmission to hospital; (4) functional outcomes: recovery and mobility; (5) anatomical outcomes: restitution and bone healing.

Results: The operating time (54 ± 8.8 min vs 59 ± 13.8 min) and intraoperative (1.37 ± 0.98 vs 1.90 ± 1.43) and at Day 3 (1.25 ± 1.05 vs 1.82 ± 1.5) blood loss (haemoglobin loss), were favourable to the screw-plate subgroup (p < 0.05). The delay to sitting in a wheelchair (4.76 ± 1.53 d vs 4 ± 1.44 d) was favourable to the nail subgroup (p < 0.05). There was a higher incidence of secondary displacements in the screw-plate subgroup (3/26 [11.5%] vs 0/25 [0%]) (p < 0.05). The screw-plate subgroup demonstrated a poorer healing rate at 3 months (88% vs 100%) (p < 0.05). Regarding functional recovery, a lesser decrease in the Parker score was observed in the nail subgroup at 3 postoperative months (2.42 ± 2.3 vs 1.52 ± 1.44) (p < 0.05).

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Introduction

Fractures of the trochanteric region are the most common fractures in the elderly and still report a high mortality risk [1]. This fragile population requires the need for a non-traumatic surgical procedure.

The screw-plate and nailing systems are the two osteosynthesis methods used in the management of trochanteric fractures. Numerous studies have compared intramedullary nailing systems such as the Gamma™ nail (Howmedica™, Rutherford, NJ, USA) with screw-plate devices. Most of these studies demonstrate no significant differences between both systems [2–5]. The main complications reported with intramedullary nailing systems, especially the Gamma™ nail, include the difficulty in properly targeting the cephalic screw, intraoperative trochanteric fractures, tendinous lesions of the abductor muscles due to the large metaphyseal diameter of the nail and postoperative fractures at the distal end of the nail [6]. The reported advantages include the ability to perform a minimally invasive insertion of the nail and good stability, particularly in unstable fractures [8,15] and plate insertion via an extended approach. The main advantage is the ability to achieve proper cephalic screw placement first in the thicker part of the femoral head which is the posterior-inferior section. For that reason, most authors resort to nailing devices in the treatment of unstable fractures, since this system provides a higher stability in such indication [8,15,16].

The Bocchi, Bertone, Caniggia, Maniscalco (BCM™) (Lima™, Villanova, Italy) nail was developed in order to combine the benefits of the screw-plate with those of intramedullary nailing, allowing the insertion of the cephalic screw first through a minimally invasive approach and providing a static assembly. In 1999, a series of 56 patients originating from Siena (Italy) had benefited from the insertion of this innovative osteosynthesis device [17].

The aim of that study was to assess the presumed advantages of this innovating and original system by comparing it with a DHS type (Howmedica™, Rutherford, NJ, USA) device in the management of trochanteric fractures in the elderly.

Material and methods

Patients

Two groups of 30 patients sustaining a pertrochanteric fracture were enrolled. Inclusion criteria were patients over 60 years of age and stable or instable pertrochanteric fractures (Table 1). Patients younger than 60 years and those with pathological fractures or subtrochanteric fractures were excluded.

During the year 2006, patients from the BCM™ subgroup were operated on by senior surgeons from the department (E.L., F.D.) who used systematically this method in the management of trochanteric fractures. Patients from the DHS subgroup were recruited from a cohort of patients operated on by senior surgeons from the service and managed during the same period.

Both groups were pair-matched according to gender, age (age bracket of 5 years), type of fracture (stable or unstable) and preoperative functional status according to the Parker’s score [18] by splitting up the patients into three groups; good, poor, bad. Patients’ characteristics are reported in Table 1. Females were predominantly represented, with a mean age of 85 years and a poor functional status.

Judgement criteria

Comparison between the two groups was based on:

- patients’ characteristics, including age and functional status according to the Parker and Katz, and ASA scores;
- the Jensen’s classification [19] to assess and classify the fracture in the stable or unstable type;
- the operating time in minutes;
- the early postoperative period: complications, blood loss evaluated from the decrease in haemoglobin at Day 0 and Day 3, the number or blood transfusion bags, the number of days prior to sitting in a wheelchair;
- the posthospital period: the time to effective weightbearing, the functional recovery at three months according to the Parker’s score, the rehospitalization rate, bone

Table 1 Patient characteristics.

<table>
<thead>
<tr>
<th></th>
<th>DHS</th>
<th>BCM™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Age (year)</td>
<td>84.6 ± 7.6</td>
<td>85.5 ± 7.9</td>
</tr>
<tr>
<td>Gender M/F</td>
<td>3/30</td>
<td>3/30</td>
</tr>
<tr>
<td>ASA score</td>
<td>2.37 ± 0.85</td>
<td>2.58 ± 0.74</td>
</tr>
<tr>
<td>Fracture type (Jensen) [19]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable</td>
<td>73%</td>
<td>73%</td>
</tr>
<tr>
<td>Unstable</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>Preoperative Parker</td>
<td>5.2 ± 2.9</td>
<td>4.9 ± 2.47</td>
</tr>
</tbody>
</table>

ASA: American Society of Anesthesiologists; BCM™: Bocchi, Bertone, Caniggia, Maniscalco; DHS: dynamic hip screw.
healing at 3 months, the mortality rate. Radiographic consolidation was defined as being the disappearance of the continuity solution; an anatomical restitution assessed through successive anteroposterior and lateral hip radiographs by measuring impaction and secondary displacements (cutout and telescoping greater than 1 cm). Impaction was calculated by measuring the distance between the centre of the femoral head and the line running through the femoral diaphyseal axis. Measurement after osteosynthesis was deducted from the preoperative measurement performed on the non-fractured hip. A cutout corresponded to the displacement of the cephalic screw within the femoral head observed on the postoperative control radiographs.

Statistical analyses were performed using the SPSS software (SPSS Inc., Chicago, IL, USA) combined with the Student’s t-test.

Operating method

The patient was placed on an orthopaedic table with traction applied to the leg and fracture reduction was performed under image intensifier. Anaesthesia was chosen according to the anaesthetist’s preference.

The DHS was inserted according to the standard technique recommended by the manufacturer. Implants consisted of 13 mm diameter canulated cephalic screws associated with plates of 130° neck-shaft angle and three diaphyseal holes intended for 5 mm diameter screws.

Figure 1  BCM™ nail featuring a 13 mm diameter cephalic screw with a 10 mm penetration index (C) through which is inserted a nail of 21 cm long, 11 mm in diameter and a 5° metaphyseal angle, with one or two 4.5 mm distal locking screws (A). A plate can be connected to the cephalic screw with a 4.5 mm screw for diaphyseal fixation (B). (1) Cephalic screw, (2) nail, (3) distal locking screw, (4) plate, (5) diaphyseal fixation screw.

The BCM™ system was made up of (Fig. 1) a 21 cm long nail featuring a valgus metaphysodiaphyseal angle of 5° and a 11 mm metaphyseal diameter. Cephalic screws had a 13 mm diameter and were available in various lengths from 8 cm to 12 cm in 0.5 cm increments. Screw dynamisation was set with a penetration index of 10 mm allowing intraoperative fracture compression only. The assembly was therefore converted into a static construct through insertion of a locking screw. The cephalic screw was canulated for insertion of the nail. The cephalic screw angle, for nail insertion, varied from 115° to 130°. The distal locking screw featured a 4.5 mm diameter and a 32 to 52 mm length.

A plate could be connected to the cephalic screw in case of difficult nail placement with four, six, 10 or 12 holes and a neck-shaft angle varying from 125° to 145°, in 5° increments. Plate insertion was performed once in our series since the surgeon was unable to introduce the nail through the cephalic screw.

The BCM™ nail was inserted by placing a threaded wire guide using a protractor in the selected part of the femoral head. Direct measurement of the selected cephalic screw was performed. A pin drill was then placed over the wire guide to prepare the cephalic screw insertion site. A specific ancillary was connected to the cephalic screw to help find the entry point of the nail at the tip of the greater trochanter and allow insertion of a nail-guide (Fig. 2). The nail was placed on the guide and slid along the latter through an opening in the cephalic screw. The ancillary was then used to perform the distal locking with one or two bicortical screws (Fig. 3). Since the assembly is a static one, a locking screw was introduced through the end of the cephalic screw for fixation of the screw within the nail.

The nail could be replaced by a plate connected to the cephalic screw and fixed to the femoral diaphysis by means of bicortical screws, which was needed once in our study, due to the surgeon’s technical inability to properly insert the nail (Fig. 4).

Postoperatively, a suction drain was left in place for three days in the DHS subgroup, whereas the nail subgroup did not require any drainage due to the minimally invasive approach. All patients received a low-molecular-weight

heparin (Enoxaparin) or a non-fractionated heparin (Calcic heparin) treatment in the prevention of thromboembolic complications. Patients could sit in a wheelchair depending on the medical prescription and on their recovery. This could be implemented during the weekend due to the continuous presence of physiotherapists. After their hospital stay, most patients were referred to care and rehabilitation centres. According to the habits of the department, full weightbearing was initiated at the 6-week follow-up visit, depending on the radiographic findings.

**Results**

Matching performed during patients selection allowed us, with minimum bias, to make a comparison between a DHS screw-plate osteosynthesis device and a BCM™ nailing system.

### Table 2  Operative technique and morbidity.

<table>
<thead>
<tr>
<th></th>
<th>DHS</th>
<th>BCM™</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>Operating time (min)</td>
<td>54 ± 8.8</td>
<td>59 ± 13.8</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Loss Hb (g/dl)</td>
<td>1.37 ± 0.98</td>
<td>1.90 ± 1.43</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Transfused blood bags</td>
<td>1.77 ± 1.33</td>
<td>1.6 ± 1.4</td>
<td>NS</td>
</tr>
<tr>
<td>Mortality at 3 months</td>
<td>4</td>
<td>5</td>
<td>NS</td>
</tr>
<tr>
<td>Complications</td>
<td>2</td>
<td>4</td>
<td>NS</td>
</tr>
<tr>
<td>Pneumopathy</td>
<td>1</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Thromboembolism</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Readmission</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS: non significant.

### Table 3  Stability and bone healing.

<table>
<thead>
<tr>
<th></th>
<th>DHS</th>
<th>BCM™</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting in a wheelchair</td>
<td>4.76 ± 1.53</td>
<td>4 ± 1.44</td>
<td>&lt; 0.03</td>
</tr>
<tr>
<td>Weightbearing (weeks)</td>
<td>6.42 ± 0.99</td>
<td>6.2 ± 0.57</td>
<td>NS</td>
</tr>
<tr>
<td>Secondary displacement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cutout</td>
<td>3/26 (11%)</td>
<td>0/25 (0%)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Telescoping &gt; 1 cm</td>
<td>18/26 (69%)</td>
<td>12/25 (48%)</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Consolidation at three months</td>
<td>88%</td>
<td>100%</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

NS: non significant; BCM™: Bocchi, Bertone, Caniggia, Maniscalco; DHS: dynamic hip screw.
The elements related to the surgical technique and morbidity are reported in Table 2. The operating time was found to be 5 mins shorter and associated with less blood loss in the DHS subgroup of patients. No significant differences were noted regarding the number of transfused blood bags and the postoperative complications.

No readmission was required in either group.

The elements related to stability and bone healing are presented in Table 3. According to the results, the BCM™ nail subgroup demonstrated a better stability of the device while secondary displacements (cutout and telescoping greater than 1 cm) were found in 18 out of 26 cases (69%) in the DHS subgroup and in 12 out of 25 cases (48%) in the BCM™ subgroup of patients (p < 0.01).

When telescoping was greater than 1 cm, no cephalic screw protrusion into the coxofemoral joint could be detected. The consolidation rate at three months was 100% in the BCM™ subgroup versus 88% in the DHS subgroup. The time to wheelchair installation was significantly shorter in the BCM™ (p < 0.03).

The functional score results are listed in Table 4. The Parker’s score evolution between the preoperative period and the three-month follow-up was significantly in favour of the BCM™ subgroup (p < 0.05).

### Discussion

The objective of that pilot study was to assess the presumed advantages of the BCM™ nail design regarding its minimally invasive insertion, stability and postoperative functional status when compared with a screw-plate device. The advantages of the minimally invasive approach in terms of operating time and blood loss were covered up by the ancillary-related difficulties. However, an increase in stability was observed probably resulting from the initial screw insertion and, above all, the static aspect of the assembly. The functional result was also significantly improved with the BCM™ system.

Various devices have been described in the treatment of pertrochanteric fractures [20,21]. Many studies were conducted to compare the Gamma™ nail, the most commonly used nailing system in the management of trochanteric fractures, with screw-plate devices.

The Gamma™ nail first appeared to report better results than previously used systems [22]. Many studies reported a shorter operating time and reduced blood loss with the Gamma™ nail compared with screw-plate devices [5]. However, level I studies have reached different conclusions. According to a study conducted by Ahrengart et al. [23] in 426 patients, the Gamma™ nail demonstrated a shorter operating time and a greater blood loss. The most commonly reported and published complications of the Gamma™ nail include intraoperative fractures of the greater trochanter induced by its large metaphyseal diameter as well as fractures occurring at the distal end of the nail [2,5,7–13]. Svenson et al [14] have reported a higher rate of secondary displacements in the Gamma™ nail subgroup of patients. Finally, Adams et al. [5] suggested that, despite the increased stability achieved by the Gamma™ nail compared with the screw-plate system, its superiority was highly debated regarding the challenging placement of the cephalic screw and the increased risk of secondary displacement such as screw cutout as well as its specific complications (diaphyseal fractures, trochanteric failures).

The Gamma™ nail had also been compared with other available nailing systems such as the Intramedullary Hip Screw™ (Smith and Nephew Richards, Memphis, Tennessee) [16,24] and the Proximal Femoral Nail™ (Synthes-Stratex, Oberdorf, Switzerland) [25]. These study reported poorer results when using the Gamma™ nail, particularly in terms of secondary displacements and intraoperative fractures. These nailing systems (Targon PF™, Proximal Femoral Nail™) were in turn compared with screw-plate devices. The published results were in favour of nailing systems except for the Targon PF™ nail for which [26] no significant difference could be established by Giraud et al. However, these nailing systems were less popular than the Gamma™ nail, since the latter was considered, in many medical centers, as the most favourable treatment option particularly in the management of unstable fractures.

No comparative study with other osteosynthesis systems had been previously conducted on this new BCM™ nailing system, highly innovative since it features primary placement of the cephalic screw.

In theory, the BCM™ nail was designed to combine the advantages of the nail and its intrinsic stability with those of the screw-plate device (cephalic screw positioning, intraoperative impaction of up to 10 mm) without having the drawbacks of the Gamma™ nail (smaller nail diameter, opportunity to change with a plate) and of the screw-plate (postoperative impaction within the fracture site).

Our study demonstrated a longer operating time with the BCM™ nail induced by the learning curve of the operative technique and difficulties in the distal locking due to the ancillary. A greater blood loss could also be correlated with a longer operating time but did not appear significant enough to increase the number of transfusion bags. According to the literature, minimally invasive techniques did reduce blood loss [27,28–33]. Regarding this nailing system, such parameter should be reassessed in a greater sample of patients once distal locking concerns have been settled.

Patients from the BCM™ subgroup could be more rapidly installed in a wheelchair probably due to the absence of drainage and a lesser degree of postoperative pain because of the minimally invasive nail insertion and the static assembly. Our results are similar to those reported with other minimally invasive nailing systems [34,35]. The mortality rate was identical in both groups which correlates the results already published in the literature.

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Functional evaluation.</th>
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<tbody>
<tr>
<td></td>
<td>DHS</td>
</tr>
<tr>
<td>Parker</td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>5.2 ± 2.9</td>
</tr>
<tr>
<td>At 3 months</td>
<td>3.23 ± 2.44</td>
</tr>
<tr>
<td>Mean delta</td>
<td>2.42 ± 2.30</td>
</tr>
</tbody>
</table>

Mean delta: mean differential Parker’s score between preoperative period and three-month follow-up; BCM™: Bocchi, Bertone, Caniggia, Maniscalco; DHS: dynamic hip screw.
Complications were identical in both groups and quite common among this specific population of hospitalized elderly patients. Contrary to what had been reported with the Gamma™ nail, no intraoperative fracture (trochanteric or under the nail) was observed in the BCM™ subgroup of patients. However, this result should be taken with caution due to the small sample of patients included in this study. The rate of rehospitalization in our study was nil in both groups, probably due to the fact that patients had been admitted for a midterm hospital convalescence during which most complications were treated without the need for a rehospitalisation in case of emergency.

The three-month follow-up rate of secondary displacement was lower with the BCM™ nail. Therefore, this device demonstrated a higher stability than the DHS. This stability was specific to the advantages of intramedullary nailing which include a shorter lever arm and a good purchase in osteoporotic bone [36—39]. However, as previously reported, many publications, comparing screw-plate systems with the Gamma™ nail, found a higher rate of secondary displacements with the nailing devices. This was certainly attributable to a wrong positioning of the cephalic screw. In order to take up for this problem, the cephalic screw was designed to be inserted first, which was a significant advantage. The static assembly of the BCM™ nail did enhance the stability without compromising bone consolidation.

The study demonstrated better functional results in the BCM™ subgroup compared with the DHS subgroup. These outcomes were probably attributable to the minimally invasive approach which allowed a decrease in pain and early sitting in a wheelchair to prevent functional status worsening secondary to a prolonged supine position. Pain was not assessed during our study since evaluation of this parameter is difficult in this type of population.

Functional improvement could also be attributable to the stability of the device with a small incidence of secondary displacements and the opportunity to benefit from early rehabilitation and weightbearing.

Conclusion

This study found no significant differences between the DHS and the BCM™ nail. One of the objectives of this nail was its insertion through a minimally invasive approach to reduce the degree of blood loss. But ancillary-related difficulties associated with the learning curve, did annihilate this potential advantage. However, the rate of secondary displacement was low mainly due to the primary insertion of the cephalic screw. This study also confirmed the better postoperative functional recovery demonstrated in the BCM™ subgroup, related to the highest stability of the nail.

This first series of BCM nails with primary insertion of the cephalic screw did show some limitations regarding its ancillary. However, these first results are encouraging and improvement of the ancillary weaknesses would allow the use of this device in daily practice. The BCM™ nail appears as a valuable treatment option in the management of trochanteric fractures due to its good stability, satisfactory postoperative functional results and the low rate of intra- and postoperative complications.

A multicenter series should be conducted to confirm the outcomes of this pilot study.

Conflicts of interest

None.

References


