



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

Percutaneous compression plate

February 2008



**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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ISBN

Publications Approval Number:

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID S000062

NAME OF TECHNOLOGY PERCUTANEOUS COMPRESSION PLATE

PURPOSE AND TARGET GROUP MINIMALLY INVASIVE TREATMENT OF PATIENTS WITH INTERTROCHANTERIC HIP FRACTURES

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Belgium	✓		
France	✓		
Israel	✓		
United Kingdom	✓		

IMPACT SUMMARY

Orthofix Inc. (Texas, United States) provides the percutaneous compression plate with the aim of providing a minimally invasive fixation alternative for intertrochanteric hip fractures. The technology is currently in the investigational stage and not yet available in Australia.

BACKGROUND

Intertrochanteric fractures are fractures in which the fracture line is between the greater and the lesser trochanter. They are the most common type of hip fracture.

Hip fractures are usually a result of a fall or direct trauma to the side of the hip (Born 2007). In many patients, medical conditions such as osteoporosis, cancer, or stress injuries can weaken the bone and make the hip more susceptible to breaking (Born 2007).

As with other hip fractures, the main symptoms associated with intertrochanteric hip fractures include substantial pain and discomfort, particularly during movements (such as when attempting to flex or rotate the hip) (Born 2007).

Currently, surgery is the most common treatment for intertrochanteric fractures. The goal of surgical treatment is to prevent the ends of the broken bones from moving and relieve pain.

However, not all patients are suitable for surgical treatment. Some patients, such as those with existing morbidity or those unable to walk prior to their injury and confined to a wheelchair or bed may not be able to undergo surgery. For those patients who are unable to receive surgical treatment, non-surgical options include prolonged bed rest, prolonged traction in bed or prolonged immobilisation in a full body (spica) cast (Goodman 2006). Healing rates from non-surgical treatment of intertrochanteric hip fractures have been acceptable; however, unacceptable mortality and morbidity rates resulting from non-orthopaedic complications associated with prolonged immobilisation or inactivity make surgery the treatment of choice (Goodman 2006). The most common complications associated with the non-surgical treatment of intertrochanteric fractures include pneumonia, deep vein thrombosis (DVT), bedsores, loss of motion of the lower extremity joints and muscle atrophy, and union of the fracture in an unacceptable position (leading to deformity) (Born 2007 and Goodman 2006).

Surgical treatment consists of first obtaining an adequate, stable or near-anatomic reduction by closed or open methods, followed by fixation of the fracture using specially designed plates and screws (Goodman 2006). Fixation of intertrochanteric hip fractures is usually performed using a compression hip screw (CHS), is also known as a dynamic hip screw (DHS) (Lorich et al. 2004). The CHS is a device composed of a metal plate attached to the outer side of the femur with screws and a large secondary screw (lag screw) placed through the plate into the neck and head of the hip. The design of the device allows for impaction/compression at the fracture site while also allowing for sliding of the lag screw and impaction of the fracture. The intramedullary nail is an alternative fixation method in which a nail is placed directly into the marrow canal of the bone (Goodman 2007). A lag screw is then placed through the nail and up into the neck and the head of the hip. In both the CHS and intramedullary nail a temporary guide wire or a separate bone screw can be temporarily or permanently left in place.

Most patients undergoing implantation of the CHS will recover well. However, implantation of the CHS traditionally involves an incision of the lateral vastus muscle of

approximately 10 cm subjecting the patients (many of whom are elderly and are multi-morbid) to substantial injury (Janzing et al. 2002). Alternatively, the vastus lateralis need not be incised but can be reflected anteriorly, which is a little slower but results in less blood loss. Additionally, substantial complication rates of 20 to 30% during the first year following CHS implantation have been reported including a 5% non-union rate, 5% infection and 11% rate of device of failure (Goodman 2007). There has also been suggestion that the single screw in the femoral neck is insufficient in certain cases to provide rotation stability in patients treated with the CHS (Buciuto and Hammer 2001).

Although the intramedullary nail is a less invasive fixation alternative for patients, a systematic review of the evidence has recently concluded that the CHS provides superior results for patients as it is associated with lower complication rates (Parker and Handoll 2005).

The PerCutaneous Compression Plate (PCCP), also known as the Gotfried plate, is a minimally invasive fixation alternative for patients with intertrochanteric hip fractures. The PCCP is comprised of a fixed-length plate, three cortical shaft screws and two dynamic neck screws with a sliding mechanism similar to the CHS (inserted at an angle of 135°) (Peyser et al. 2007). The PCCP are inserted via two small incisions (2 cm to 3 cm) and is assembled within the patient (Kosygan et al. 2002 and Peyser et al. 2007).

CLINICAL NEED AND BURDEN OF DISEASE

Due to the population growth of older age groups, it is expected that the incidence of hip fractures in Australia will rise (Sanders et al. 1999). Between 2002 and 2003 it is estimated that 18,616 persons were hospitalised as a result of a hip fracture (Kreisfeld and Newson 2006). Of these, 5,167 were estimated to be intertrochanteric fractures (Kreisfeld and Newson 2006).

DIFFUSION

The PCCP has received approval from the United States Food and Drug Administration.

COMPARATORS

The CHS is currently the most common fixation method for intertrochanteric fractures of the hip. In terms of minimally invasive methods of fixation, the intramedullary nail is an alternative to the PCCP although it appears to be inferior to the CHS. Recently a minimally invasive insertion method of the CHS has been reported in the literature (Lee 2007). However the technique appears to be in the early stages of development and is not yet widespread.

SAFETY AND EFFECTIVENESS ISSUES

Three randomised controlled studies were selected for inclusion in this Prioritising Summary. Each study compared the PCCP to the CHS for the fixation of intertrochanteric hip fractures.

Peysers et al. (2007) included one hundred and four patients with stable intertrochanteric fractures (AO/OTA classification 31.A1 – A2) which were randomly assigned to undergo treatment with either the PCCP or CHS following closed reduction of their fractures. All baseline characteristics with the exception of age were similar between the groups. Patients in the PCCP were significantly ($p < 0.04$) younger at 78.9 years than patients in the CHS group at 82.4 years.

The randomised controlled study by Janzing and colleagues (2002) included a cohort of 115 patients in similar condition to those presented by Peysers et al. (2007) with stable intertrochanteric fractures (AO classification 31.A1 – A2). Fifty three patients were randomly selected to undergo fixation with the PCCP and 62 patients were randomly selected to undergo fixation with the DHS following closed reduction of their fractures.

Kosygan et al. (2002) compared the PCCP to the CHS in a randomised controlled study of 111 patients. Fifty-five patients were randomised to receive fixation using the PCCP while 56 patients were randomised to receive fixation using the CHS. Among the 111 patients there were 50 stable and 61 unstable fractures as classified according to the method of Evans/Jensen.

a) Safety

In the study conducted by Peysers et al. (2007), device related complications were reported in two patients in the PCCP group and four patients in the VHS group. The complications included one case of osteonecrosis (resulting in revision to hemiarthroplasty) and one device failure by varus collapse and cutting out within seven days, resulting in revision using the CHS. In the CHS group, intraoperative complications of fracture of the lateral cortex of the femur at the level of the greater trochanter ($n = 1$) and loss of fracture reduction were reported ($n = 1$). Two additional CHS patients experienced cutting out of the hip screw. In one of these patients removal of the implant and arthroplasty was performed while the other patient died before action could be taken.

The number of complications (including life threatening complications¹) was not significantly different between the two groups indicating that use of the PCCP does not expose the patient to more danger than the CHS. Eighteen deaths were reported, five in the PCCP group and 13 in the CHS group ($p = NS$). The cause of the deaths was not reported.

¹ Life threatening complications: defined as serious cardiovascular complications, cerebrovascular accidents, pulmonary embolism and the need for orthopaedic surgical intervention.

Janzing and colleagues (2002) randomised 53 patients to receive fixation with the PCCP and 64 patients to receive fixation with the DHS. Intraoperatively, three complications were reported in the PCCP group. One patient unable to undergo closed reduction required open reduction of their fracture. In a second patient, narrowness of the hip neck prevented the upper PCCP's neck screw from being placed, instead a large fragment cancellous screw was used. In the third patient the shaft screws were placed beside the femoral shaft requiring open correction and a revision fixation of the same plate. Each of these patients underwent implantation of a DHS instead of the PCCP and were analysed separately to the PCCP and DHS groups.

Revision surgery was required in six patients (two in the DHS group and four in the PCCP group). In the DHS group, the second operation was required for the occurrence of a fracture beneath the DHS plate (n = 1) and perforation of the hip by the DHS (n = 1). In the PCCP group there were three cases of upper neck screw perforation of the head of the femur. These were treated using a bipolar hip prosthesis (n = 1), revision osteosynthesis with a DHS and trochanteric side plate (n = 1), and replacement of the screw with a large fragment cancellous screw (n = 1). In the fourth PCCP patient, progressive loosening of the neck screw with perforation of the overlying skin at one year postoperatively (after complete fracture healing) required the removal of the perforating screws.

By the 12 month follow-up 23 deaths had been reported (12 in DHS group and 11 in PCCP group) while an additional nine patients had been lost to follow-up. There were no statistically significant differences between the two groups in terms of intraoperative implant related problems, unplanned reoperations and mortality at 12 months

While Kosygan et al. (2002) reported 17 deaths in their randomised study they did not specify the cause of death. Seven deaths were reported in the PCCP group, nine deaths in the CHS group and one death among the three patients who underwent PCCP to CHS revision.

According to the authors, in the PCCP group there were three cases of technical difficulties. These included excessive varus in one patient and excessive valgus of the neck-shaft angle after reduction in another patient. In the third patient, increased anterior bowing of the proximal femur was reported. All three of these patients underwent explantation of the PCCP followed by implantation of the CHS with the authors citing that because the PCCP is a fixed angle device it was unsuitable in these patients. This argument however was disputed by Gottfried et al. (2003) in a letter suggesting that the authors made a mistake in concluding that because the PCCP is a fixed-angle device it cannot be universally applicable. Instead Gottfried (2003) suggested that while the appropriate angle of a CHS/DHS plate is determined by the neck-shaft angle achieved on reduction of the fracture, the PCCP philosophy is that of adapting the fracture to the angular configuration of the plate.

The incidence of individual postoperative complications² in the PCCP and CHS group were not statistically different. Patients in the PCCP group experienced pulmonary embolism (n = 1), chest infection (n = 1), non-specified cardiac complication (n = 1), pressure sore (n = 1), implant cut-out/black-out (n = 1) and heel raise (n = 1). There were two cases of cut-out in the CHS group (converted to intramedullary fixation) and none in the PCCP group.

In total six complications were reported in the PCCP group and 21 complications in the CHS group. While the authors of the study did not perform statistical analysis of this difference, Gottfried (2003) noted that this difference was statistically significant (p = 0.0014).

b) Effectiveness

Peysen and colleagues (2007) performed clinical and radiological analysis to test the theoretical benefits of the PCCP in their randomised controlled study of 104 patients. Forty five patients were available for functional outcome analysis and 51 patients were available for radiological analysis in each group. Due to the substantial differences between the devices, blinding was not feasible during radiological and outcome analysis. However, blinding was possible during the recording of blood loss and medical complications and was performed.

While the operating time did not significantly differ between groups, patients in the PCCP group experienced significantly (p < 0.03) less mean blood loss³ than patients in the CHS group (161 ml v 374 ml). This observation however was not coupled with a significant difference between groups in postoperative levels of Hb blood transfusion requirements.

Functional recovery was measured using a pain score and weight bearing test. There was no significant difference in pain between groups between postoperative day and 24 weeks postoperatively, with the exception of significantly (p = 0.04) less pain in the PCCP group at six weeks (3.9 versus 5.8 on the Visual Analogue Scale, VAS). At six months one patient underwent removal of the PCCP due to mild pain despite healing of the fracture.

In terms of the ability to bear weight on the injured or uninjured leg, there was no significant difference between groups between postoperative day one through to 24 weeks postoperatively, with an exception occurring at six weeks when patients in the PCCP group were able to bear significantly more weight on both the injured and uninjured leg (p = 0.04 and p = 0.006 respectively). At six weeks the mean amount of weight on the injured leg was 86.7 kg for PCCP group patients and 71.0 kg for CHS

² Postoperayive complications included: deep vein thrombosis, pulmonary embolism, chest infection, cardiac complications, cerebrovascular accident, upper gastrointestinal bleeding, superficial wound infection, deep wound infection, pressure sore, implant cut-out/back-out and requirement of a heel raise.

³ Blood loss: included blood lost during surgery and blood collected in suction drain postoperatively.

group patients, while the amount of weight on the uninjured leg was 97.4 kg in PCCP group patients and 92.5 kg in CHS group patients.

The PCCP did not lead to significantly better or quicker postoperative mobilisation or shorter hospital stay.

Radiological analysis of both groups revealed a significantly ($p = 0.02$) greater occurrence of collapse⁴ in the CHS group ($n = 10$) compared to the PCCP ($n = 2$). Additionally, at six weeks, a significant lateral protrusion of the hip screw through the barrel of the plate in the CHS group compared to the PCCP group was observed ($p < 0.01$). There were also no significant differences between the groups in terms of mean compression of the hip screws or angular instability⁵.

It is important to note that the surgeries were carried out by a team consisting of an orthopaedic resident and attending surgeon from a pool of six attending surgeons and ten orthopaedic residents.

At the 12 month follow-up of the Janzing et al. (2002) randomised controlled trial there were 83 patients available including 44 patients from the HDS group and 39 patients from the PCCP group.

Multiple regression analysis demonstrated that the time in theatre and surgical time required was significantly less ($p = 0.001$) in the PCCP group than the DHS group. Similarly, multi regression analysis demonstrated the type of fracture (31.A1 or A2) also had a significant ($p = 0.02$) impact on the time in theatre and surgical time required.

There were no significant differences between groups in terms of fracture types reported. Similarly, no statistically significant differences between groups in terms of postoperative blood transfusion and decrease of haemoglobin levels were reported. Postoperative pain however, measured using the VAS score on the first post-operative week was significantly ($p < 0.01$) lower in the PCCP group compared to the DHS group (4.2 versus 3.2). At the 12 month follow-up all fractures had healed and no further implant related complications were reported.

Kosygan and colleagues (2002) reported a statistically significant ($p = 0.001$) longer operating time in patients undergoing implantation of the PCCP (58 ± 15.3 minutes) versus patients undergoing CHS (49 ± 13.1) implantation. There were no statistically significant differences between groups in terms of postoperative blood transfusion and decrease of haemoglobin levels. No other effectiveness measurements were reported by the authors.

⁴ Collapse: defined as the loss of reduction with medial displacement of the shaft, predominately accompanied by additional fracturing of the lateral cortex.

⁵ Angular instability: defined as a change equal to or greater than 10° in the postoperative neck-shaft angle.

COST IMPACT

The cost of the PCCP was not revealed from the retrieved material.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The PCCP device offers a minimally invasive alternative to the CHS for the fixation of intertrochanteric fractures. The device appears to offer advantages over the conventional CHS in terms of its minimally invasive nature and low rate of complications while achieving similar success rates than the CHS.

HEALTHPACT ACTION

Based on the similar success rates to the CHS in a minimally invasive setting without increased safety risks, the PCCP will be monitored for 12 months.

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level II intervention evidence	3

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SEARCH CRITERIA TO BE USED

Percutaneous compression plate

PCCP

Hip fracture\$

Intertrochanteric