Evidence Review

Topic: Clinical effectiveness of two-incision total hip arthroplasty

Introduction

There is considerable interest in the use of less invasive procedures in total hip arthroplasty (THA). Although THA is among the most successful surgeries available today, with predictably excellent and reproducible results [1], the principles of minimally invasive surgical trauma such as less blood loss, reduced pain and quicker recovery have guided the development of less invasive THA procedures. Since its inception in the late 1990s, the two-incision less-invasive THA has been increasingly viewed as a technique that could deliver shorter recovery times and reduced health care costs. The aim of this evidence review is to evaluate the clinical outcomes and safety of the two-incision THA technique compared to the single mini- and standard-incision THA based on the best available evidence.

Total hip arthroplasty

THA is the surgical replacement of a severely diseased or dysfunctional hip joint with an artificial joint. The main reasons for THA is to relieve the severe pain and disability of the hip associated with osteoarthritis, rheumatoid arthritis, avascular necrosis, traumatic arthritis or hip fractures. [2] The goal of a total hip replacement is to provide the patient with a pain-free, well-fixed, stable arthroplasty that restores function and survives for many years [3]. The long term results of standard THA feature survival rates of up to 95% after 10 years and up to 90% after 20 years. [4]

In THA, the prosthesis consists of three main parts: a ball to replace the femoral head, a stem which is inserted into the femur, and a cup that is inserted into the acetabulum of the pelvis. In a standard incision THA, the prosthesis is inserted into the body through an opening of 20-25cm in length. [5,6] Most orthopaedic surgeons prefer a posterior or anterolateral approach, [5,6] although other approaches such as the anterior, direct lateral (transgluteal) and lateral transtrochanteric [7] are also used. The incision length is based on surgeon preference and patient factors, and is of sufficient length to permit complete and continuous viewing of the entire hip joint and periarticular structures. Drawbacks of lengthy incisions include significant soft tissue disruption, pain and lengthy rehabilitation time. [8]

Recent reports [9,10,11] have indicated that a two-incision THA technique could significantly speed up postoperative recovery and allow a majority of patients to be discharged home on the same day of surgery. Therefore, this particular form of THA could provide considerable cost savings and increase patient turnover, and thus merits careful assessment.

Less-invasive total hip arthroplasty

Ideally, surgical intervention should be optimized to give the best results while minimizing potential complications and hastening recovery. The use of minimally invasive techniques in other surgical fields has made these goals achievable. For example, fast recovery times, lower postoperative morbidity rates, and reduced costs have been achieved with laparoscopic gall-bladder and hernia surgery. [3,12] Even within the orthopaedic field, minimally invasive techniques have yielded improvements over standard approaches. Examples include arthroscopic meniscetomy, arthroscopic subacromial decompression, arthroscopic rotator cuff repairs, endoscopic ACL reconstruction, and microdiscectomy, among others. [13]

Since the late 1990s, surgeons have been developing and promoting two forms of less invasive THA that use either one small incision or two very small incisions (one 2 cm, the other up to 6 cm) to perform the same THA performed in the standard incision procedure. [14] Among the minimal

incision techniques, there is variance in incision lengths, incision placements, surgical approaches, and the amount of underlying tissue dissection. This evidence review will assess the clinical outcomes associated with the two-incision THA techniques.

Two-incision THA

The two-incision approach for THA was first studied in 1997 by Dana Mears. [15] Based on his work on cadavers, Mears developed an intermuscular anterior approach for the implantation of the acetabular component, and an intermuscular posterior incision for preparation and implantation of the femoral component. [15] Since 2001, Zimmer Inc. (Warsaw, IN) has overseen the further development and refinement of this technique, and has contributed to the global marketing campaign of this procedure. The first clinical use of the Zimmer 2-incision THA technique was performed by Dr. Richard Berger (Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL) in February 2001. As of April 2004, over 500 surgeons had completed the Zimmer-sponsored training on the technique and instrumentation needed to perform the procedure. [15]

The two-incision technique was born out of a desire to avoid transecting any muscle and tendon, thereby minimizing morbidity and recovery. [10] The technique developed by Mears and Berger is described as a completely intermuscular approach; meaning muscle and tendon are left intact during the procedure. [3] Other two-incision approaches have been developed (see table 1), such as the Irving approach [16] and the Light and Keggi approach [17], although it should be noted that these techniques incorporate the intentional cutting of muscle and tendon during the procedure. For example, the Mears/ Berger technique preserves the short external rotators (hence its intermuscular description) whereas in the Irving technique the short external rotators are detached. [3]

Table 1. Classification of single-incision approach THA

Classification	Approach	Method of dissection	Previous Designation
A-IM/P-IM	Anterior/Posterior	Intermuscular	Mears/Berger
A-IM/L-TM	Anterior/Lateral	Inter- and transmuscular	Light and Keggi
A-IM/P-TM	Anterior/Posterior	Inter- and transmuscular	Irving

Adapted from Duncan et al. 2006

The two-incision technique developed by Mears has been described by Berger and Duwelius [10] and Berger. [9] This technique uses an anterior incision (4 to 6cm) with special lighted retractors and beveled reamers to insert the acetabular component, which is confirmed with fluoroscopy. Next, through a posterior incision (1.5 to 3.0 cm), the femoral canal is reamed and broached, and the stem is inserted percutaneously through the posterior incision. Placement of the femoral component is verified by direct visualization and with fluoroscopy.

Minimally-invasive or Less-invasive THA?

A review of the literature shows conflicting terminology used in the description of the same group of procedures used to perform THA through a minimal incision. These terms often include 'minimally-invasive' and 'less-invasive'. A unifying concept among these procedures is that the approach is not just about the skin incision, but the entire management of the deep soft tissues. Some authors argue that total hip replacement surgery, even with the goal of minimal soft tissue disruption, is not minimally-invasive by its very nature, but that the surgical process can be performed less invasively. [18,3,19] Duncan et al (2006) [3] have noted that THA, regardless of the technique used, requires the surgeon to expose the hip, excise the femoral head, ream the acetabulum, and insert two relatively large implants, and that this inherently invasive surgery almost always requires hospitalization and is associated with substantial morbidity. Woolson (2006) [14] has illustrated the invasive nature of THA by noting the invalid comparison between small incision THA and truly minimally-invasive orthopaedic procedures such as arthroscopic menisectomy. In particular, that author notes that the later procedure does not involve the placement of a large prosthesis within the body but involves the removal of relatively small portions of soft tissue from the open anatomic

space of the knee joint, and this procedure is almost always performed on an outpatient basis. For the purposes of this evidence review, THA procedures performed through minimal incisions will be described as 'less-invasive' or 'minimal-incision', rather than 'minimally-invasive'.

Possible advantages and disadvantages of two-incision THA

The expected benefits of the two-incision THA are attributable to the minimized soft tissue disruption as compared to standard THA. These benefits include reduced postoperative pain, reduced blood loss, accelerated recovery, shorter hospitalization, lower risk of complications, and cosmetic appeal. [5,13]

Conflicting messages can be readily found in the press. This is true among published studies on the two-incision THA technique reported in case series, case studies and expert opinions. Berger, an innovator of the technique, presented a case series [9] of the first 100 THAs peformed with the less invasive two-incision procedure and reported a complication rate of 1%. Moreover, 85% of the last 88 patients in that series were discharged home on the day of surgery. The protocol of that study included an accelerated rehabilitation protocol, non-general anaesthesia, and a new pain management system. No readmissions, no dislocations, and no revisions were required among this group. Another case series report with 225 two-incision THA cases found encouraging short-term results with good component positioning, early recovery and a 4% complications rate. [20]

However, other reports have found less favourable results with the two-incision technique. Mardones et al. (2005) [21] found damage to the abductors and external rotators that was significantly greater with the two-incision technique compared to the single-incision technique, which contrasts Berger's claim of sparing muscles and tendons from damage with the technique. Archibeck and White (2004) [15] surveyed the outcomes of 49 surgeons trained in with the two-incision technique and found that the rate of key complications did not decrease over the first 10 cases. Moreover, the authors reported a 9.4% complication rate in 851 patients from 159 surgeons' first 10 cases with the two-incision technique. These results suggest that the learning curve may last beyond 10 operations for most surgeons.

A proper assessment of the clinical effectiveness of two-incision THA techniques must come from good quality scientific studies with an adequate control group. Case series reports, studies and expert opinions are subject to numerous biases that limit the validity and reliability of their conclusions. [22]

Aim of review

The aim of this evidence review is to assess the clinical effectiveness and safety of THA performed with the two-incision technique compared to either the standard open-incision or mini-incision THA. Evidence from comparative studies will be relied on in this review.

Review Design

Search Strategy

The objective of this evidence review was to assess the outcomes of two-incision primary THA with respect to effectiveness and safety in comparison to standard exposure or single mini-incision THA. To ensure that studies of good scientific quality were selected, preference was given for systematic reviews and randomized controlled trials. However, all types of comparative studies could be included in this review. Non-comparative studies, such as case series reports, case studies, and expert opinions, are regarded as having the lowest level of evidence [22] and, thus, were not included in this review.

Searches of the major medical electronic databases (Cochrane DSR, PubMed, EMBASE, CINAHL) were conducted with the following search strategy:

Search Term: (dual OR two OR multiple OR component) AND (mini OR minimal OR micro OR small OR limited OR short OR abridged) AND (approach OR incision OR exposure OR invasive) AND (arthroplasty OR replacement) AND (hip) AND English[la]

Study inclusion criteria

The selection criteria for published studies were as follows:

- Comparative studies that assess outcomes (efficacy, safety, cost-effectiveness) of minimal-incision THA vs. standard-approach or single minimal-incision THA
- Studies based on primary THA patients
- Studies wherein the primary diagnosis is OA
- Studies limited to English-language reporting

Exclusion criteria included:

- Non-comparative studies (e.g., case series, case report, expert opinion)

- Studies that do not contain patient data
- Studies that report on hip replacement prostheses that are not conventional total hip replacement devices (e.g., hip resurfacing devices)

Studies selected for inclusion:

- Pagnano et al. 2005. [23] Two-incision THA had modest outcomes and some substantial complications. Clin Orthop Rel Res. 441: 86-90
- Tanavalee et al. 2006. [24] Early outcomes following minimally invasive total hip arthroplasty using a two-incision approach versus a mini-posterior approach. Hip International. 16(2 suppl. 4): S17-S22
- Bal et al. 2005. [25] Early complications of primary total hip replacement perfomed with a two-incision minimally invasive technique. J Bone Joint Surg. 87-A(11): 2432-2438

Studies excluded but of interest:

- Pagnano MW et al. Patients preferred a mini-posterior THA to a contralateral two-incision THA. Clin Orthop Rel Res. (Epub ahead of print) [bilateral THA patients examined, single series]
- Mardones R et al. 2005. The Frank Stinchfield Award: muscle damage after total hip arthroplasty done with the two-incision and mini-posterior techniques. Clin Orthop Relat Res. 441:63-7 [bilateral THA cadavers examined]
- Archibeck MJ and White RE. 2004. Learning curve for the two-incision total hip replacement. Clin Orthop Relat Res.(429):232-8 [Case series of outcomes of 49 surgeons' initial 10 cases]
- Yoon TR et al. 2006. A modified two-incision minimally invasive total hip arthroplasty: Technique and short-term results. Hip International. 16(suppl. 4): S28-S34. [Case series report]
- Irving JF. 2004. Direct two-incision total hip replacement without fluoroscopy. Orthop Clin N Am. 35: 173-181. [Case series report]
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- Berger RA. 2003. Total hip arthroplasty using the minimally invasive two-incision approach. Clin Orthop Relat Res.(417):232-41 [Case series report]
- Duwelius PJ. 2006. Two-incision minimally invasive total hip arthroplasty: techniques and results to date. Instr Course Lect. 55:215-22 [Reference to case series with no patient data]

Quality control

No relevant systematic reviews or randomized controlled trials were identified in the literature search.

Results

Six comparative observational studies were included in this review. These studies are summarized in tables 2 and 3.

Table 2: Description of two-incision THA Observational Studies

Study	Study Type	Study period	Groups	Incision Size (range)	Number of hips	Mean Patient Age (range)	Mean BMI kg/m^2 (range)
Tanavalee et al. 2006	Case control	2002-2004	2-incision	Anterior: 5.2cm (4.5-6.0) Posterior: 3.6cm (3.0-4.0)	35	53 (34-75)	25 (17.1-33.3)
			Mini-incision	9cm (7.0-12.0)	35	54.9 (38-76)	24.2 (19.3-33.3)
Bal et al. 2005	Case control	2003-2004	2-incision	Anterior: 5.1cm Posterior: 2.5cm	89	58.5 (24-85)	30.7 (17.6-59.4)
			Mini-incision	(7.0-12.0cm)	96	57.4 (25-87)	31.3 (17.9-55.8)
Pagnano et al. 2005	Case control	2003-2004	2-incision	Anterior: 5cm Posterior: 3.8-5cm	80	70.5 (40-88)	NR
			Stnd-incision	(7.0-12.0cm)	120	71.0 (35-89)	NR

Data are mean ± SD, unless otherwise indicated. Stnd incision: Standard open procedure. NR: Not Reported.

Table 3: Perioperative results of two-incision THA Observational Studies

Study	Groups	Operating Time (range)	Blood Loss (BL; range)	LOS (range)	Complications	Study Follow-up Period (range)
Tanavalee et al. 2006	2-incision Mini-incision	168min (130-210)* 113min (90-140)*	699mL (380-1090)* 603mL (300-980)* [Total BL]	NR	2-incision group (n=35) 4 fractures 4 transient numbness 1 superficial wound infection Mini-incision group (n=35) 2 skin abrasions	20.2 months (12-36)
Bal et al. 2005	2-incision Mini-incision	127min (82-225)* 96min (77-125)*	545.2mL (50-2000)* 328.9mL (50-1000)* [Intraoperative BL]	4.5days (2-8)* 5.1days (3-12)*	2-incision group (n=89) 7 fractures 4 loose stems (required revision) 22 thigh numbness 2 would irrigation and debridement 1 dislocation 1 femoral nerve injury Mini-incision group (n=96) 2 fractures 1 loose stem (required revision) 2 would irrigation and debridement 1 dislocation	2-incision: 11months (6-17) Mini-incision: 22months (18-30)
Pagnano et al. 2005	2-incision Stnd-incision	69min (48-128)* 54min (38-108)*	NR NR	2.8days (1-7)* 5.2days (3-11)*	2-incision group (n=80) 4 intraoperative fractures 3 postop fractures, req'd revision 2 femoral nerve palsies 1 disclocation Stnd-incision group (n=120) 4 intraoperative fractures 2 dislocations	12 months

Data are mean ± SD, unless otherwise indicated. NR: Not Reported. * Statistically significant comparison ($p < 0.05$)

Description of Observational Studies

Tanavalee et al. (2006) prospectively compared the short-term clinical and radiographic outcomes of THA patients who received the surgery via a two-incision approach (n=35) and mini-posterior approach (n=35). All procedures were performed by the same surgeon, and it was stated that the two-incision series results included the physician's learning curve. All patients received the same cementless hip system and the same anaesthetic and postoperative pain management protocol was administered to both groups. Both groups were comparable in age, BMI, and the primary indication for surgery was osteoarthritis. It should be noted that the two-incision group had a higher percentage of females (77%) compared to the mini-group (43%). Operative data comparisons found a significantly longer mean surgery time for the two-incision group (168min vs. 113min), which resulted in more total blood loss (699mL vs. 603mL), and higher units of transfused blood (1.4 vs. 0.9). The authors attributed the longer operating time to the femoral preparation with minimum visualization. Postoperative comparisons revealed that the two-incision group had a faster ability to walk with ambulatory aids, an increased ability to walk without aids at discharge, and quicker return to work and driving. However, the two-incision group had no activity limitation at discharge while the mini-incision group was prohibited from activities of high hip flexion and internal rotation for 6-8 weeks after surgery. The authors concede that the restrictions on ambulation on the mini-incision group may have delayed their return to independent function. Lastly, no differences on Harris hip scores, ability to climb stairs, and radiographic assessment of implant positioning were observed between the groups at 1 year postoperatively.

Strengths of this study include the fact that all operations were performed by the surgeon, the same cementless prosthesis was used in all patients, and the same anaesthesia and pain management protocol were applied to both groups. On the other hand, there were an inordinate number of female patients in the two-incision group, and the overall sample sizes were low. Also, the results of the two-incision group were based on the surgeons' initial clinical experience with the technique, unlike his established expertise with the single mini-incision technique.

Bal et al. (2005) retrospectively compared the clinical and safety outcomes of 89 consecutive primary THA patients who received the procedure via the two-incision technique with 96 patients who received a mini-lateral incision THA. All surgeries were performed by the same surgeon. All patients received the same uncemented acetabular component, but 3 different femoral stem designs were used throughout the study period. The groups were similar in age, gender distribution, BMI, and the main reason for THA was osteoarthritis for both groups. Postoperative recovery instructions differed between the groups as the two-incision patients were allowed to place full weight on the involved hip after surgery with the use of a walker or crutches, while the mini-incision group patients were permitted to begin full weight-bearing four weeks after surgery and were asked to use assistive devices for walking for the fist six weeks. Several perioperative differences emerged between the groups. The two-incision group averaged longer operating times (127min vs. 96min), higher intraoperative blood loss (545mL vs. 329mL), but were discharged from hospital sooner (4.5days vs. 5.1days). The overall rate of complications was significantly higher in the two-incision group (42% compared to 6%), and the overall reoperation rate was 10%, compared to 3% in the mini-group. The authors note that the higher complication rate of the two-incision group occurred despite the fact that the surgeon's practice was limited to joint replacement surgery and had fellowship training with the two-incision procedure. A comparison of the complication rates in the first 40 and next 49 two-incision procedure patients revealed a significant decrease (55% vs. 31%, $p = 0.02$), presumably indicating the steep learning curve of this technically demanding procedure. Lastly, radiographic analysis found significantly more hips with poor fit and fill grading of the cementless femoral component in the two-incision group as compared to the single mini-incision group.

Several limitations exit with this report. Three different femoral stem designs were used as the authors gained experience with the two-incision procedure. Also, post-surgical weight-bearing instructions differed between the groups, and both had substantially different follow-up periods. Strengths of this study include its adequate sample sizes.

Pagnano et al. (2005) retrospectively compared the clinical outcomes of 80 patients who received THA via the two-incision technique with the results of 120 standard open-incision patients. The same surgeon performed all of the operations, and all patients received a cementless implant. Both groups were comparable in mean age and weight, although BMI was not reported, and the most common indication for THA was osteoarthritis. The authors noted that the two-incision THA was technically more difficult as reflected by its longer mean operative time (68min vs. 54min) and significantly higher rate of complications (14% vs. 5%). The two-incision group had significantly shorter hospital stays (2.8days vs. 5.2days), and a

higher percentage of those patients were discharged directly to home (90% vs. 65%). This study did not utilize preoperative physical therapy to instruct patients on postsurgical self-care. The authors suggest that if such a protocol existed, it may have reduced hospitalization stays. Furthermore, the authors note that improvements in anaesthesia, changes in patient expectations, and the lifting of weightbearing restrictions after THA applied to the later two-incision group but not the standard THA group, which may have had an impact on the discharge data.

The major limitation of this study was the changes in postoperative treatment of the two-incision group that were not applied to the control group. This study had adequate sample sizes.

Discussion

Considerable interest exists among surgeons, patients and policymakers about the potential benefits of two-incision less invasive THA. Unfortunately, there are an extremely limited number of comparative studies available on this new surgical technique from which to draw conclusions from. The surgeon developers of this technique have presented case series accounts where THA patients who received the implant via the two-incision procedure had very low complication rates and the vast majority of operations were performed on an outpatient basis. [10,11] To date, those findings have not been duplicated in controlled trails. Summarized below are findings of the comparative studies with regards to the potential benefits of the two-incision technique.

Blood loss

A strong advantage of the two-incision technique over other surgical THA procedures is the minimal soft tissue disruption with no or limited dissection of muscles and tendons. [11] This should result in less intraoperative and total blood loss compared to other procedures. The comparative studies did not confirm this. Bal et al. and Tanavalee et al. found greater intraoperative and total blood loss, respectively, compared to the single mini-incision technique. All of the included studies reported longer operating times with the two-incision technique, which is reflective of the surgeons' learning curve, and which is likely responsible for the higher blood loss associated with the procedure.

Recovery and discharge

Berger found that two-incision THA patients recovered faster than patients with traditional THA, and that most of the two-incision patients reported less post-surgical pain and expressed a desire to be discharged earlier than traditionally had been done. [9] Consequently, when the author introduced an outpatient protocol that included accelerated physical therapy, non-general anaesthesia, and a new pain management plan, all two-incision patients were discharged to home within 23 hours. Pagnano et al. found that the early functional outcomes of the two-incision group were modest and the length of hospital stay significantly shorter compared to the standard THA patients. Bal et al. found a significantly reduced hospital stay for the two-incision group. Unfortunately, validated outcome tools such as the SF-36 and WOMAC were not used to assess patient recovery profiles. Overall, it is likely that patients who receive THA with this surgical procedure will experience quicker recovery of function and require less hospitalization than their standard THA counterparts, and this difference will be maximized with the implementation of protocols aimed at rapid recovery. Factors such as surgeon experience and patient selection must be taken into account.

Complication rates

Major concerns with the two-incision technique stem from the impaired visual field during surgery. [26] Poor visualization may result in increased neurovascular injury, inaccurate reaming, or suboptimal component placement, even though the procedure is often assisted with fluoroscopy imaging technology. In his first 100 two-incision procedures, Berger found a 1% complication rate (one femoral fracture), with no dislocations, readmissions or revisions. The comparative studies of this review found substantially higher complication rates with the two-incision technique compared to single-incision procedures. Bal et al., in particular, noted that their complication rate (42%), repeat surgeries and radiographic malpositioning of components with the two-incision technique was higher compared to the case series reports of developer surgeons. [9,10,27] The two-incision technique is a technically demanding procedure with a steep learning curve. Archibeck and White [15] found that rate of key complications does not decrease over the first 10 two-incision cases performed by 49 surgeons trained in the technique. They suggest that the learning curve exists beyond the 10th case, where complication rates could approach the low values achieved by the Berger and others, although the amount of experience required to achieve this proficiency has not been established.

Costs of minimal-incision THA

The costs associated with the specialized training and instrumentation required for the two-incision THA has not been reported in the literature. Compared to conventional THA, costs could be higher with the two-incision technique with the use of navigation systems, specialized surgical instruments, longer operating times, and potentially higher complication rates. On the other hand, reduced hospital-associated costs could be achieved with this technique if it results in faster patient recovery and discharge. A higher patient turnover rate could be achieved in this scenario. Other potential savings may include quicker return to function and work.

Conclusion

There are a surprisingly limited number of comparative studies available of any type on the short-term clinical outcomes and safety of two-incision THA. Therefore, no firm conclusions can be reached on the clinical effectiveness and safety of this new technique for THA. The two-incision THA is a technically demanding procedure that requires extensive training, careful patient selection, and the use of clinical management protocols to facilitate recovery. It is unclear what contribution is made by the two-incision surgical technique towards earlier improvements in pain and recovery and to what degree these proposed benefits are due to new anaesthesia protocols, new postoperative pain management protocols, patient education and quicker rehabilitation protocols, and patient selection. [21] Randomized, prospective clinical trails are needed to confirm and define the potential benefits of dual-incision THA. At present, there is no strong evidence to suggest that this procedure has any significant clinical advantages to the patient over a single minimal- or standard-incision THA. Confirmation of the potential benefits of the two-incision THA, such as faster physical therapy, recovery and hospital discharge, could represent significant health care cost savings.

Summary and Recommendations

- Low quality comparative studies show two-incision THA to be technically demanding but offers potential of quicker recovery and discharge
- Non-comparative reports suggest technique could be done on outpatient basis with low complications, if performed on appropriate patients with improved recovery protocols.
- There is a lack of controlled trails on the effectiveness and safety of two-incision THA
- No randomized, prospective studies are available
- No mid- and long-term outcomes reports are available
- Most of published reports (case series, case studies, expert opinions) are likely to have biased conclusions
- The degree of intended minimization of soft tissue dissection and damage remains uncertain
- Candidates for less-invasive THA should understand that procedure is investigational, and that traditional THA is among the best surgical treatments currently available.
- Randomized, prospective clinical trials are urgently needed to ascertain the clinical effectiveness, safety and cost benefits of the numerous forms of less-invasive THA.

Limitations

A publication bias is present as only studies published in English were selected.

Potential conflict of interest

None known

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Enquiries and Contact Information:

Kursat Barin, Information Analyst
Email: kbarin@albertaboneandjoint.com

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