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Complications - Other

Morbidity and Safety of Iliac Crest Reference Array Pins in Navigated Total Hip Arthroplasty: A Prospective Cohort Study

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ABSTRACT

Background: Navigated total hip arthroplasty (THA) can employ intra-osseous pins through a separate incision to secure reference arrays to the iliac crest. This study is the first to investigate the consequences of pin use in THA in vivo.
Methods: A prospective, consecutive series of 43 patients presenting for navigated THA were included. Two temporary 125 × 4 mm Schanz screws were inserted into the iliac crest for the attachment of a reference array. Telephone follow-up occurred at 6 and 12 weeks post-operatively. Patients were asked about pain, interference with daily activities, how often the wound was noticed, and duration of discomfort. Patient body mass index was recorded.
Results: The follow-up rate was 100%. Pin site pain at any time post-operatively was reported by 24 patients (56%). This improved to 30%, 9%, and 2% at 3, 6, and 12 weeks, respectively. On average, pain lasted for 16 days total. The most common complaints after pain were clothing discomfort (23%), pain when wearing a belt (12%), or pain when mobilizing (9%). For the majority (98%) of patients, all symptoms had resolved by 12 weeks. There was no nerve injury, pin site fracture, infection, or screw breakage. Patients with body mass index greater than 30 kg/m^2 were up to 3 times more likely to experience pin site pain ($P = .05$), and had a longer duration of pain ($P = .04$).
Conclusion: Surgeons and patients should be aware that using navigational pins for array fixation carries low complication rates but often will cause pain and irritation that resolves in the short term.

The introduction of navigation to total hip arthroplasty (THA) has been thoroughly investigated for its measurement accuracy, along with its claimed effects on leg length discrepancy, offset manipulation, and cup positioning [1–8]. It is equally important to examine the pitfalls it may pose so that patients can be counseled pre-operatively.

The use of intra-osseous reference arrays has the potential to harm the patient. These are pinned to the bone to register the patient position to the navigation software. Several case reports and cohort studies, predominantly in total knee arthroplasty (TKA), have commented on complications such as pin site infection, neurovascular injury, thermal necrosis, reference screw retention, soft tissue injury, pin or drill bit breakage, and pin site fractures [9–20]. Only one cadaveric study examines percutaneous pin use in THA, and this paper explores the relationship among pin arrangement, soft tissue dissection, and stability rather than in vivo, patient-reported consequences [20].

Yet to be explored are the complication rates, pain characteristics, and impact on activities associated with the additional wound and temporary intra-osseous iliac crest pins. There are no previous studies published on this topic in the English literature.

The iliac crest is a well-known source of pain in other procedures such as bone marrow biopsies and bone graft harvesting. Several studies in pediatric and adult spinal surgery populations document a 2.5%-55% incidence of chronic pain in the iliac crest lasting up to 4 years [21–30]. Owens and Swank [31] examined tibial pin site pain in their follow-up of navigated TKA patients and found that 2 of 984

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Fig. 1. Insertion of pins (left) and attachment of reference array (right).

cases (0.2%) had pain, which resolved within 6 weeks. It is also known that arthroplasty patients with a higher body mass index (BMI) carry greater risk of complications [32,33]. Average BMI is steadily increasing, and one North American study recently investigated a large cohort with a mean BMI of 28.6 kg/m^2 with a maximum of up to 60 kg/m^2 [34].

It was hypothesized that pinned reference arrays would be associated with short-term to medium-term pain and discomfort in the iliac crest area. Secondary hypotheses were that patients who received 2 stab incisions rather than a single longer incision would be less symptomatic and that patients with a greater BMI would be predisposed to pin site–related complications. This study investigates for the first time the pain, irritability, and impact on quality of life associated with the use of iliac crest navigational array pins in THA.

Materials and Methods

A prospective, consecutive series of 43 Australian patients presenting to the Royal Melbourne Hospital for unilateral navigated THA performed by the lead surgeon (A.B.) or the fellow (R.J.) were included. Study size was defined by temporal limitations. Patients presented between August 2010 and April 2011 and had a mean age of 62.6 years (SD 14.3, range 23-86). The cohort was 61% male and 39% female with a mean BMI of 30.3 kg/m^2 (SD 5.4, range 20-42). For analysis of BMI influence, the patients were divided into non-obese (BMI $<$ 30 kg/m^2, n $=$ 20) and obese (BMI $>$ 30 kg/m^2, n $=$ 23) cohorts.

In all patients 2 temporary self-drilling and self-tapping 125 $\times$ 4 mm Schanz screws were inserted into the iliac crest on the operative side for attachment of an infrared optical tracking reference array (Fig. 1). This was performed through a single 3- cm incision for the first 21 patients chronologically, and through 2 separate 1-cm stab incisions for the subsequent 22 patients. All patients were positioned in lateral decubitus. Closure of the navigation pin incision(s) was performed using a continuous 2-0 braided absorbable deep dermal suture and a continuous buried 3-0 monofilament absorbable dermal suture. A waterproof island-type dressing was then placed for 2 weeks. No difference in pin placement, wound closure, dressing, or other component of pin site wound care changed irrespective of patient BMI. The target region of the iliac crest was accessible for all patients. Post-operative care was standardized as per department protocols. The imageless navigation system (Hip 5.1; BrainLAB, Feldkirchen, Germany) used a pinless femoral reference array, where the plate was fixed to the skin using a sterile adhesive.

Surveys were conducted in person pre-operatively and by telephone at 6 and 12 weeks post-operatively and included both quantitative and qualitative questions. Pin site pain was rated out of 10 pre-operatively, and at 3, 6, and 12 weeks post-operatively. Survey questions are outlined in Table 1. Statistical analysis on quantitative data was performed using Microsoft Excel (Excel for Mac 2008; Microsoft Corporation). To compare obese and non-obese cohorts, a 2-tailed Fisher's exact test was performed to analyze the reported incidence of pain and a 2-tailed Mann-Whitney U-test was performed to compare pain duration. The research has been performed with the approval of an appropriate ethics committee in compliance with the Helsinki Declaration, and informed consent was obtained from all participants.

Table 1
Survey Questions.

Question	Data Type	Response
How much pain do you experience from the wound on the iliac crest?	Quantitative	0-10 pain scale
If the pain is no longer there, how long did it take to disappear?	Quantitative	Numerical, in days
How does it interfere with your daily activities?	Qualitative	Short answer
Does it cause discomfort when wearing clothing? How?	Quantitative/qualitative	Yes/No and short answer
How often do you notice the wound?	Quantitative	Never, some days, most days, everyday
Does it cause itchiness?	Quantitative	Yes/No

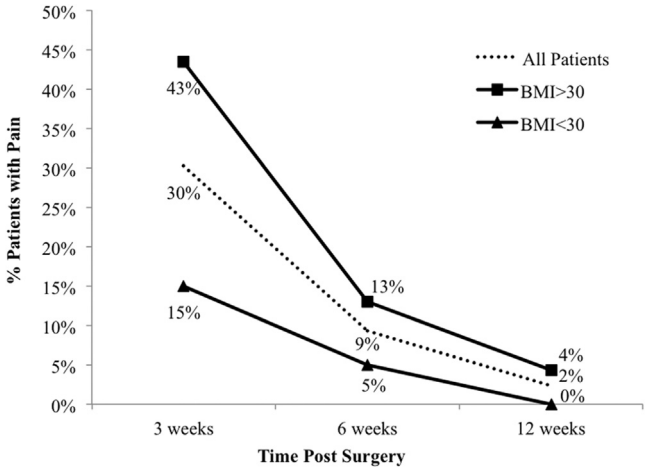

Fig. 2. Line chart with proportion of patients with pain.

Results

All 43 patients (100%) responded to all follow-up surveys. Pre-operatively, none of the patients described pain in the iliac crest or had a diagnosis of meralgia paresthetica. Figure 2 demonstrates the proportion of patients complaining of pain from the pin site in the post-operative period, including a breakdown of obese and non-obese patients. The mean pain score for those who experienced pain was 5/10 both at 3 and 6 weeks. The only patient with residual pain at 12 weeks reported 6/10 pain.

At 3 weeks post-operatively, obese patients were approximately 3-fold more likely to be experiencing pain at the pin site (43% vs 15%, $P = .05$). There was no statistically significant difference at 6 or 12 weeks ($P = .6$ and 1.0, respectively). There were no differences in the severity of pain between the 2 groups.

Overall, 24 patients (56%) experienced pain in the pin site area at any point in time (some less than 3 weeks). The mean duration of pain was 16 days (SD 25, range 0-122; Fig. 3). A comparison between obese and non-obese cohorts (Fig. 4) demonstrated that obese patients suffered pain from the pin site for a longer duration (median: 6 vs 0 days, $P = .04$).

In terms of impact on daily activities, 30 patients (70%) complained that the pin site had affected their daily living. The most common complaints are outlined in Table 2. All cases of clothing discomfort had resolved by 12 weeks.

Table 2
Most Common Interferences With Daily Activities.

Complaint	No. of Patients (%)
Clothing discomfort	10 (23%)
Itchiness	10 (23%)
Discomfort wearing belt	5 (12%)
Pain when moving	4 (9%)
Discomfort sleeping on side	2 (5%)
Chaffing/rubbing	2 (5%)

In examining the qualitative survey responses, clothing discomfort was something that a significant portion of the patients felt strongly about, whereas issues such as itchiness and pain when moving were mentioned less emphatically. By 12 weeks post-operatively, the majority of patients had forgotten about the pin site (Fig. 5). There were no significant differences in frequency of noticing the pin site between obese and non-obese patients.

There was no significant difference shown between the 2 incisions or single incision methods for insertion of the pins in terms of pain at any time point, duration of pain, or interference with daily activities.

Aside from symptoms of bother described above, there were no complications relating to pin use including lateral femoral cutaneous nerve injury, pin site infection, iliac crest fracture, or pin breakage.

Discussion

The results demonstrate that from the patient's perspective, iliac crest reference pins are not to be overlooked as an important part of the pre-operative counseling process and their recovery, with the majority of patients reporting some level of pain in the area and a significant proportion describing downstream effects on their daily activities. The study demonstrates no other complications relating to pin use.

The frequency of patient-reported pain fits within the spectrum of broader results previously reported in iliac crest bone grafting patients, albeit shorter lived. When compared to similar literature in TKA patients, early post-operative pin site pain was demonstrated to be far more common in the THA cohort [31]. There were no studies available for direct comparison in other THA patients.

It was interesting to observe the differences between obese and non-obese cohorts. Although our Australian population had a comparable mean BMI to that reported by Purcell et al [34] in a North American population, we had fewer patients in the higher

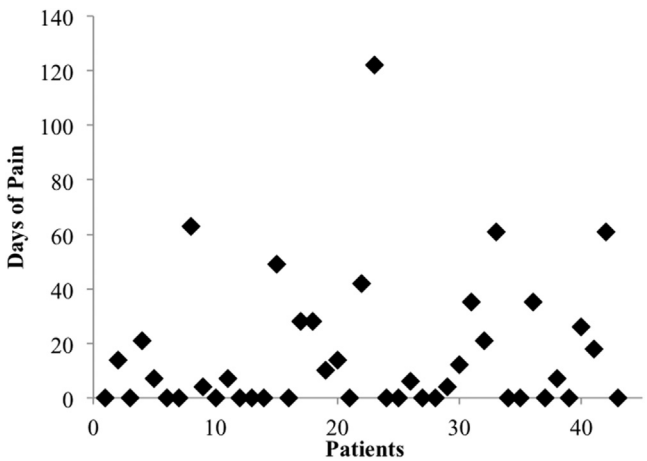

Fig. 3. Scatterplot of the duration of pin site pain.

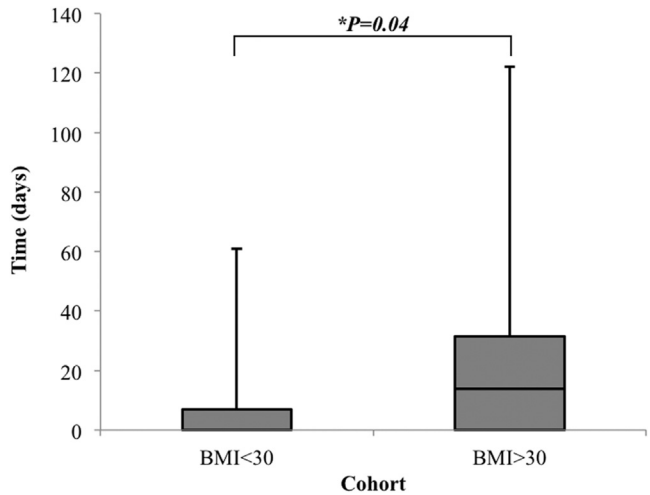

Fig. 4. Box plot of the duration of pin site pain for non-obese and obese patients.

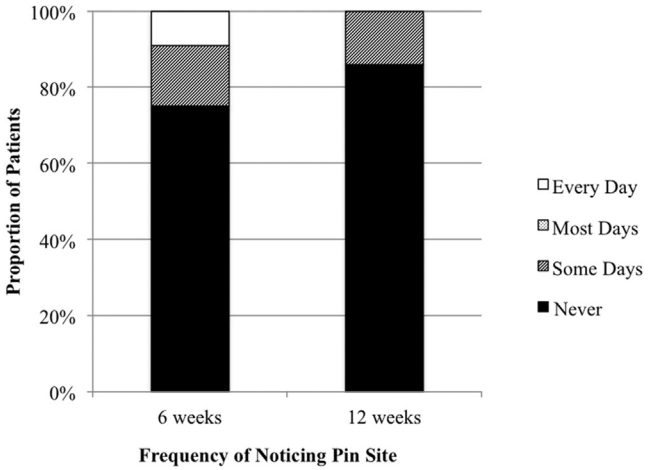

Fig. 5. Hundred percent stacked column chart of frequency noticing the pin site.

echelons of obesity compared with their 25% with BMI >35 kg/m^2 up to a maximum of 60 kg/m^2. As was hypothesized, patients with greater BMI reported more morbidity from the pin site, with a greater frequency and duration of pain. This may be multifactorial, with possible contribution from a greater surgical dissection to identify the iliac crest along with other obesity-associated conditions including chronic pain and psychosocial sequelae.

This article draws strength from being a novel research question, having a moderate sample size, close frequent follow-up, and the collection of both qualitative and quantitative data. Thanks to a dedicated and persistent research team, there were no patients lost to follow-up across any survey time points.

A limitation of the study is that pin site wound infections were assessed by self-reporting over the phone, and patients were not routinely booked for a 2-week wound evaluation. An avenue for further research would be to include physical visits in order to more accurately detect pin site infection by examination. Furthermore, expanding the population sample and formally randomizing incision technique (2 stabs vs single wound) may help determine whether a symptomatic difference exists with smaller skin incisions. This study was underpowered to formally evaluate for any differences between the 2 incision techniques.

There was a greater than expected frequency of patients reporting issues with the wearing of clothing and belts. It would be interesting to assess whether placing the pins further laterally, and thus superiorly, along the iliac crest would reduce the frequency of clothing discomfort.

Conclusion

This study is the first of its kind to prospectively examine the consequences, from the patient perspective, of introducing temporary intra-osseous reference arrays to the THA surgical technique. It also formally assesses complication rates, demonstrating no incidences of infection, fracture, nerve injury, or drill and pin issues.

Surgeons need to be aware, for both counseling and technical purposes, that the use of navigational pins does cause a noticeable degree of pain and bother for the patient. Fortunately, patients can be reassured that this usually resolves in the short term.

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