MONASH University

A PROSPECTIVE RANDOMISED CLINICAL TRIAL IN TOTAL HIP ARTHROPLASTY

Comparing Early Results between the Direct Anterior Approach and the Posterior Approach

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ABSTRACT

Early functional outcomes following direct anterior approach (DAA) total hip arthroplasty (THA) when compared with other approaches remains a contentious subject. This study aims to compare early clinical, functional and radiological outcomes in patients randomised between the DAA and posterior approach (PA) for THA.

Between March 2014 and March 2015, 73 participants (35 DAA, 38 PA) received THA surgery at Eastern Health. Participants were evaluated pre-operatively, 2 weeks, 6 weeks and 3 months post operatively following THA surgery with multimodal outcome measures. The primary outcome measure was the Western Ontario McMasters Arthritis Index (WOMAC). Secondary measures included the Oxford Hip Score, EQ-5D, 10 metre walk test, radiological and clinical parameters. Clinical parameters analysed were length of stay, surgical time, opiate analgesic requirements, post-operative haemoglobin levels, complications, hip function and range of movement. The primary end point was time, 3 month post operatively. Statistical analysis was performed using liner mixed models and Wilcoxon Rank Sum Tests.

The DAA group had longer operative times, smaller surgical wounds and higher blood loss. The length of acute hospital stay was significantly shorter for the DAA group with surgeon 1 but not for surgeon 2 or the combined results. There was no difference in total length of hospital stay between both groups. The DAA group also had a lower post-operative opiate analgesic usage 2 weeks after THA surgery. The DAA group additionally had better hip bending function 2 weeks and 6 weeks post-operatively. The DAA group had significantly weaker straight leg raise function at 2 weeks and 6 weeks post-operative time points compared to the PA group. The incidence of lateral cutaneous nerve of thigh (LCNT) neuropraxia was 83% in the DAA group. Excluding LCNT neuropraxia the other complications were not statistically significant between both groups.

The study concludes that DAA THA has comparable results with PA THA. Results obtained support current evidence in the literature for both early outcomes and complications. Outcomes following DAA THA can vary between surgeons. DAA THA has benefits in improved hip bending in the early post-operative period in the absence of hip precautions. This comes at a price of weaker straight leg raise function.

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DECLARATION

This thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Tze Ern Cheng

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ABBREVIATIONS

AOA	Australian Orthopaedic Association
ASA	American Society of Anaesthesiologists
ASIS	Anterior Superior Iliac Spine
BJS	British Journal of Surgery
BMI	Body Mass Index
CI	Confidence Interval
CK	Creatinine Kinase
CORR	Clinical Orthopaedics and Related Research
CRP	C - Reactive Protein
DAA	Direct Anterior Approach
DVT	Deep Vein Thrombosis
GT	Greater Trochanter
HHS	Harris Hip Score
HOOS	Hip Outcome Score
IL	Interleukin
IQR	Interquartile range
ITB	Iliotibial Band
JBJS	Journal of Bone and Joint Surgery
JOA	Journal of Arthroplasty
LA	Lateral Approach
LCNT	Lateral Cutaneous Nerve of Thigh
LEFS	Lower Extremity Functional Scale
LIA	Local Infiltration Analgesia
MPA	Mini/Minimally Invasive Posterior Approach
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
OARSI	Osteoarthritis Research Society International
OHS	Oxford Hip Score
OR	Odds Ratio
PA	Posterior Approach
PROM	Patient Reported Outcome Measure
RI	Risk Index
SEM	Standard Error of Mean
SF-12	Short Form 12
SF-36	Short Form 36
TFL	Tensor Fascia Lata
THA	Total Hip Arthroplasty
TUG	Timed Up and Go Test
VAS	Visual Analogue Scale
WOMAC	Western Ontario & McMaster Universities Arthritis Index

CHAPTER 1

INTRODUCTION

INTRODUCTION

Review of current preferences in approach for hip arthroplasty

Hip arthroplasty revolutionised the treatment of fractures and arthritis. With excellent reproducibility and long term results, hip arthroplasty has been hailed as one of the most successful surgeries of modern medicine. (1) From Themistocles Glück to Sir John Charnley, developments in aspects of hip arthroplasty continue to this day. (2) (3) This thesis focuses on the surgical approaches and techniques utilised in primary total hip arthroplasty (THA).

Different surgical approaches have historically been utilised in hip arthroplasty. The detail of each approach, associated development and modifications are too detailed to cover in this dissertation. As such, emphasis is placed on the common approaches utilised in the 20th century. Approaches utilised in THA can broadly be divided into the anterior, posterior and lateral approaches. To appreciate the utilisation of each approach, data from peer reviewed journals and joint registries were obtained.

Chechik et al reported in 2013 the preferences of over 200 Orthopaedic surgeons in THA. Chechik's results identified a preference of 45% for the posterior approach (PA), 42% for the direct lateral approach (LA) and 10% for the anterior approach (DAA) (10 %). Other unspecified approaches formed the remaining 3 % of the survey. North American surgeons

favoured the PA more often than Europeans (69 % compared to 36 %, $P < 0.01$) and surgeons from other countries (69 % versus 45 %: $P = 0.01$).

The Kaiser Permanente Total Joint Replacement Registry by the Kaiser Group in the United States reported similar findings to Chechik with the exception of preference pertaining to the LA. From December 2011, 42,438 primary THA's were recorded in the Kaiser Registry. Surgical approaches utilised by surgeons of the practice in order or preference was the PA (75%) followed by the anterolateral approach (10%), the DAA (4%) and the LA (2%). (4)

Not all national joint registries report data on surgical approach utilised during primary THA. No local national data was available to reference the preferences of surgical approach of Australian Orthopaedic surgeons with regards to primary THA. The Australian Orthopaedic Association (AOA) National Joint Registry has no prior annual reports on the incidence of approach utilised in THA. A recent Norwegian Joint Report within the past 5 years was not available in an English version for perusal. Data pertaining to surgical approach was then obtained from the English, Swedish & New Zealand Joint Registries.

English Joint Registry

The 10th Annual Report of the English Joint Registry in 2012 reported that out of 76,448 primary THA surgeries, 25,234 (33%) hips were implanted using a LA, 46,989 (61%) were implanted using a PA and 3,865 (5%) were implanted using other approaches. 3,741 (5%) cases were reported to be minimally invasive and 5,239 (7%) of cases being performed in

the supine position. Though no specific figures were provided for the DAA, it can be safely estimated that approximately 5% of THA were performed with the DAA. This estimation factors in known techniques of the DAA being performed in the lateral position and the Hardinge/Watson Jones performed in the supine position. The LA is presumably not distinguished between the Hardinge and Watson Jones Approach(5)

Table 1.1 – Surgical Technique for primary THA in 2012 – English Joint Registry

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total hip primaries	**25,316**	**33%**	**34,143**	**45%**	**15,907**	**21%**	**1,082**	**1%**	**76,448**	
Patient position										
Lateral	22,965	91%	31,864	93%	15,303	96%	1,077	100%	71,209	93%
Supine	2,351	9%	2,279	7%	604	4%	5	<1%	5,239	7%
Incision										
Lateral (inc. Hardinge)	10,131	40%	10,878	32%	4,092	26%	133	12%	25,234	33%
Posterior	13,731	54%	21,185	62%	11,157	70%	916	85%	46,989	61%
Trochanteric osteotomy	310	1%	26	<1%	11	<1%	13	1%	360	<1%
Other	1,144	5%	2,054	6%	647	4%	20	2%	3,865	5%
Minimally-invasive surgery										
Yes	478	2%	2,884	8%	365	2%	14	1%	3,741	5%
No	24,838	98%	31,259	92%	15,542	98%	1,068	99%	72,707	95%
Image-guided surgery										
Yes	32	<1%	158	<1%	31	<1%	33	3%	254	<1%
No	25,284	100%	33,985	100%	15,876	100%	1,049	97%	76,194	100%
Bone graft used - femur										
Yes	173	<1%	400	1%	44	<1%	13	1%	630	<1%
No	25,143	99%	33,743	99%	15,863	100%	1,069	99%	75,818	99%
Bone graft used - acetabular										
Yes	1,014	4%	1,321	4%	841	5%	79	7%	3,255	4%
No	24,302	96%	32,822	96%	15,066	95%	1,003	93%	73,193	96%

Despite interest in DAA THA from the early 2010's, the 12th Annual Report of the English Joint Registry in 2014 identified no growth in other approaches, minimally invasive and

supine type THA surgeries. There was a trend towards the PA away from other approaches. Out of 88,763 primary THA surgeries, 25,488 (29%) hips were implanted using the LA, 59,244 (67%) were implanted using a PA and 3,789(4%) were implanting using other approaches. This coincided with a drop in supine positioning (4,499 – 5%) and minimally invasive (3,985 - 4%) type THA surgeries.(6)

Table 1.2 – Surgical Technique for primary THA in 2014 – English Joint Registry

	Primary total prosthetic replacement using cement		Primary total prosthetic replacement not using cement		Primary total prosthetic replacement not classified elsewhere (e.g. hybrid)		Primary resurfacing arthroplasty of joint		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total hip primaries	27,616	31%	36,339	41%	23,896	27%	912	1%	88,763	
Patient position										
Lateral	25,712	93%	34,366	95%	23,278	97%	908	100%	84,264	95%
Supine	1,904	7%	1,973	5%	618	3%	4	<1%	4,499	5%
Incision										
Posterior	16,524	60%	24,147	66%	17,745	74%	828	91%	59,244	67%
Lateral (inc. Hardinge)	10,061	36%	10,179	28%	5,178	22%	70	8%	25,488	29%
Trochanteric Osteotomy	174	1%	17	<1%	48	<1%	3	<1%	242	<1%
Other	857	3%	1,996	5%	925	4%	11	1%	3,789	4%
Minimally-invasive surgery										
Yes	450	2%	2,977	8%	541	2%	17	2%	3,985	4%
No	27,166	98%	33,362	92%	23,355	98%	895	98%	84,778	96%
Image-guided surgery										
Yes	31	<1%	193	1%	54	<1%	29	3%	307	<1%
No	27,585	100%	36,146	99%	23,842	100%	883	97%	88,456	100%
Bone-graft used - femur										
Yes	138	<1%	370	1%	72	<1%	17	2%	597	1%
No	27,478	100%	35,969	99%	23,824	100%	895	98%	88,166	99%
Bone-graft used - acetabular										
Yes	937	3%	1,139	3%	1,005	4%	128	14%	3,209	4%
No	26,679	97%	35,200	97%	22,891	96%	784	86%	85,554	96%

New Zealand Joint & Swedish Registry

In 2013 the 14th New Zealand Joint Registry Annual Report identified 3,500 DAA THA on record. This was in comparison with 54,347 PA and 23,434 LA THAs. In 2014, the 15 year report showed little change in the distribution. A total of 59,563 (67.4%) PA, 25,219 (28.5%) LA and 3,636 (4.1%) DAA THAs were recorded in 2015. (7, 8)

The Swedish Joint Registry did not directly report the number of DAA THA procedures. However, the use of DAA THA in Sweden is estimated to be less than 1% from 839 recorded "other mini incision" THAs from 1999-2013.(9)

Choice of Approach

Comparing the available data above, the current preference of Orthopaedic surgeons including non-hip arthroplasty specialists favour the PA, followed by the lateral approach and finally the DAA. The DAA is estimated based to make up less than 5% of the approaches utilised to perform THA.

The Posterior Approach

The PA to the hip is often termed the Southern or Moore's approach. Despite the approach's name, Bernhard von Langenbeck a German surgeon was credited with the invention of the PA. Langenbeck first described this incision in 1867, and referred to it as "the longitudinal incision". Langenbeck had used the PA primarily for infections, war wounds involving the hip and resection of the femoral head. Theodor Kocher, a Swiss

surgeon and student to Langenbeck further developed the Langenbeck approach through an incision caudally. Lastly Gibson and Moore popularised this technique in the 1950's in hip arthroplasty. (10-12)

The original descriptions by Langenbeck, Kocher, and Moore can still be applied to this day. Excerpts of the original descriptions by the approach's innovators describe "An incision fashioned from above the greater sciatic notch to the middle of the greater trochanter (GT)". (13) "The incision is curved obliquely in the direction of the gluteus maximus". Division of the gluteus maximus tendon and anterior reflection of the gluteus medius and minimus was then followed by internal rotation of the hip and detachment of the piriformis and the other short external rotators.(14) "Usually it is not necessary to divide the abductor muscles at their attachment to the GT. By retraction of the capsule the hip joint is brought fully into view. The hip can easily be dislocated when the limb is brought into flexion, adduction and internal rotation." (15)

The PA is considered by many to be the workhorse approach for posterior wall fractures of the acetabulum, femoral neck fractures treated via hemiarthroplasty, and THA.(10) Recognised modifications of the technique include a mini version, short external rotator sparing variants and the SuperPath approach. (16-20)

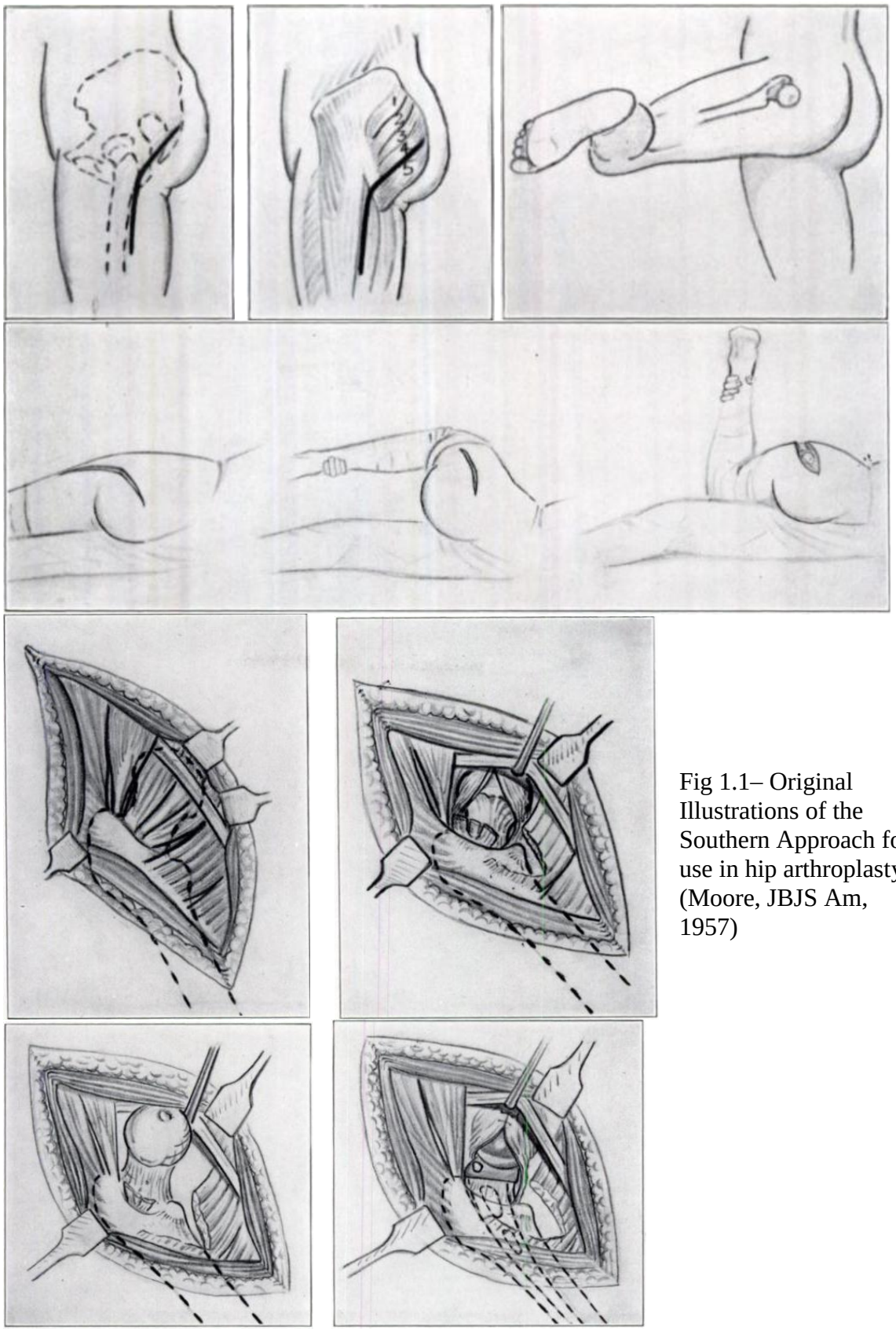


Fig 1.1– Original Illustrations of the Southern Approach for use in hip arthroplasty (Moore, JBJS Am, 1957)

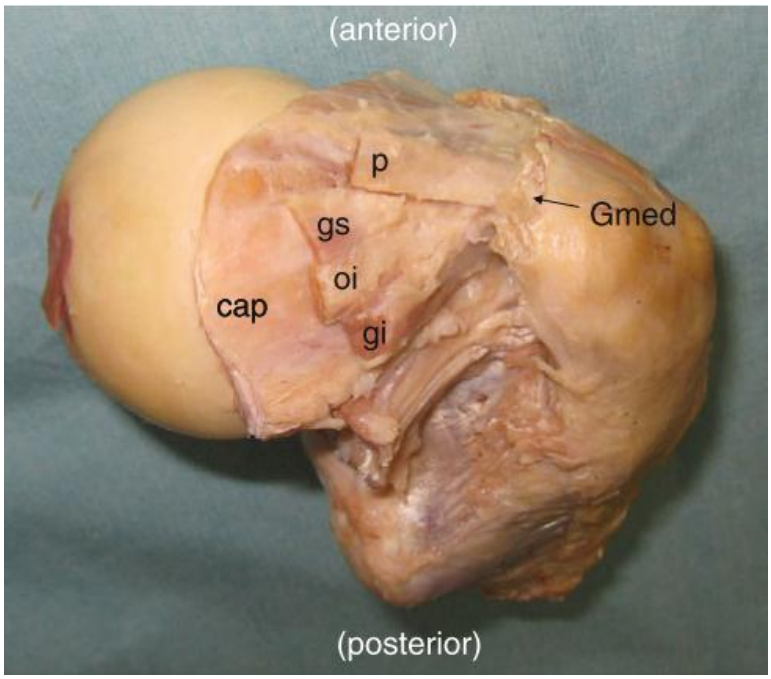


Fig 1.2 Anatomy of the Short External Rotators and capsule of the hip joint. (Ito, CORR, 2012)

p: piriformis
gs – Superior Gemellus
oi – obturator internus
gi – inferior gemellus
cap – hip capsule
Gmed – gluteus medius

Surgical Technique

The PA to the hip is routinely performed with the patient placed in the lateral decubitus position. The operative hip faces up towards the ceiling. The pelvis is stabilised with padded braces that typically consist of a posterior sacral pad and two separate anterior pads placed on the anterior superior iliac spines (ASIS). A padded support can also be placed between the knees to prevent excessive adduction of the operative leg. The apex of the GT is identified. A curvilinear incision line is made centring on the GT. The curved superior portion is made in line with the fibres of the gluteus maximus muscle whilst the linear inferior portion of the incision is made posterior and parallel to the femur. The incision length of the conventional PA is approximately 15 centimetres (cm) while the mini version is between 8 to 10 cm. The suitability of the mini posterior approach (MPA) is dependent on surgeon preference, skill and patient body habitus. The hip is then flexed and abducted to relax the fascia lata. Superficial dissection continues with division of the fascia lata extending superiorly along the fascial plane. This follows the skin incision into the gluteus

maximus muscle. Gluteus maximus is then divided bluntly and gently along its fibres. Blunt dissection is performed meticulously to avoid damage to the inferior gluteal neurovascular structures.

The innominate fat pad covering the short external rotators is now encountered. The fat pad is removed to identify the short external rotators of the hip (Piriformis, Obturator Internus, Superior and Inferior Gemillus). The sciatic nerve is palpated and protected during this step. The hip is then flexed and internally rotated to stretch the piriformis and conjoint tendon to allow precise division close to the tendinous insertions. The divided tendons are tagged with suture and reflected posteriorly to protect the sciatic nerve. The quadratus femoris muscle can be released to fully expose the posterior capsule of the hip but this is not routinely performed. The posterior capsule of the hip is now on view. A capsulotomy is performed to complete access to the hip joint.

Advantages

The PA to the hip is easy to learn as anatomy is easily defined when using the conventional incision size. The PA requires a basic arthroplasty setup for simple cases and can be performed on a standard surgical table. This negates the requirements of specialised equipment needed for other surgical approaches such as the DAA. Unlike the LA that disrupts the hip abductors to access the hip joint, the PA approaches the hip joint through superficial dissection of gluteus maximus and deep dissection of the short external rotators. The sparing of the hip abductors potentially prevents abductor dysfunction following surgery.(21) The PA can safely be adopted into a mini incision version that potentially reduces soft tissue damage. (22) This option is limited by surgeon skill and patient body

habitus. The extensibility of the PA is one of the reasons why surgeons prefer it in complex THAs such as congenital hip dysplasia, trauma and revision THA. The extensibility of the PA enables surgeons to adequately expose the posterior acetabulum and femur. This allows surgeons to employ advanced techniques and more varied implants potentially required for during complex THAs. The PA also has good access to the sciatic nerve and this can be valuable in scenarios requiring its exposure. Lastly, leg length discrepancies originating from the hip joint can reliably be assessed and corrected while using the PA.

Disadvantages

The PA does not utilise an internervous plane. This can increase risk of denervation to structures divided and retracted during surgery. Damage to superior/inferior gluteal artery and nerve compromises the gluteus maximus muscle if dissection is not carried out meticulously. (23) Trauma can also occur to the first perforating branch of the anterior femoral neurovascular bundle and the profunda femoris artery in careless dissection or retractor placement.(24) The sciatic nerve although not directly in the surgical field is at risk of trauma. Slower healing and poorer outcomes are associated with damage of common peroneal nerve component due to its higher nerve fibre density.(25) The PA also has a reportedly higher dislocation rate compared to other approaches. This is thought to originate from the disruption of the short external rotators and posterior capsule. The rate of dislocations following PA THA reported in the literature varies from 0.3%-10%. (26) The dislocation rates are reportedly reduced with the preservation or repair of the short external rotators.(20) Dislocations in THA performed through PA are frequently posterior and most commonly result from hyperflexion, adduction and internal rotation. Hip precautions are commonly instituted to prevent this. Although most patients cope well with

temporary restrictions, others may find that it interferes with rehabilitation and return to normal activities.(27) Lastly, although flexible in its extensile incision, the PA has limited access to address anterior acetabular pathology.

The Lateral Approach

History

The LA has an extensive history in hip arthroplasty. Despite the approach's name, its modern counterpart has two commonly used variations. The first is the anterolateral approach which is also known as the Watson-Jones approach. Second is the direct LA, commonly known as the Hardinge approach. Both techniques share a similar history but utilise different planes during dissection to obtain access and views of the hip joint. Both techniques are described separately in this thesis(28).

Anterolateral Approach

The anterolateral approach to the hip joint was first described by Lewis Sayre in 1894.The approach utilises the interval between gluteus medius and tensor fascia lata (TFL) to gain access to the hip.(28) The technique was then adopted by Watson-Jones and reported in his use for treatment of proximal femoral and femoral neck fractures.(29) Lastly, Muller's preference and teaching of the anterolateral approach saw the spread of this technique in THA. (30)

Watson Jones description of the approach has changed little to this day. “The neck of the femur is exposed in the interval between the gluteus medius and the tensor fascia femoris. To assist in retracting the gluteus medius sufficiently to see the side as well as the front of the neck, the anterior fibres of insertion are dissected off the trochanter…. The capsule is incised along the upper border of the neck, dissected away from the intertrochanteric line, and turned forwards as a triangular flap…. Upper fibres of the vastus externus are now turned down subperiosteally, a wonderfully clear view of the whole line of the neck is secured.”(29)

The Direct Lateral Approach

The LA was first described by Bryan McFarland and Geoffrey Osbourne in 1954. (31)The LA was adopted by Sir John Charnley with the addition of an osteotomy of the GT for use in THA. (3) Complications associated with the trochanteric osteotomy saw a reversion to the LA without a trochanteric osteotomy. Hardinge in 1982, a student of Charnley popularised the LA without a trochanteric osteotomy in THA. Hardinge preserved the GT by dividing the gluteus medius and vastus lateralis tendinous complex into an anterior and posterior flap.(32)

Modifications described for the LA include a dual incision anterolateral approach, minimally invasive versions and the omega approach. (33-38)

Fig 1.3 – Illustration of the incision of the anterolateral approach. (Muller 1970 CORR)

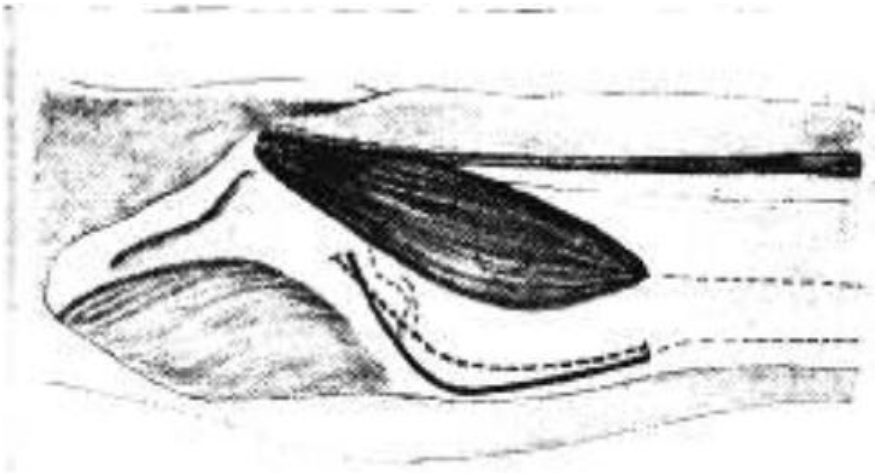


Fig 1.4: Exposure of the hip joint anterolateral approach (Watson-Jones, BJS, 1936)

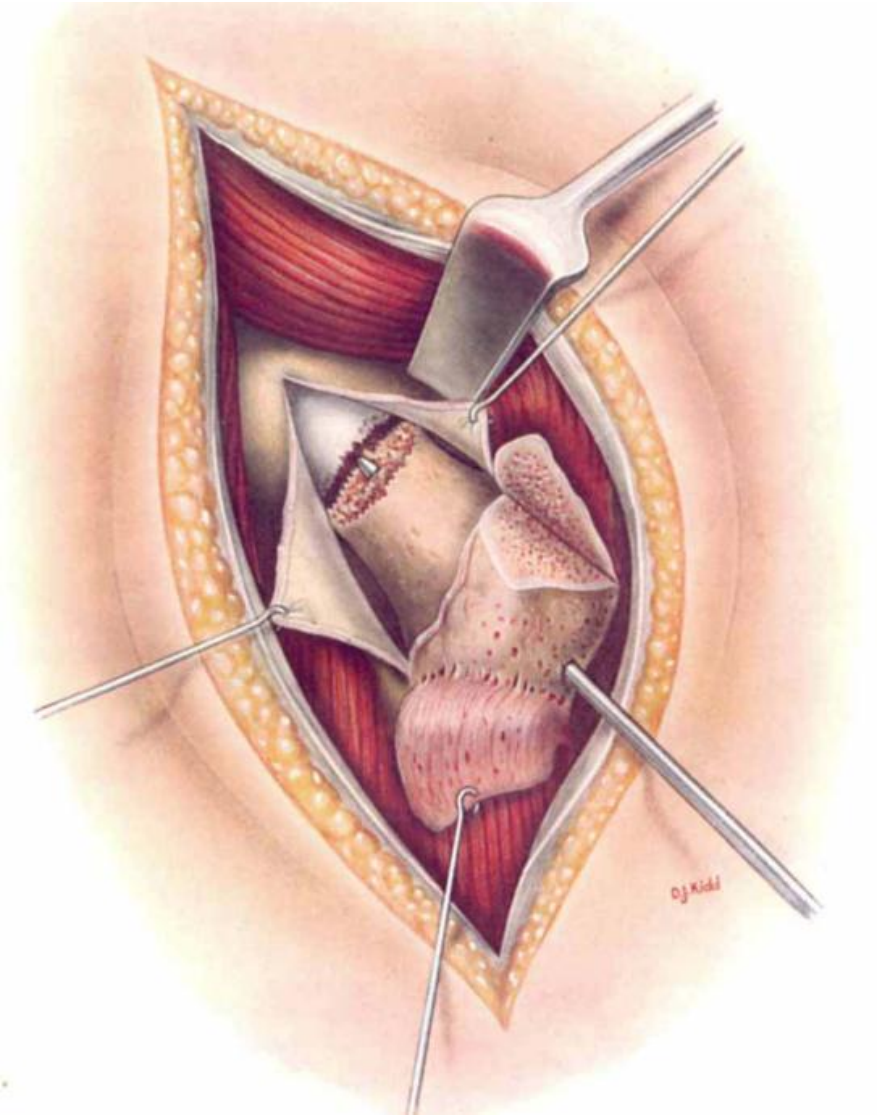


Figure 1.5: Illustrations of the lateral approach to the hip joint (McFarland, JBJS Br, 1954)

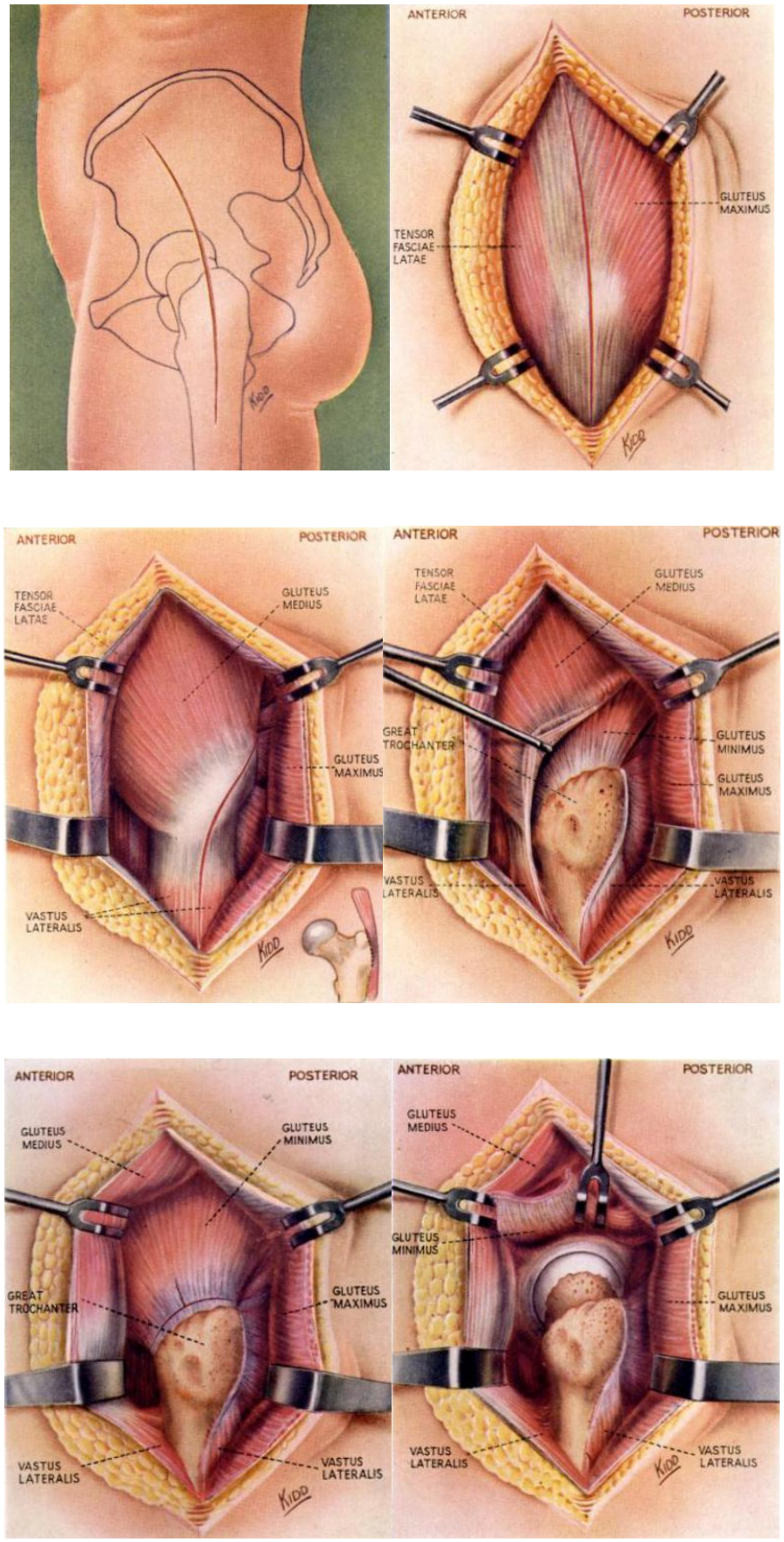
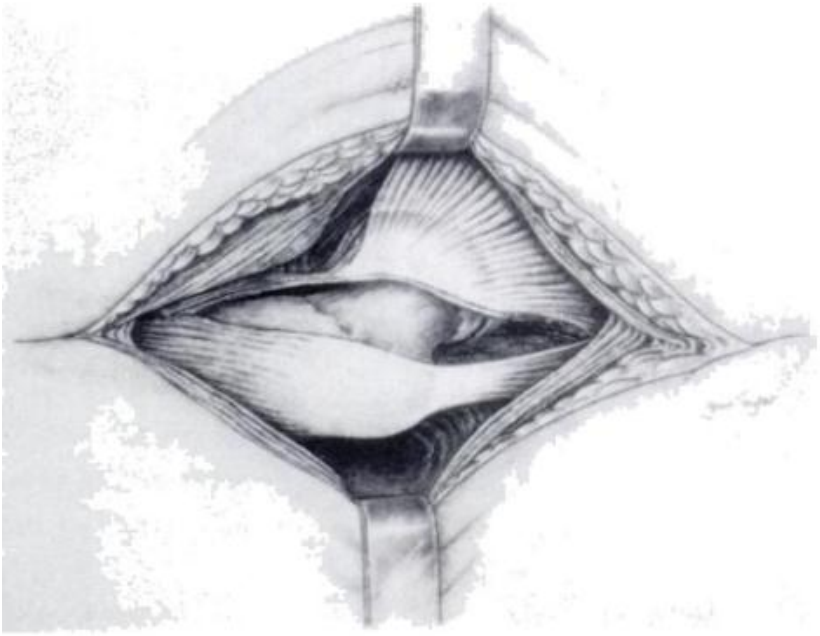


Fig 1.6 - The lateral approach to the hip with the development of anterior and posterior flaps (Hardinge, JBJS Br 1982)



Surgical Technique (Anterolateral Approach)

The anterolateral approach to the hip can be performed in a supine or lateral position. This description follows the lateral positioning of the patient. The pelvis is stabilised using clamped pads placed on the sacrum and both ASIS. The tips of the GT and ASIS on the operative side are identified. The cephalad portion of the incision begins 2.5cm posterior to the ASIS and continues down to meet the tip of the GT. For a minimally invasive approach, the incision stops here. The conventional approach continues with the incision curving over the GT and then in line with the femur. This should result in an incision length of approximately 10cm for the minimally invasive incision and 15cm for the conventional incision. The superior portion of the incision should be parallel with the fibres of gluteus minimus.

Superficial dissection proceeds with dissection through fascia. The intermuscular plane between gluteus medius and TFL is identified and developed. Caution should be taken here as both the TFL and gluteus medius muscles can be denervated if the superior gluteal nerve is damaged with excessive muscle splitting. Deeper dissection reveals gluteus minimus and reflected head of rectus femoris. The partial release of the anterior fibres of the abductors together with reflected head of rectus femoris may assist in providing exposure of the hip joint. Once an adequate exposure is obtained, a capsulotomy is performed and the hip dislocated. The hip is dislocated anteriorly with adduction and external rotation. Alternately if dislocation is still difficult despite adequate soft tissue release, a wedge osteotomy can be performed at the proposed neck cut prior to dislocation of the hip joint.

Surgical Technique (Lateral Approach)

Similar to the anterolateral approach, the LA can be performed supine or with the patient positioned in a lateral position. The centre of the incision is focused on the GT of the femur. An upside down "J" incision is made relative to the lower limb. The hockey stick end of the "J" angles superiorly and posteriorly. This begins approximately 2-4cm proximal to the GT and then parallels the femur distally.

Superficial dissection is performed through the TFL proximally and distally in line with the skin incision. Care is taken here to not extend dissection too far proximally as it potentially damages branches of the superior gluteal nerve that innervate the tensor.

Deeper dissection is performed by incising the anterior third portion of gluteus medius tendon. This spares its thicker tendinous posterior segment. The incision is extended distally in a cresenteric manner into the musculature of vastus lateralis. A cuff of tendon on the GT is left to facilitate repair of the abductor complex whilst closing. An anterior flap is developed with this layer. Branches of the lateral circumflex femoral artery encountered here are ligated. The hip is then adducted and externally rotated to reveal gluteus minimus and the iliofemoral ligament. Gluteus minimus and the iliofemoral ligaments are then released off the anterior portion of the femoral neck to unveil the anterior capsule of the hip. A capuslotomy is performed to access the hip joint. Dislocation is achieved with adduction and external rotation of the hip.

Advantages

The LA was popular when first introduced as it maintained the integrity of the posterior capsule and short external rotators. This was thought to enhance hip stability and reduce dislocation rates.(39, 40) For this reason, the LA is preferred for patients who were at high risk of dislocation. Examples for this include patients with poor compliance, high spasticity, high range of motion, small socket sizes, abductor deficiencies, and alcoholics. The anterolateral approach has been shown to not require hip precautions following THA.(41) The LA enables the operator to adequately address pathology associated with the gluteal tendons and trochanteric bursa. Like the PA, there is minimal need for specialised equipment to perform THA. Specialised equipment may only be required if a minimally invasive approach is adopted. Lastly, the LA has excellent extensile potential. The LA can be extended proximally past the acetabulum for treatment of pelvic/acetabular fractures. The LA can also be extended distally as far down as to the knee joint for treatment of

midshaft to distal femoral fractures without significant compromise to surrounding structures. The use of a trochanteric osteotomy enables surgeons to properly assess access and prepare the femur. It is for these reasons that the LA can also be utilised for revision hip surgery. Previous metalware and cement can be removed whilst circlage wires, proximal femoral plates and acetabular systems can be implanted under direct vision.

Disadvantages

While having many advantages, the main drawback of the LA is the post-operative incidence of abductor weakness and a positive Trendelenberg gait.(39, 42) Opponents of the LA suggest that this is due to the devitalisation with or without denervation of the gluteus medius, minimus and TFL muscles during dissection.(43, 44) The superior gluteal nerve innervates the TFL, gluteus medius and gluteus minimus muscles. Careless dissection proximally can inadvertently cause partial or complete denervation of the gluteus medius during exposure. Compared the direct LA, the anterolateral approach has reportedly less damage to the abductor musculature on MRI. (45) The femoral nerve is located anterior to the incision is at risk of compression neuropraxia. There is also a reportedly increased risk of heterotopic ossification compared to PA.(46)

The Direct Anterior Approach

History of the Direct Anterior Approach

The earliest recorded description of the DAA to the hip was by a German surgeon Carl Hueter (1838-1882). Hueter apprenticed under Berhard von Langenbeck, a pioneer of hip joint surgery and the PA. An excerpt from Hueter's textbook, Grundriss Der Chirurgie describing his approach to the hip joint is as follows

"The anterior oblique incision for resection of the coxae was first performed by Lücke and then by Max Schede. I have adopted this incision with a modification that I will explain later on. Following numerous experiences in the living and dead I have established the method as follows. Define the anterior iliac spine and the tip of the greater trochanter. Halve the line between the two points and pierce the tip of the knife in the middle of this line with the blade directed caudally and somewhat inferiorly. The incision is directed parallel to the outer border of the Sartorius muscle, but somewhat external; in children 6–8 cm, in adults relative to muscular development 10–15 cm. It falls into the muscular interval between m. sartorius on one side and m.tensor fasciae latae and m. gluteus medius on the other side, and meets the fibres of the m. vastus lateralis, which originate at the anterior face of the trochanter major at the base of the femoral neck. Those fibres have to be detached by knife or elevator; but it is the only muscle which is injured through the operation; and only in a small part of its fibres. Knife and elevator pierce into the anterior face of the major trochanter and the femoral neck. At the lower border of the femoral neck preference has to be given to the elevator to prevent transection of the anterior circumflex artery. Following the opening of the hip joint capsule, it is cut with the probe-pointed

knife superiorly and inferiorly as much as possible; the femoral neck can be encompassed by the index finger superiorly and inferiorly within the capsule." (47)

Hueter then presents his rationale for favouring the anterior oblique approach to the hip.

1. Only one muscle, the m.vastus lat. is injured which facilitates rehabilitation
2. There is minimal bleeding such that not a single ligature is applied.
3. The patient does not lie on his wound in the supine position
4. The wound facilitates the drainage of secretions

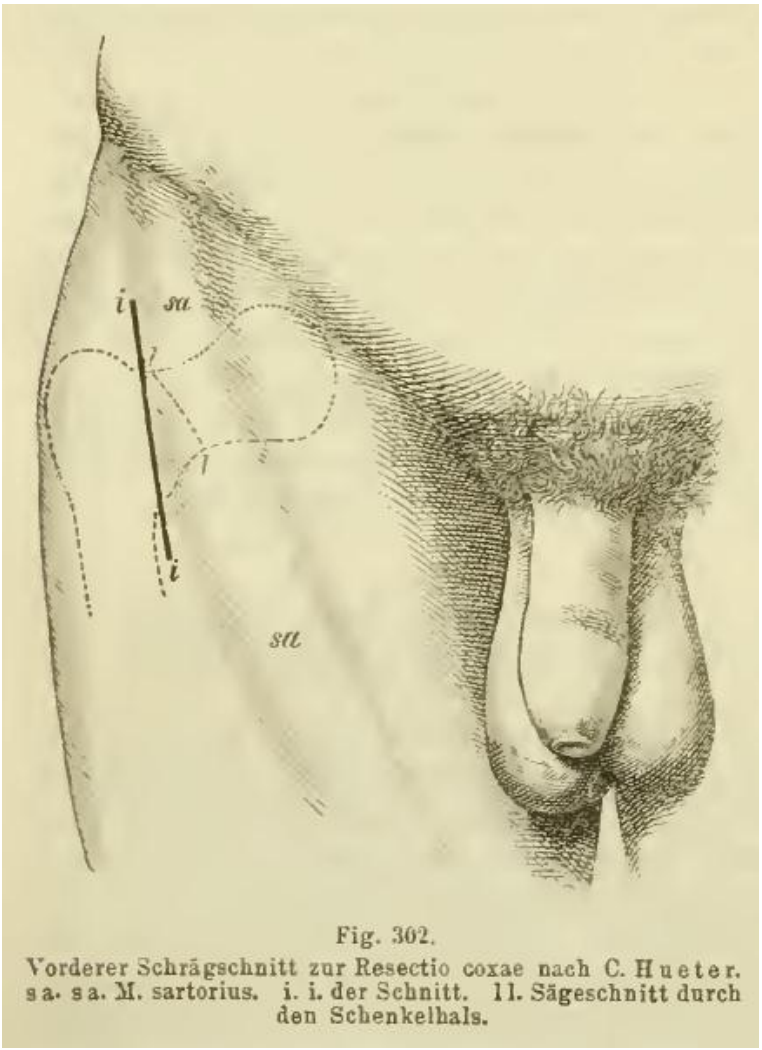


Fig. 302.
Vorderer Schrägschnitt zur Resectio coxae nach C. Hueter. s a. s a. M. sartorius. i. i. der Schnitt. l l. Sägeschnitt durch den Schenkelhals.

Fig 1.7: Anterior oblique cut for resection of coxae. C. Heuter. Grundriss Der Chirurgie, 1882

(sa – sa: Sartorius)
(i- i: The incision)
(l-l: Proposed femoral neck cut)

After Hueter, other famed historical proponents of the DAA were Smith-Petersen and the Judet brothers.

The DAA was studied further by American Norwegian born Marius Nygaard Smith-Petersen (1886-1953). Smith-Petersen's first description of the technique was in its application for open reduction of congenital hip dislocations. Smith-Petersen employed his incision further in the treatment of other hip joint disorders such as femaroacetabular impingement and osteoarthritis. (48-50) Smith-Petersen was credited with the promotion of the DAA in the United States and Britain.

In his original description of DAA, Smith-Petersen described his version in 5 steps,

1. An anterior incision – The incision starts from the ASIS and continues inferiorly along the border of TFL and stops below the GT. The fascia lata is divided subcutaneously in the direction of its fibres. The dissection then follows the intermuscular plane between sartorious and tensior fascia lata muscles.
2. A curved incision – The incision begins from the ASIS and continues along the iliac crest stopping half an inch from the periosteal attachment of gluteus medius.
3. Subperiosteal dissection – A flap consisting of the abductor muscles and TFL is raised and reflected posteriorly through subperiosteal dissection. This preserves the neurovascular supply to the flap musculature. The size of the flap is determined by its operative needs.
4. Capsular incision – The incision is made on the superior portion of the capsule so as to preserve the Y shaped ligament of Bigelow. The capsulotomy is completed with dissection posteriorly along the acetabular labrum.
5. Closure – A reversal of sequence is then performed for closure. Capsular closure and repair of the raised muscular flap. The curved portion of the incision is repaired by suturing the origin of gluteus medius to its periosteal attachment. Final closure is performed in layers.

In subsequent descriptions, Smith-Petersen modified his technique, minimising the size of the incision, limiting the curved dissection to the anterior third of the iliac crest. To obtain better views of acetabulum, either or both the direct and tendinous heads of rectus femoris were divided. In Smith-Petersen's approach for mould arthroplasty, the inguinal ligament was released the anterior inferior iliac spine exposed. This enabled Smith-Petersen to dislocate the hip anteriorly after sacrificing the anterior acetabular wall and anterior inferior iliac spine.(48)

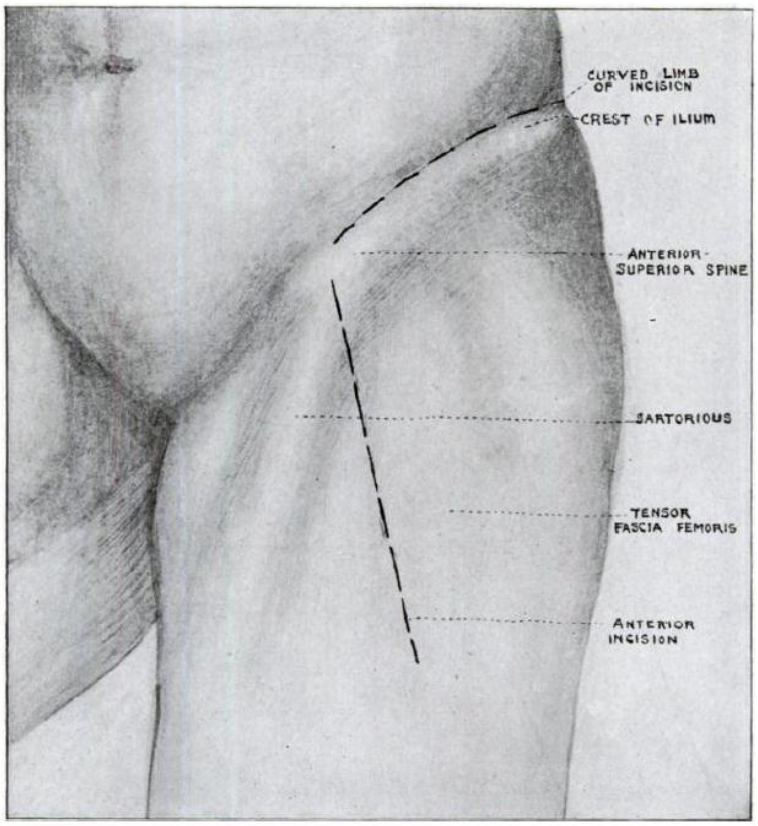


Fig 1.8: The Smith-Petersen Incision (Smith-Petersen, JBJS Am, 1917)

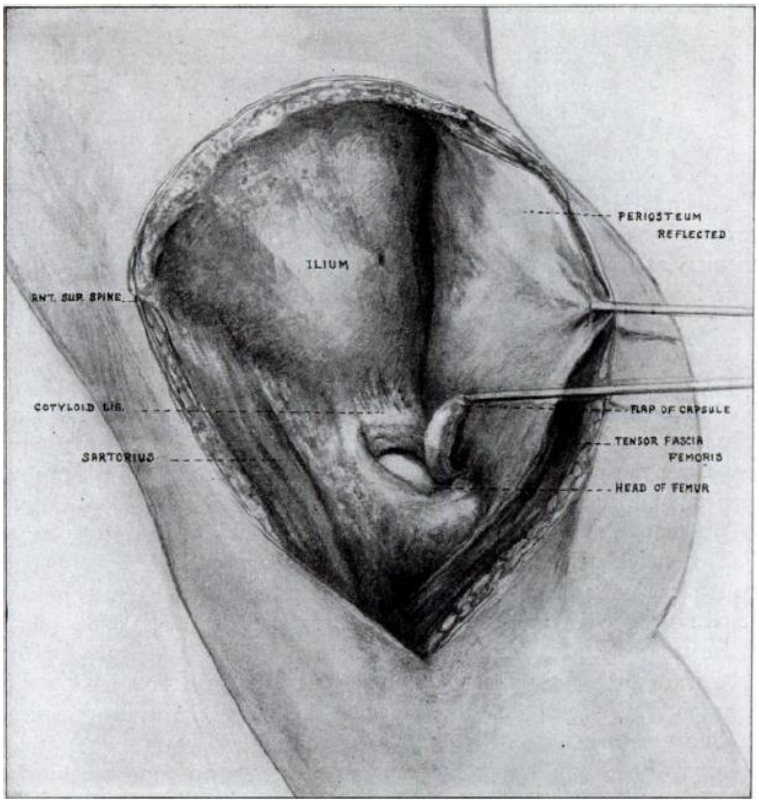


Fig 1.9: Sub periosteal dissection and flap formation with capsulotomy for reduction of congenital hip dislocations. (Smith Petersen, JBJS Am 1949)

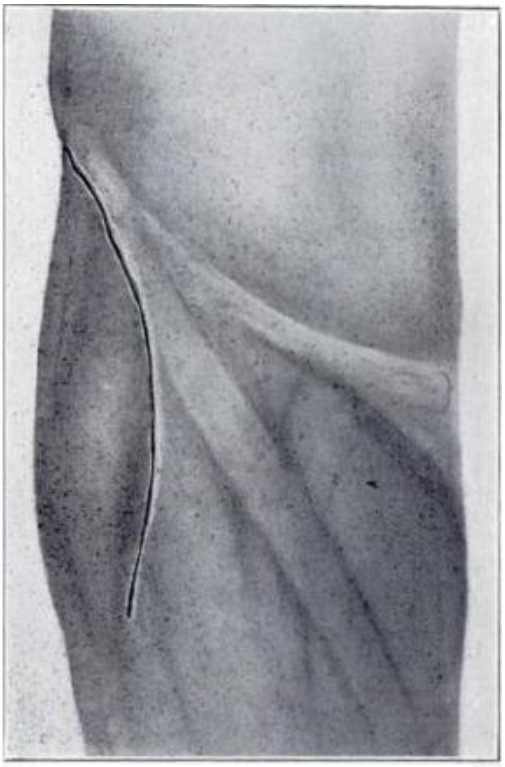
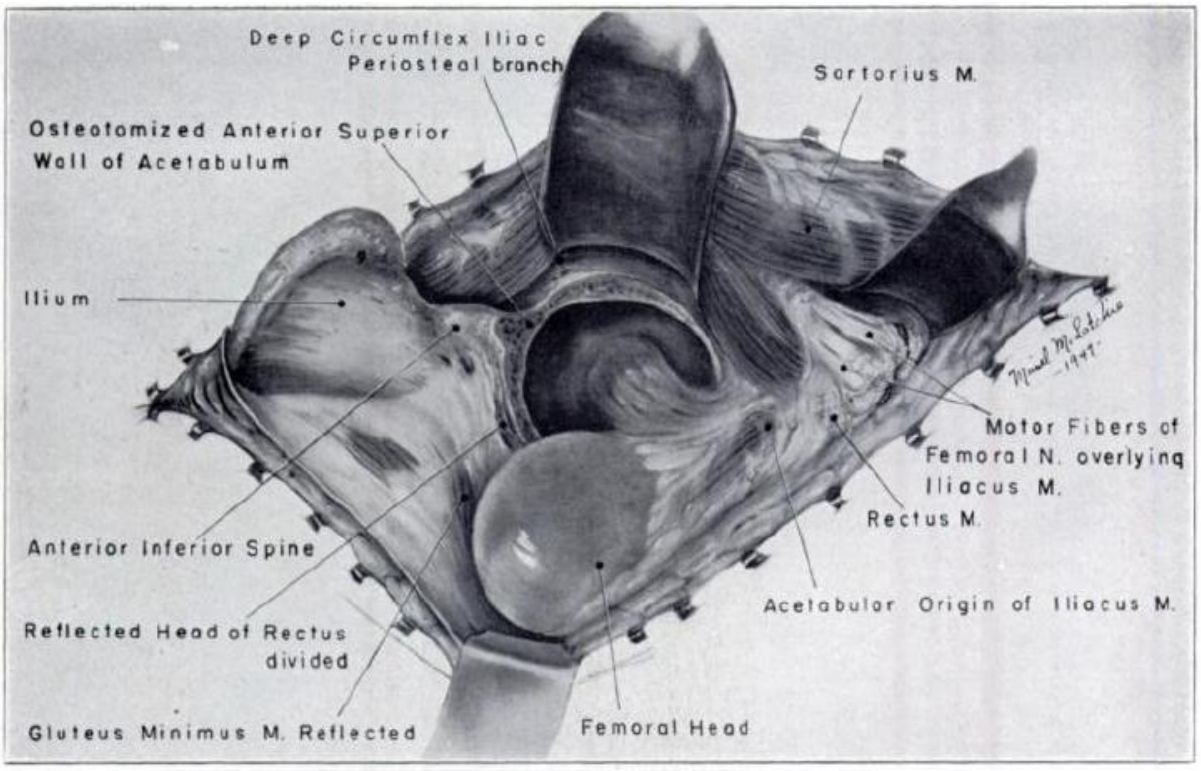


Fig 1.10: Evolution of the anterior incision in use of mould arthroplasty (Smith Petersen, JBJS Am 1949)

Fig 1.11: Dislocation of the hip for interpositional mould arthroplasty following anterior acetabular osteotomy (Smith-Peterson, 1949 JBJS Am)



In 1950, brothers Jean and Robert Judet described an operation that replaced the femoral head using highly polished acrylic hemiarthroplasty prosthesis. In their operative technique, they utilised Hueter's vertical approach and described a femoral neck osteotomy prior to dislocation and the use of traction to reduce the dislocated hip. (Judet, 1935) The Judet's also successfully introduced the use of an Orthopaedic traction table to assist intraoperative dislocation of the femoral head and to prepare the femur during THA. (51-53)

The original techniques described above are still in current use in modern hip arthroplasty today albeit modifications of instrumentation such as single and double offset instruments.(54) The following section describes its current operative technique. A modern

modification of the DAA is the bikini incision that follows the anatomic skin crease of the groin. (55)

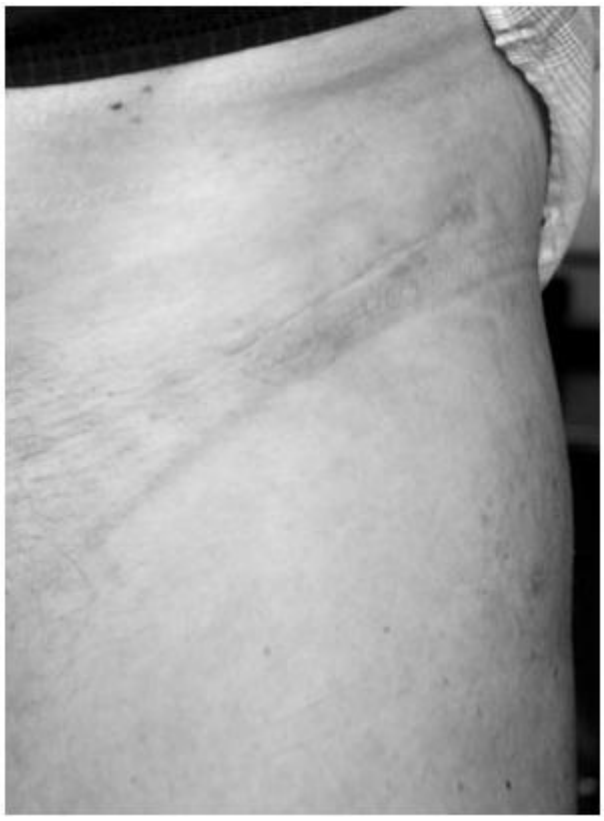


Fig 1.12: Bikini DAA 6 month post-operative wound (Leunig, CORR, 2013)

Surgical Technique

The patient is placed supine on the operating table. After the patient is prepped and draped, the ASIS and GT are identified and marked. A line is drawn commencing from 2cm lateral and inferior to the ASIS. This is continued in a linear fashion intersecting a point halfway between the GT and ASIS. The line if extended should intersect the lateral border of the patella. The incision begins from the proximal portion of the line and ends approximately 8 to 12cm in length.

The fascial layer is now encountered. Here the muscular bellies of Sartorius (femoral nerve) and TFL (superior gluteal nerve) are identified and the interval between the two palpated. Proper identification of the muscles is required as dissection in the wrong plane can result in iatrogenic damage to the femoral neurovascular bundle. Once identified, the fascia is cut in line with the interval. Care is taken here to identify and preserve the lateral cutaneous nerve of the thigh (LCNT). Occasionally small branches cross the operative field and need to be sacrificed to obtain access. The Sartorius muscle is retracted anteriorly and the TFL retracted posteriorly. At the inferior angle of the wound are ascending branches of the lateral circumflex femoral vessels. Ligation of these vessels prior to deeper dissection can reduce intraoperative bleeding and post-operative haematoma.

Deep surgical dissection now reveals the rectus femoris muscle (innervated by the femoral nerve) anteromedially and the gluteus medius muscle (innervated by the superior gluteal nerve) posterolaterally. Access to the hip joint continues through the intermuscular and internervous plane between these two muscles. The tendinous reflected head of rectus femoris can be partially or completely released to facilitate capsular exposure. Here, peri-capsular fat is often encountered and removed. Care should be taken with retractor placement and tension to prevent inadvertent neurovascular trauma. The femoral head, superior border and inferior border of the femoral neck can now be palpated directly underneath the capsule. Access to the hip joint is completed with a capsulotomy.

The DAA can be performed with or without the use of an Orthopaedic traction table. Use of the traction table is preferred by many surgeons as it requires only one surgical assistant but it is associated with issues such as cost, availability, traction injuries and fracture risk.

The latter technique requires one or two assistant who are familiar with the nuances of traction and hip dislocation via the DAA. Without a traction table the surgeon can evaluate limb length and component stability using conventional methods. Described below are the operative techniques with and without a traction table.

DAA with an Orthopaedic Traction Table

After placing the patient supine on the operating table, a perineal post is inserted into the operating table. Both legs are then placed securely into boots attached to the table. The non –operative leg is maintained in a neutral position. The patient is prepped and draped in the standard manner. Upon access to the hip joint capsule, a capsulotomy is performed with the edges tagged for retraction and repair. The hip can be internally rotated to access the lateral portion of the hip joint capsule and externally rotated to access the medial portion of the hip capsule. The femoral neck is now exposed. Utilisation of gentle traction during this step allows the automatic development of a space upon completion of femoral neck osteotomy. The neck cut is done in situ using an oscillating saw. Femoral head extraction is accomplished using a corkscrew. In the event of a difficult retrieval of the femoral head; a wedge resection of the femoral neck measuring 1cm can be performed. This manoeuvre reduces the size of the femoral head to ease retrieval.

The hip is placed in 45˚ of external rotation to facilitate access to the acetabulum. Preparation of the acetabulum can now begin. To circumnavigate the small incision, offset handle reamers and introducers are used. Once the acetabular component is trialled and fitted, femoral preparation commences. Femoral preparation should be undertaken carefully as this is the step in which intraoperative fractures of the femur or ankle

commonly occurs. A large bone hook is placed into the femoral canal with retractors placed under the GT and along the medial calcar. The leg is slowly externally rotated and the femur elevated out of the wound. A superior capsulotomy is performed to aid in delivery of the femoral shaft. If this is insufficient, the short external rotators and piriformis muscle can be released at its attachment to the femur.(56) Alternatively a table jack can be used assist in the elevation of the proximal femur. (57) Repair of the short external rotators following release is difficult and not routinely performed during the DAA.

Once sufficient soft tissue release is achieved, the leg can be fully externally rotated (foot pointing to 6 o'clock), adducted and extended. In this position, preparation of the femur can begin. Broaching should be performed carefully to prevent accidental perforation. Upon satisfactory femoral fit, stability of the hip is assessed. The hip joint is reduced with traction, flexion and internal rotation. Assessment of stability focuses on anterior dislocations given the sparing of the posterior structures. Anterior stability is tested with external rotation in a neutral position. Posterior stability is difficult to assess with a traction table. Fluoroscopy can be used to assess component position and leg length. Dislocation of the hip joint is performed in a reversed manner to allow implantation of the definitive prosthesis.

Anterior Approach with a Standard Operating Table

The patient is positioned supine on the operating table with the hip joint over the table break. This is essential to allow for hyperextension of the operative leg. A perineal post can be used to stabilise the patient intraoperatively but this can make hip adduction difficult. An armboard is placed adjacent to the non-operative leg to facilitate abduction of

the non-operative limb. Options exist for unilateral or bilateral draping of the lower limbs depending on surgeon preference.

The hip joint is approached using the technique described earlier. Upon reaching the capsule, the hip is then internally rotated to release the lateral portion of the capsule. Following this, the hip is repositioned into a figure of four to facilitate release of the medial portion of the hip capsule. Capsular edges are tagged and the femoral neck cut performed. The femoral head is retrieved. Preparation and implantation of the acetabulum is similar to that described in the approach with use of a traction table with the operative limb in extension and slight external rotation.

For femoral preparation the non-operative leg is abducted onto the prepared arm board and the operative leg hyperextended to 40˚ of extension. The operating table is then positioned into a Trendelenburg position to prevent the distal end coming close to the floor. The operative leg is externally rotated and adducted under the non-operative leg. Mobilisation of the proximal femur is achieved with similar soft tissue releases and retractor placement as described previously. The femur is gently elevated and pulled laterally. This manoeuvre facilitates delivery of the femoral shaft and provides a workable angle for femoral broaching. Care must be taken to identify the angle and direction of the femoral shaft. This is done through palpation and visualisation of the knee joint.

Once the femoral components are fitted and trialled, final checks of stability and leg lengths can be performed. Without a traction table, the hip is fully mobile and stability can

be tested in a conventional manner. Palpation of both patellae and malleoli provides a good estimate of leg length. Supplementary fluoroscopy can also be used to confirm leg lengths and component position.

Advantages & Disadvantages

A detailed discussion of the potential advantages and disadvantages of the DAA are in the literature review section of the paper.

General advantages associated with DAA THA

- Smaller wounds
- Potentially less soft tissue trauma
- Potentially better PROMs
- Potentially better functional recovery
- Low dislocation rates

General disadvantages associated with DAA THA

- Learning curve
- LCNT neuropraxia
- Increased bleeding
- Complications with an Orthopaedic traction table
- Need for specialised equipment
- Radiation exposure if fluoroscopy is used
- Limitations in complex revision THA

Literature Review

The primary focus of the thesis is on surgical technique in primary conventional THA for osteoarthritis and its effect on short term clinical outcomes. A literature review was conducted to determine the current scope of research on the topic and to identify areas of paucity in the literature that can be addressed with further research.

The latest Australian National Joint Registry report was analysed with regards to primary conventional THA. This was to determine the general demographics of patients, surgeon implant preference and revision rates. The National Health Performance Agency report was accessed to obtain data on the length of hospital stay following THA.

A broad search of PubMed, Ovid MEDLINE and the Cochrane Central register was conducted. Key words and search terms used were "Total Hip Arthroplasty", "Direct Anterior", "Hueter Approach", "Modified Hueter", "Smith-Petersen" and "Modified Smith-Petersen". Bibliographies of relevant publications were reviewed for relevant articles.

The literature review was then stratified into articles from last decade (2000-2010) and articles after 2010. Articles prior to 2000 were considered historical and referenced if relevant.

Statistics of Primary Conventional Total Hip Arthroplasty from the Australian National Joint Registry

Analysis of the joint registry serves to determine the scope of the studies participants and also implant choice. For this purpose, analysis of outcomes related to cemented, uncemented THA systems, age/gender related revision risks and their relations with the principal diagnosis of osteoarthritis are reviewed. Information and tables were directly referenced from the 2014 and 2015 annual reports. (58, 59)

The AOA National Joint Registry monitors outcomes of joint arthroplasty with revision being the primary focus. From September 1999 to December 2014, the AOA National Joint Registry Report (NJRR) registered 312,828 primary total conventional hip replacement surgeries. Of these 55.2% were female and 44.8% were male. This proportion has remained the same since the Registry first received full national data in 2003. 32,306 total conventional total hip replacements were performed in 2014.

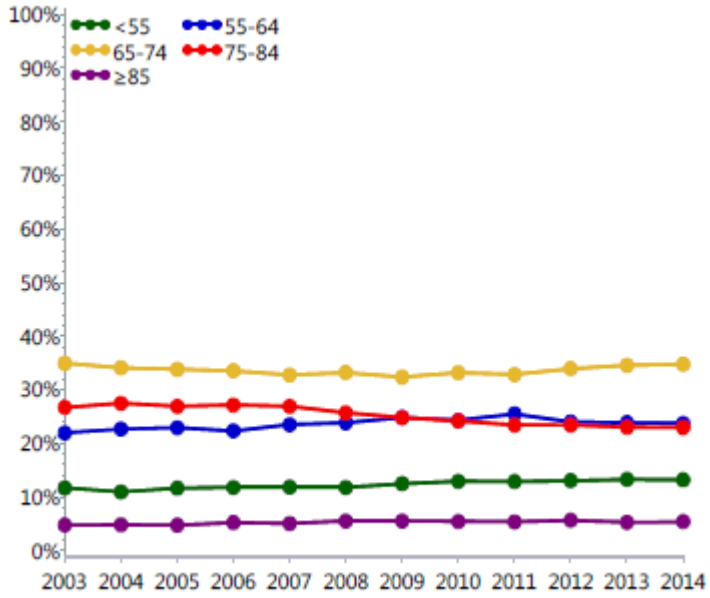


Fig 1.13: Primary Conventional THA by age group

The average recorded age for patients undergoing primary hip replacement was 69 years old for females and 66.4 years old for males. There has been little change in this demographic age of primary conventional THA patients since 2013. 23.7% of patients receiving primary conventional THA were 55 to 64 years old and 13.2% were less than 55years old in 2014.

Osteoarthritis was the principal diagnosis for primary total conventional hip replacement (88.5%), followed by fractured neck of femur (4.1%), osteonecrosis (3.4%), developmental dysplasia (1.3%) and rheumatoid arthritis (1.1%).

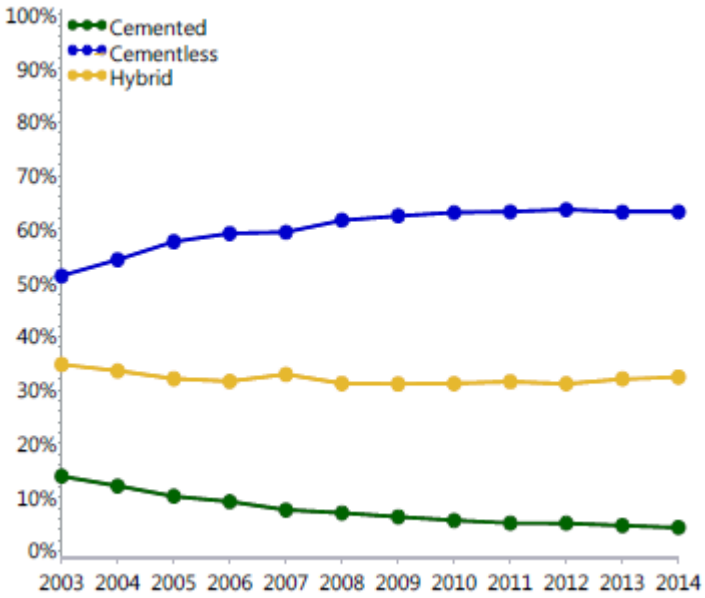


Fig 1.14: Primary Conventional THA by fixation

Surgeons preferred uncemented conventional THA. Use of uncemented conventional THA systems in 2014 was 63.2%. During the same year cemented systems was reported at 4.4% and hybrid systems at 32.4% respectively. For primary conventional THA uncemented acetabular implants were preferred. Femoral stem preference was based on pathology and patient femur type.

2014		2014	
N	Model	N	Model
7311	Exeter V40	7251	Trident (Shell)
4971	Corail	6069	Pinnacle
2866	Quadra-H	3392	R3
1543	CPT	2773	Versafitcup CC
1180	Polarstem	1475	Continuum
831	Anthology	1299	Trinity
711	CPCS	1084	Trilogy
708	Taperloc	647	Exeter X3 Rimfit
707	Secur-Fit	643	Trident/Tritanium (Shell)
566	Synergy	608	Allofit

Fig 1.15: Top 10 Femoral and Acetabular Implants used in Primary Conventional THA

The most common reasons for revision of primary conventional THA irrespective of pathology was loosening/lysis (28.0%), followed by prosthesis dislocation 24.2%), fracture (18.2%) and infection (17.3%). During the first 4 years, the main reason for revision was dislocation. After 7 years, this changed to loosening/lysis.

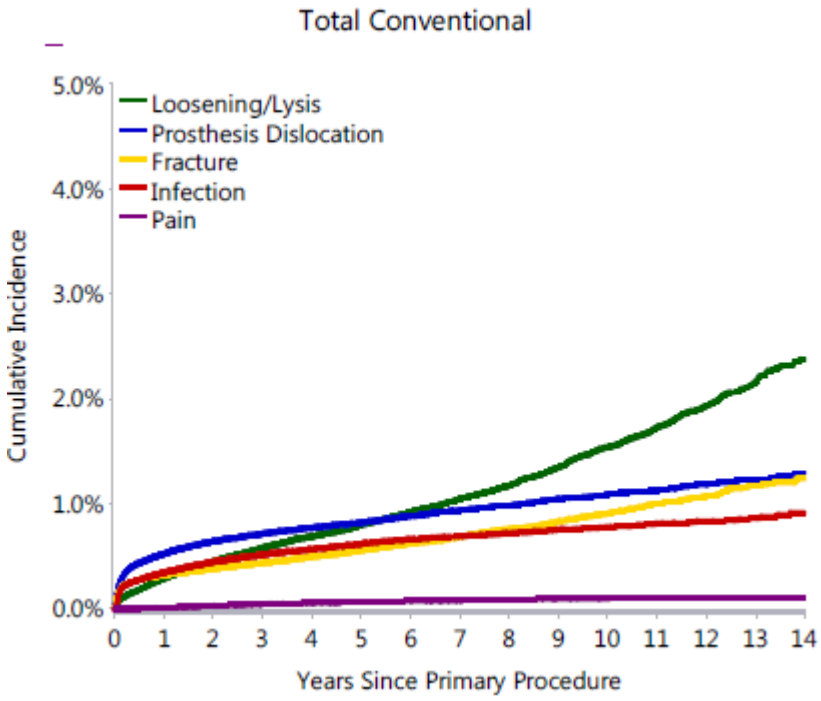


Fig 1.16: Cumulative Incidence Revision Diagnosis of Primary Total Conventional THA

The revision rate for primary conventional THA with a diagnosis of osteoarthritis was 1.5% at 1 year, 3.1% at 5 years, 5.2% at 10 years and 7.8% at 14 years. With an uncemented system, the revision rate was not dissimilar to the general revision rate with 1.7% at 1 year, 3.4% at 5 years, 5.4% at 10 years and 7.6% at 14 years.

Table 1.3: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Diagnosis

Primary Diagnosis	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	14 Yrs
Osteoarthritis	8837	262454	1.5 (1.5, 1.5)	2.4 (2.3, 2.5)	3.1 (3.0, 3.2)	3.9 (3.8, 4.0)	5.2 (5.1, 5.4)	7.8 (7.5, 8.2)
Fractured Neck Of Femur	564	12243	2.9 (2.6, 3.3)	4.5 (4.1, 4.9)	5.4 (4.9, 5.9)	6.3 (5.7, 6.9)	8.0 (7.1, 9.1)	
Osteonecrosis	480	9955	2.5 (2.2, 2.8)	3.6 (3.2, 4.0)	4.4 (4.0, 4.9)	5.4 (4.9, 5.9)	7.1 (6.4, 7.8)	9.2 (8.0, 10.5)
Developmental Dysplasia	174	3646	2.3 (1.9, 2.9)	3.4 (2.8, 4.0)	3.9 (3.3, 4.6)	4.8 (4.1, 5.7)	5.9 (5.0, 7.0)	11.9 (8.4, 16.8)
Rheumatoid Arthritis	167	3250	2.1 (1.6, 2.6)	3.4 (2.8, 4.1)	3.9 (3.3, 4.7)	4.8 (4.0, 5.7)	6.7 (5.6, 8.0)	11.9 (9.4, 15.1)
Other (6)	242	4984	3.1 (2.6, 3.6)	4.7 (4.0, 5.4)	5.5 (4.7, 6.3)	6.3 (5.4, 7.3)	8.6 (7.3, 10.1)	
TOTAL	10464	296532						

Note: Only primary diagnoses with over 2,000 procedures have been listed.
All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

When comparing cemented versus uncemented systems, cementless fixation initially had a higher rate of revision. Patients aged >75 years did not benefit from an uncemented systems and have a higher rate of revision. However, for patients aged < 75 years, uncemented systems have a lower rate of revision at later time periods when compared with cemented or hybrid fixation.

Table 1.4: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Fixation - Primary Diagnosis OA

Fixation	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	14 Yrs
Cemented	929	20694	1.1 (1.0, 1.3)	2.1 (1.9, 2.3)	3.1 (2.8, 3.3)	4.0 (3.7, 4.4)	6.0 (5.6, 6.4)	10.1 (9.1, 11.2)
Cementless	5362	155063	1.7 (1.6, 1.8)	2.7 (2.6, 2.8)	3.4 (3.3, 3.5)	4.1 (4.0, 4.3)	5.4 (5.2, 5.6)	7.6 (7.1, 8.1)
Hybrid	2546	86697	1.2 (1.1, 1.3)	2.0 (1.9, 2.1)	2.6 (2.5, 2.7)	3.3 (3.2, 3.5)	4.7 (4.5, 4.9)	7.1 (6.5, 7.6)
TOTAL	8837	262454						

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

Table 1.5: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Age and Fixation - Primary Diagnosis OA

Age	Fixation	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	14 Yrs
<55		**1049**	**27318**	**1.5 (1.3, 1.6)**	**2.6 (2.4, 2.8)**	**3.4 (3.2, 3.7)**	**4.3 (4.1, 4.7)**	**5.9 (5.5, 6.4)**	**9.9 (8.9, 11.0)**
	Cemented	62	820	1.4 (0.8, 2.5)	2.4 (1.5, 3.7)	3.5 (2.4, 5.1)	4.6 (3.2, 6.5)	8.3 (6.2, 11.1)	
	Cementless	813	21949	1.5 (1.4, 1.7)	2.7 (2.5, 2.9)	3.5 (3.2, 3.8)	4.3 (4.0, 4.7)	5.6 (5.2, 6.1)	8.8 (7.8, 10.1)
	Hybrid	174	4549	1.1 (0.9, 1.5)	1.9 (1.5, 2.4)	2.8 (2.3, 3.4)	4.4 (3.6, 5.2)	6.6 (5.5, 7.8)	11.0 (8.6, 14.0)
55-64		**2211**	**62084**	**1.4 (1.4, 1.5)**	**2.4 (2.3, 2.5)**	**3.1 (3.0, 3.3)**	**4.0 (3.8, 4.2)**	**5.6 (5.4, 5.9)**	**8.7 (8.0, 9.4)**
	Cemented	180	2571	1.4 (1.0, 2.0)	2.9 (2.3, 3.7)	4.1 (3.4, 5.0)	5.3 (4.4, 6.4)	8.5 (7.3, 10.0)	14.3 (11.6, 17.6)
	Cementless	1523	45134	1.5 (1.4, 1.7)	2.5 (2.3, 2.7)	3.1 (3.0, 3.3)	3.9 (3.7, 4.2)	5.3 (5.0, 5.7)	7.6 (6.8, 8.5)
	Hybrid	508	14379	1.2 (1.0, 1.4)	2.0 (1.8, 2.3)	2.8 (2.5, 3.1)	3.7 (3.4, 4.2)	5.7 (5.1, 6.3)	9.2 (8.0, 10.7)
65-74		**3092**	**93130**	**1.4 (1.3, 1.5)**	**2.3 (2.2, 2.4)**	**3.0 (2.9, 3.2)**	**3.7 (3.6, 3.9)**	**5.0 (4.8, 5.2)**	**7.5 (7.0, 8.0)**
	Cemented	378	6992	1.1 (0.9, 1.4)	2.2 (1.8, 2.5)	3.1 (2.7, 3.6)	4.4 (3.9, 5.0)	6.5 (5.8, 7.2)	11.2 (9.7, 13.0)
	Cementless	1777	54848	1.6 (1.5, 1.7)	2.5 (2.4, 2.7)	3.2 (3.1, 3.4)	3.9 (3.7, 4.1)	4.9 (4.7, 5.2)	6.7 (6.1, 7.4)
	Hybrid	937	31290	1.2 (1.0, 1.3)	1.9 (1.8, 2.1)	2.6 (2.4, 2.8)	3.2 (3.0, 3.5)	4.5 (4.2, 4.8)	6.5 (5.9, 7.3)
≥75		**2485**	**79922**	**1.7 (1.6, 1.7)**	**2.4 (2.3, 2.6)**	**3.1 (3.0, 3.2)**	**3.8 (3.6, 3.9)**	**4.9 (4.6, 5.1)**	**5.7 (5.3, 6.2)**
	Cemented	309	10311	1.1 (0.9, 1.3)	1.9 (1.6, 2.1)	2.7 (2.4, 3.1)	3.3 (2.9, 3.7)	4.3 (3.8, 4.9)	5.1 (4.4, 5.9)
	Cementless	1249	33132	2.3 (2.1, 2.4)	3.2 (3.0, 3.4)	3.9 (3.6, 4.1)	4.7 (4.4, 5.0)	6.0 (5.6, 6.4)	
	Hybrid	927	36479	1.3 (1.2, 1.4)	2.0 (1.8, 2.1)	2.5 (2.3, 2.7)	3.1 (2.9, 3.3)	4.0 (3.7, 4.4)	5.1 (4.4, 5.9)
TOTAL		**8837**	**262454**						

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

Males had a slightly higher revision rate than females. There was no apparent relationship between age and revision risks for males. The revision risk for males >75 years increased initially in the first 1.5 years but then normalises. Younger females aged <55years at the index operation had a higher rate of revision than females >75 years. Age seemed to be a protective factor for revision in older females.

Table 1.6: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Age and Gender - Primary Diagnosis OA

Gender	Age	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	14 Yrs
Male		**4180**	**119257**	**1.5 (1.5, 1.6)**	**2.5 (2.4, 2.6)**	**3.2 (3.1, 3.4)**	**4.1 (3.9, 4.2)**	**5.6 (5.4, 5.8)**	**8.5 (8.0, 9.0)**
	<55	506	14726	1.3 (1.1, 1.5)	2.3 (2.0, 2.6)	3.1 (2.7, 3.4)	3.9 (3.5, 4.3)	5.4 (4.9, 6.0)	8.8 (7.7, 10.2)
	55-64	1108	30431	1.5 (1.4, 1.7)	2.5 (2.3, 2.7)	3.2 (2.9, 3.4)	4.1 (3.8, 4.4)	5.7 (5.3, 6.1)	9.4 (8.3, 10.5)
	65-74	1461	43115	1.4 (1.2, 1.5)	2.3 (2.1, 2.4)	3.1 (2.9, 3.3)	3.9 (3.7, 4.1)	5.3 (5.0, 5.6)	7.9 (7.2, 8.7)
	≥75	1105	30985	1.9 (1.8, 2.1)	2.9 (2.7, 3.1)	3.7 (3.5, 3.9)	4.5 (4.2, 4.8)	5.9 (5.5, 6.4)	6.6 (6.0, 7.2)
Female		**4657**	**143197**	**1.5 (1.4, 1.5)**	**2.3 (2.2, 2.4)**	**3.0 (2.9, 3.1)**	**3.7 (3.6, 3.8)**	**4.9 (4.8, 5.1)**	**7.3 (6.8, 7.7)**
	<55	543	12592	1.7 (1.5, 1.9)	2.9 (2.6, 3.2)	3.8 (3.4, 4.2)	4.9 (4.4, 5.3)	6.5 (5.9, 7.2)	11.2 (9.4, 13.3)
	55-64	1103	31653	1.4 (1.3, 1.5)	2.4 (2.2, 2.5)	3.1 (2.9, 3.3)	3.9 (3.7, 4.2)	5.6 (5.2, 6.0)	7.9 (7.1, 8.9)
	65-74	1631	50015	1.5 (1.4, 1.6)	2.3 (2.2, 2.5)	3.0 (2.8, 3.2)	3.6 (3.4, 3.8)	4.7 (4.5, 5.0)	7.1 (6.5, 7.8)
	≥75	1380	48937	1.5 (1.4, 1.6)	2.2 (2.1, 2.3)	2.7 (2.6, 2.9)	3.3 (3.1, 3.5)	4.2 (4.0, 4.5)	5.2 (4.7, 5.9)
TOTAL		**8837**	**262454**						

Note: All procedures using metal/metal prostheses with head size larger than 32mm have been excluded

Prior to 2015, the Australian National Joint Registry had not reported approach as a factor in revision. Due to a growing interest in surgical approach affecting survivorship of implants, this has recently been included in the report cards completed during each THA in Australia. This may be difficult to interpret as the learning curve discussed by many articles is associated with an increased revision rate that may skew the eventual long term outcomes of DAA THA. The Australian National Joint Registry does not record Patient Reported Outcome Measures (PROM) following THA.

Hospital length of stay

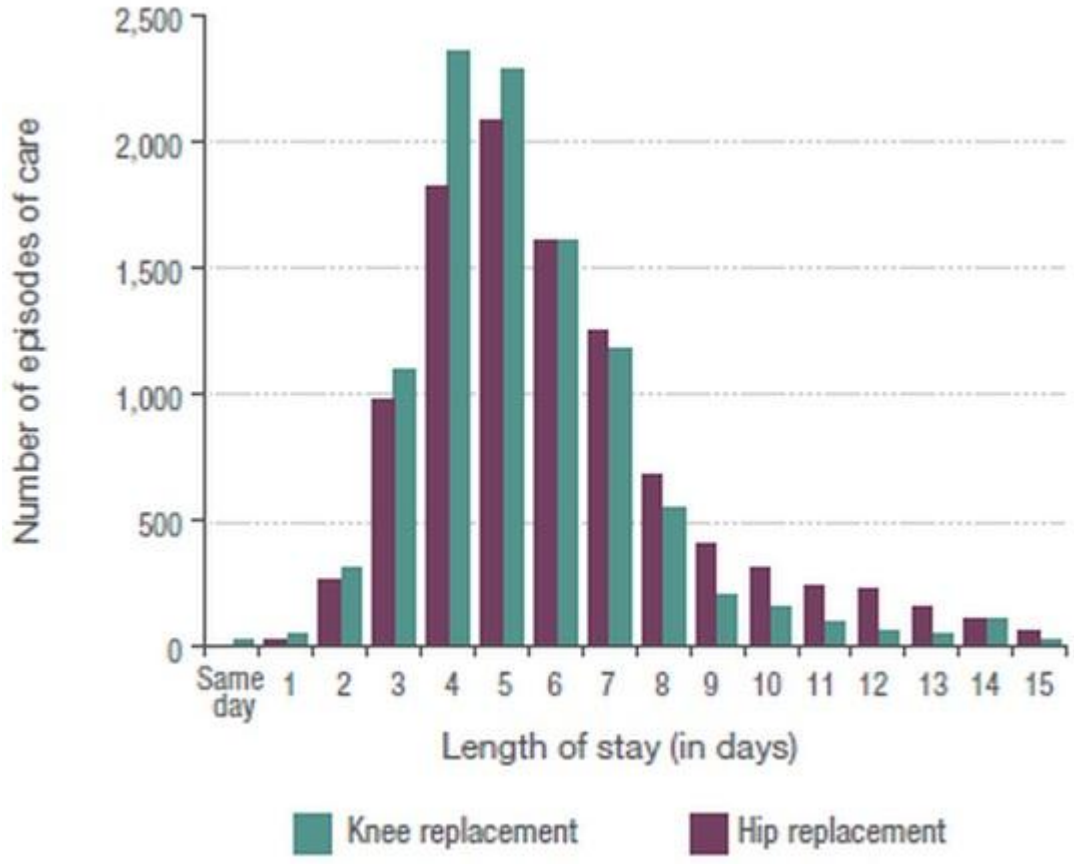
A relative performance index of hip arthroplasty surgery is related to the duration of hospital stay. The National Health Performance Authority (NHPA) published in its report data pertaining to the number of days stayed for hip arthroplasty from 2011-2012. (60) The data collected by the NHPA reflects hospital stay for patient who stayed one or more nights for knee replacements without complications and for hip replacements without complications or comorbidities.

Hospital 'stay' is defined in the report as a period of care in a hospital for a single type of care, for example, acute care, rehabilitation or palliative care. If a patient changes from one type of care to another, or transfers hospital, this would be two episodes of care. Hence 'stay' is calculated as the period a patient remains in care of the operating hospital until discharge home or to a rehabilitation facility.

According to the NHPA, in 2011–12, there were 10,199 knee replacements and 10,549 hip replacements, accounting for 55,858 and 67,163 bed days respectively. The national mean length of stay for patients undergoing hip arthroplasty surgery was 6.4 days.

In the same period of 2011-2012, Box Hill Hospital performed 113 hip replacements with an average hospital stay of 5 days. From 2012-2013 this average improved to 4.7days. Maroondah Hospital performed 95 hip replacements with an average stay of 5.7 days that also improved to 5.1 days in the 2012-2013 year.

Fig 1.17: National Performance Health Authority Hospital Performance: Length of stay in public hospital 2011-2012



Key Articles from 2000-2010

Following the relative indolence of the DAA from THA surgery in the 1990's, the 2000's saw a gradual resurgence of DAA in the literature. Various technicalities with the DAA were analysed such as the surgical approach, use of a traction table and comparisons with other approaches in THA. The DAA has also been explored in its use for femoral neck fractures and revision THA. Below is a chronologically based dissertation on developments of the DAA since the early 2000's to its current state, its uses and controversies.

In 2003, R Kennon, from the Keggi Orthopaedic Foundation published a series of 2,132 patients who had DAA THA. The Keggi modified DAA utilises percutaneous stab incision to access the femur and acetabulum. This DAA technique did not employ specialised instrumentation or an Orthopaedic traction table. Cemented and uncemented prosthesis were utilised for both straight forward and complex primary THAs. In this series Kennon reported a low dislocation rate of 1.3%, 4% fracture rate (higher risk with uncemented implants) and a 0.02% LCNT neuropraxia rate. (61)

This differed slightly from Light and K Keggi's publication from 1980 which described the supine DAA without a traction table. The differences described were mainly during femoral preparation. If femoral exposure was inadequate, release of the TFL from the ilium was performed. A trochanteric osteotomy was reportedly performed for 3 participants to assist femoral exposure. A modified rasp was used to broach the femur to avoid soft tissue impingement. (62)

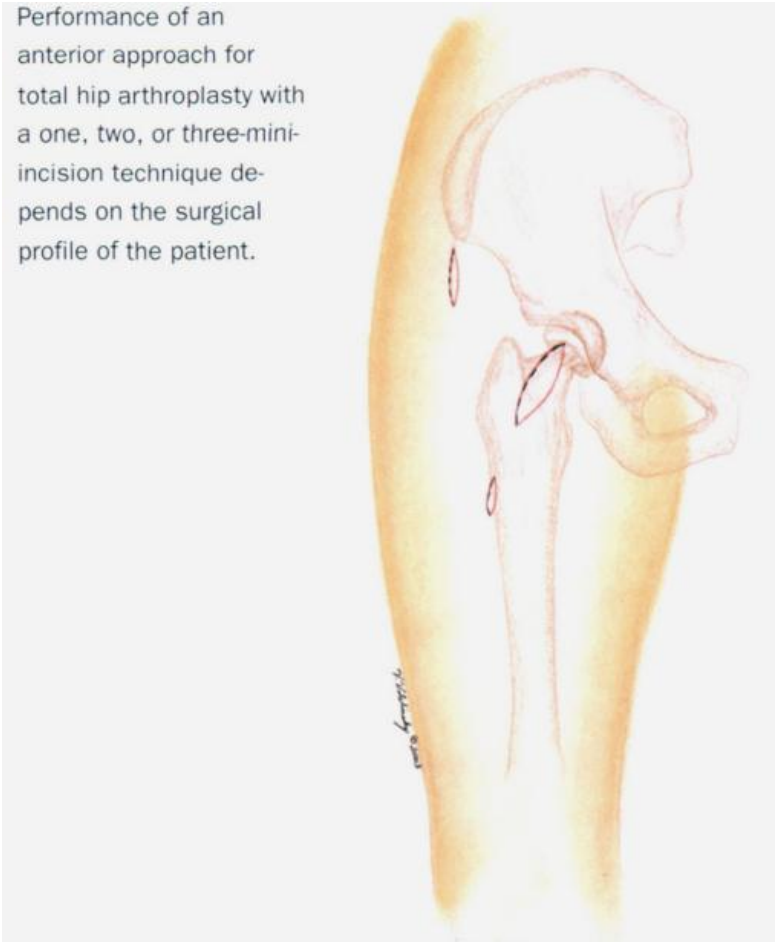
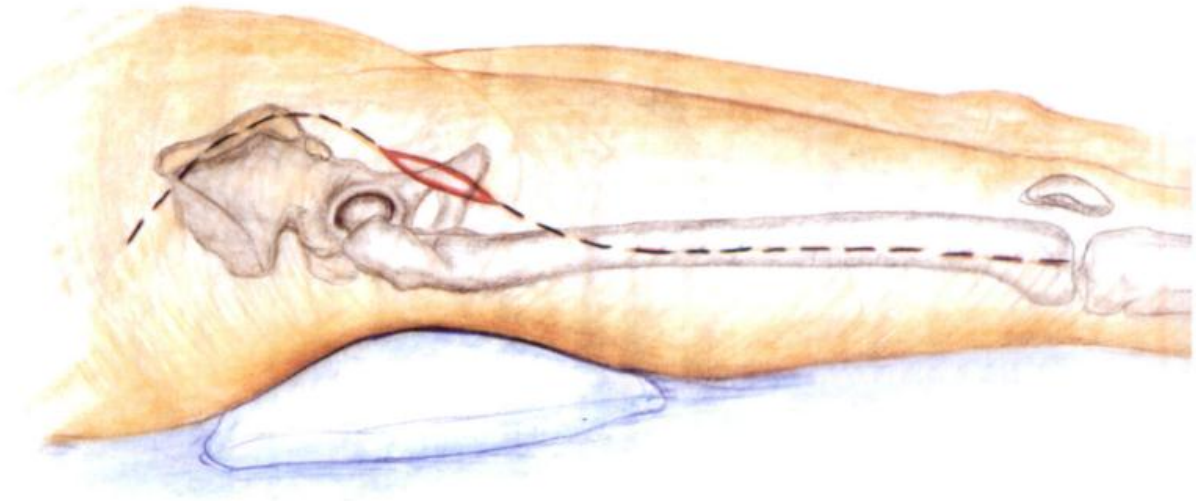


Fig 1.18: Keggi DAA THA (Kennon JBJS Am,2003)

Kennon then reported his technique and extensions utilising the DAA for revision THA. The proximal extension was similar to that of Smith Petersen's exposure whereas distally it curved to the lateral aspect of the thigh to allow a direct lateral approach to the midshaft and distal femur.(63) In this series of revision, it was interesting to note a low rate of infection, DVTs, dislocations and short operative time of which the author credits to the muscle sparing nature of the approach.

Fig 1.19: Extensile Exposure of Kennon DAA for use of acetabular cage, stem revisions and total femoral replacements. JBJS Am, 2004



From 2004 to 2005 seemingly to support Kennon, Siguier and Matta published their case series to affirm low dislocation rates with DAA THA. Unlike Kennon, only a single incision was used albeit in a different location but utilising the same intermuscular and internervous interval of sartorius and TFL. The dislocation rates for the DAA were 0.96% out of 1,037 patients (Siguier) and 0.61% out of 437 participants (Matta). (57, 64) Of note Matta in his series utilised a traction table unlike Kennon and Siguer. Matta's results were also impressive at the time with a reported hospital stay of 3 days. However, Matta had a 2.75% (12/437) intra-operative fracture rate.

Fig 1.20: A modern fracture table for use with the DAA. (Matta, CORR, 2005)

In the wake of these results, there was an apparent interest in the DAA. Many studies were published from 2005 to 2010. Meneghini in 2006 published a landmark cadaveric study comparing the DAA and PA. In his study, 6 cadavers and 12 hips were utilised with each cadaver being its own control. 2 surgeons were involved, one specialising in the DAA and another with the PA. Muscle damage was assessed based on a visually graded scale. Meneghini identified less damage in the gluteus minimus muscles and minimus tendon with the DAA (8%) compared with the PA (18%). However, the DAA resulted in a mean of 31% of TFL muscle damage and 12% rectus femoris damage. Half of the DAA approach required release of the piriformis or conjoined tendon. (65)

Also in 2006, a report of DAA THA being performed in the lateral position was published.(66) Nogler developed a double offset broach handle to facilitate improved femoral broaching without soft tissue impingement. (54) Henri Judet contributed again to the field of DAA THA reporting improved acetabular anteversion with the use of computer navigation. (67). Nogler reported similar outcomes of improved acetabular anteversion with navigation in a cadaveric study in 2008.(68)

Sariali in 2008 identified a total dislocation rate of 1.5% with the DAA in 1,764 patients. On subgroup analysis, Sariali reported the dislocation rate for 28 millimetre (mm) heads was 0.5%. (69) This contradicts Berry's 2005 findings of increased dislocation risks with smaller femoral heads. Although Berry did not include DAA THA in his results, he noted that the effect was greatest with the PA.(70) With the knowledge that hip stability is due to multiple intrinsic and extrinsic factors, it is most interesting to observe and hypothesise that the DAA surgical technique conferred more stability to a hip joint than an increase in

femoral head diameter size. Despite evidence of inherently stable & reproducible THA, a lack of functional and clinical measures comparing the DAA to other approaches was present. Of note, there was a distinct absence of randomised clinical trials.

The year 2009 saw more developments with clinical trials comparing the DAA against other approaches. The lack of randomised trials was also duly addressed. Mayr and Nogler compared gait analysis results in a randomised trial for 16 patients having DAA THA. This was against a control of 17 patients who had THA surgery using the anterolateral approach. Mayr concluded that patients having DAA THA surgery improved in a larger number of gait parameters than patients receiving the anterolateral approach. Mayr also identified that the majority of improvements occurred between the 6-and 12-week follow-ups. The parameters that improved in the DAA group were a significant improvement in cadence, stride time, length, walking speed, hip flexion at foot contact, maximum hip flexion in swing, and hip total range of motion in the sagittal and the coronal planes. The anterolateral group had fewer parameters that improved in comparison the with DAA group. These parameters were in opposite foot contact and step time, hip flexion at foot contact, maximum hip flexion in swing, and range of flexion at the hip joint. (71)

Another gait analysis study in 2009 by Maffiueletti compared 17 DAA, 17 PA patients and 17 case-matched normal patients. Maffiueletti reported that THA patients irrespective of approach demonstrated impaired gaits compared to normal individuals during fast walking but not at a self-selected pace. Maffiueltti also found that patients operated with the PA reported significantly higher stiffness (DAA 0 versus PA 12.5) than DAA and control

patients. The PA group had similar pain and function with no further differences in gait characteristics after six months. (72)

Two Japanese 2 studies comparing the DAA to the PA were published in 2009. The first study by Sugano utilised Computed Tomographic Scans for pre-operative DAA and PA THA planning in 72 patients with 2 year follow-up. Sugano concluded that with no component malposition, that DAA and PA results were similar. There was no difference between the Japanese Orthopaedic Association & Oxford Hip Scores at 6 months and 2 years post-operatively. However, the DAA group had faster recovery and could walk 20m without cane 1 week earlier than the PA group.(73) The second Japanese study by Nakata compared 99 DAA THAs with 96 MPA hips. Nakata reported more rapid recovery for hip function and gait ability for DAA THA when compared to MPA THA in the domains of hospital stay and function (less post-operative Trendelenberg, better single leg stance, better 50m walking times) up to 2 months post-operatively. This was offset however by increased intra-operative and post-operative bleeding. Of note there was a long mean length of stay for the DAA group was 22.2 days and the PA was 30.4 days.(74)

The final clinical trial in 2009 was by Berend. Berend published his findings of 258 DAA THAs compared 379 mini LA THA. Berend reported that the DAA group was associated with better Harris Hip Scores (HHS) at 6 weeks, had equal operative times and had slightly more blood loss. The length of stay (1.8 days DAA versus 2 days LA) and complication rate between both approaches were low and identical.

Whilst initial early outcomes with the DAA were thought to be superior in comparison with other approaches, two studies by Wayne and Woolson identified issues in adopting the DAA. Wayne's Norwegian cohort study compared 100 DAA THAs to 100 LA THAs. Wayne reported an association of DAA THA with increased operative time, increased bleeding, increased rates of nerve trauma, increased intraoperative femoral fractures and increased acetabular component malposition. This was offset with shorter hospital stay and fewer infections of the operative site.

Woolson's results echoed Wayne's findings. Two hundred thirty-one consecutive patients (247 hips) of 5 community practice surgeons were studied. Surgeons involved in the study had not had prior fellowship training with DAA THA. Woolson reported a substantial increase in average surgical time of (164 minutes), estimated blood loss (858 mL) and major complications (9%). The only benefit seen was that no post-operative dislocations were identified.

At the turn of the decade, evidence of the safety and efficacy of DAA THA was still unclear. Whilst many studies reported benefits, there was only a single randomised gait analysis study and several prospective clinical studies that compared the DAA with other surgical approaches. Increased complications identified by Wayne and Woolson identified that surgeon experience with the DAA was an important factor in obtaining results comparable with other approaches in THA.

Articles from 2010 to 2015

From 2010, DAA THA was a chief issue of contention amongst hip arthroplasty surgeons. Burgeoning articles and debates in peer reviewed literature reflected two schools of thoughts in embracing DAA THA. More prospective cohort and randomised clinical studies have since been published. Due to the large number of articles on DAA only major articles with critical findings are discussed. The literature review first focuses on published randomised trials and systematic reviews. Main aspects of domains involved in DAA THA are further elaborated in their titled sections.

- Randomised Controlled Studies
- Systematic Reviews & Meta-Analysis
- Potential Advantages with DAA THA
    - PROMS
    - Operative time and Hospital Stay
    - Pain and Analgesia
    - Soft Tissue Trauma
    - Hip Function
- Potential Disadvantages & Complications with DAA THA
    - Neurovascular Injury
    - Wound problems and Obesity
    - Fractures and Component Malposition
    - Learning Curve, Revision & Long Term Survivorship

Randomised Controlled Trials

At the time of write-up, there were 9 published randomised trials analysing various outcomes of DAA THA compared with other surgical approaches. These randomised trials were broad in their scope and encompassed various domains such as gait analysis, PROM, analgesics and clinical parameters. The general trend of randomised trials had favourable reports associated with DAA THA particularly in the early post-operative period.

Restrepo et al

In 2010, Restrepo et al published the first clinically based randomised trial comparing the DAA to the LA. (75)The inclusion criteria to the study were an age between 18 to 75 years old with underlying osteoarthritis. The exclusion criteria were a BMI greater than 30 and cognitive or psychiatric illness that could preclude study follow-up. The criteria used by Restrepo formed the baseline of further clinical studies to come. Follow-up occurred at 6 weeks, 6 months, 1 year and 2 year post-operative time points. 50 patients were randomly allocated to DAA and LA groups. Clinical outcomes and PROMs were analysed. PROMS utilised were the HHS, Lower Extremity Functional Score (LEFS), WOMAC and Short Form 36 (SF-36) questionnaires. A standard operating table was used during DAA THA surgery. Restrepo reported significantly better PROMs with DAA THA compared to the LA. The differences in PROMs were between 6 weeks to 1 year post-operatively. There were no differences in post-operative analgesic requirements, operative time, blood loss, transfusions or hospital stay.

Table 1.8: Demographic Data (Restrepo, JOA, 2010)

Variables	Approach Direct Anterior	Range	Approach Direct Lateral	Range	*P*
Age, y	62.02	(35.0-84.5)	59.91	(40.1-76.1)	.34
Body mass index, kg/m^2	25.18	(18.8-29.9)	25.17	(19.2-29.1)	.85
Operative time, min	56.42	(35-90)	54.88	(36-100)	.54
American Society of Anesthesiologist Score	2.32	(1-3)	2.20	(1-3)	.3
Incision at start	9.45	(8-11)	9.94	(8-12)	.32
Incision at end	10.09	(9-12)	10.58	(8-13)	.19
Blood loss, mL	172.50	(100.0-650.0)	170.00	(50.0-500.0)	.67
Preoperative Hb	13.68	(10.3-16.3)	13.50	(5.9-16.0)	.97
Postoperative Hb	10.84	(8.6-12.7)	10.48	(3.8-13.3)	.21
Hb drop	2.84	(−1.2 to 6.4)	3.02	(0.2-6.3)	.44
Preoperative Hct	41.14	(31.9-47.5)	40.71	(15.6-47.9)	.73
Postoperative Hct	32.96	(28.0-39.0)	31.81	(11.6-40.7)	.2
Transfusion needed	15 yes, 35 no	–	17 yes, 33 no	–	.83
Transfusion, U	0.38	(0-3)	0.42	(0-3)	.77
Hospital stay, d	3.56	(3-6)	3.50	(2-8)	.56
Discharged to	45 home, 5 rehabilitation	–	46 home, 4 rehabilitation	–	1
Patients enrolled	50		50	Total	100
Total patients enrolled	100				

Hb indicates hemoglobin; Hct, hematocrit.

Table 1.9: 6 week post-operative outcome data (Restrepo, JOA, 2010)

	Approach		Approach		
	Direct Anterior	Range	Direct Lateral	Range	*P*
Outcome values 6 wk postoperative					
Harris Hip Score	93.64	(77.1-100.0)	88.80	(65.0-99.7)	.03
Lower Extremity Functional Score	10.36	(7-15)	9.90	(7-12)	.36
Western Ontario McMaster Osteoarthritis Index	4.40	(0-19)	9.70	(0-40)	0
Linear Analog Scale Assessment					
Energy level	7.71	(4.0-10.0)	7.15	(3.0-10.0)	.06
Daily activities	8.13	(4.0-10.0)	7.48	(2.9-10.0)	.49
Overall quality	8.23	(4.0-10.0)	7.33	(2.9-10.0)	0
Short Form-36 Scores					
Physical functioning	88.67	(44.4-94.4)	70.78	(27.8-100.0)	0
Role limitations	86.00	(0.0-100.0)	46.00	(0.0-100.0)	0
Bodily pain	95.55	(67.5-100.0)	78.35	(32.5-100.0)	0
Social functioning	95.75	(50.0-100.0)	83.25	(12.5-100.0)	0
General mental health	89.60	(64.0-96.0)	76.00	(52.0-96.0)	0
Role limitations due to emotional problems	94.67	(33.3-100.0)	90.67	(0.0-100.0)	.23
Vitality, energy, or fatigue	79.90	(55.0-85.0)	72.60	(45.0-90.0)	0
General health perceptions	88.60	(65.0-95.0)	84.00	(35.0-100.0)	.02
Health compared with last year	81.50	(50.0-100.0)	81.50	(50.0-100.0)	.77
Short Form-36 Scores (2 dimensions)					
Physical health A	87.74	(53.4-94.9)	70.35	(42.2-94.9)	0
Mental health B	89.70	(62.1-95.2)	81.30	(44.8-95.6)	0
Time with cane Postoperative, wk					
	2.40	(0-5)	3.76	(2-5)	0
Patients operated on	50		50	Total	100
Patients followed 6 wk	50		50	Total	100
Total patients enrolled	100				

Restrepo's mean operative time and length of stay in hospital for both groups was approximately 55 minutes and 3.5 days respectively. Approximately 90% of each patient from each group were discharged home and the remaining 10% to a rehabilitation facility.

Restrepo's study whilst interesting and well-designed had a very high dropout rate from recruitment. Restrepo also included participants with bilateral total hip replacements. Interestingly there were no surgical complications in the study. There were also no femoral fractures or LCNT neuropraxia. Finally, there was also external funding from a major Orthopaedic medical technology company. This raises the possibility of a reporting and performance bias.

Auffarth et al

The next randomised trial to follow suit was by Auffarth et al in 2011.(76) Auffarth conducted a smaller scale study that randomised equally 48 geriatric patients who sustained femoral neck fractures into the DAA or lateral groups for hemiarthroplasty. Patients were followed up to 6 months and assessed clinically using the HHS. Although being different in its entity to primary THA, it was hypothesised that a muscles sparing approach could lead to better outcomes and faster rehabilitation.

Auffarth reported that the DAA group had significantly increased post-operative pain within the first 4 days based on the Visual Analogue Scale (VAS) and no difference in HHS at the 6 month review. This study was difficult to interpret due to the general cohort of patients and indication for surgery. The average age of participants was 83.2 years with

an average ASA of 3.1. Mortality less than 6 months follow-up was 12.5% in the lateral group and 25% in the DAA group. Although well intended and designed, the inherent performance bias and high mortality of patients who sustain neck of femur fractures would preclude relevant data from being obtained for purposes of elective THA.

Reininga et al

In 2012, Reininga answered the call for a gait analysis study comparing the DAA to PA. (77) In Reininga's randomised study, the DAA THA surgery was Computer Navigated while the PA group was conventionally instrumented. 35 and 40 participants were randomised to the DAA and PA groups respectively. Gait analysis was conducted pre-operatively, post-operatively at the 6 weeks, 3 month and 6 month time points. This was compared to a control of 30 healthy patients. Inclusion and exclusion criteria for the study were similar to Restrepos. Patients included were required to be suitable for an uncemented THA. Patients with previous surgery to the study hip, inflammatory polyarthropathy and a BMI > 32 were excluded.

Walking speed, step length, cadence, frontal plane angular movements of the pelvis and thorax were assessed. Following complex analysis of spatiotemporal gait parameters measured during 6 months recovery period of patients who underwent DAA and PA THA, Reininga concluded that there were no significant differences between both surgical groups. Reininga also reported that despite improvements over 6 months, there were still small differences between surgical patients and healthy controls.

Barrett et al

Barrett et al in 2013 published his landmark study comparing the DAA to PA.(78) Participants were randomised into DAA (43) and PA (44) groups and evaluated at 6 weeks, 3, 6 and 12 months post-operatively. Inclusion and exclusion criteria were not specific aside from meeting the requirements for uncemented THA and not having inflammatory joint disease. A single fellowship trained surgeon conducted both surgeries and utilised a specialised Orthopaedic table for DAA THA. The primary end point of the study was the ability to climb stairs normally and to walk an unlimited distance. Secondary end points were assessed using HHS, Hip Disability and Osteoarthritis Outcome Score (HOOS), VAS and the 6 minute walk test.

Table 1.10: Surgical & Pre-operative Data (Barrett, JOA, 2013)

Variable (Mean ± SD)	DAA	PA	*P*-Value
Surgery time, min	84.3 ± 12.4	60.5 ± 12.4	<.0001
Incision, cm	13.7 ± 0.9	12.7 ± 1.3	<.0001
Blood loss, ml	391 ± 206	191 ± 107	<.0001
Cup Inclination, deg	47.1 ± 6.1	42.4 ± 7.6	0.0022
Cup Anteversion, deg	20.1 ± 5.9	25.8 ± 8.1	0.0005
Stem Orientation*			0.0034
Valgus	0 (0%)	0 (0%)	
Neutral	41 (98%)	31 (74%)	
Varus	1 (2%)	11 (26%)	
Discharged on Day 2*	32 (74%)	17 (39%)	0.0028
Length of Stay-days	2.28	3.02	0.0374
Morphine Equivalents, mg			
Post-op, day of surgery	32.2 ± 26.2	41.4 ± 29.1	0.1271
1 day post-op	50.7 ± 33.7	54.6 ± 30.3	0.5715
2 days post-op	33.7 ± 33.5	42.0 ± 28.0	0.2132
VAS			
Post-op, day of surgery	4.2 ±1.4	4.6 ±1.8	0.2257
1 day post-op	4.0 ±1.0	4.5 ±1.2	0.0472
2 days post-op	3.8 ±1.1	4.1 ±1.0	0.2042
Distance walked, m			
Post-op, day of surgery	44.6 ±28.3	17.7 ±23.1	0.0003
1 day post-op	173.6 ±83.8	121.1 ±89.8	0.0062
2 days post-op	217.7 ±88.5	162.7 ±80.5	0.0030

* N (%).

Table 1.11: Post-operative outcome data (Barrett, JOA, 2013)

Variable (Mean ± SD)	6 Weeks			3 Months			6 Months			12 Months		
	DAA	PA	*P*-Value	DAA	PA	*P*-Value	DAA	PA	*P*-Value	DAA	PA	*P*-Value
HHS												
Distance Unlimited AND Stairs Normally*	21 (50%)	6 (15%)	0.0011	26 (74%)	19 (50%)	0.0532	29 (85%)	27 (75%)	0.3740	33 (97%)	36 (88%)	0.2122
Stairs Normally*	21 (50%)	7 (18%)	0.0023	26 (74%)	20 (53%)	0.0828	30 (88%)	27 (75%)	0.2211	33 (97%)	36 (88%)	0.3692
Distance Unlimited*	34 (81%)	17 (55%)	0.0005	33 (94%)	28 (74%)	0.0260	33 (97%)	35 (97%)	1.0000	34 (100%)	40 (98%)	1.0000
Shoes and Socks With Ease*	28 (67%)	1 (3%)	<0.0001	30 (86%)	29 (76%)	0.3800	31 (91%)	36 (92%)	1.0000	30 (88%)	35 (85%)	1.0000
Pain	39.8 ± 4.4	38.4 ± 5.4	0.2056	37.5 ± 7.0	39.4 ± 6.2	0.2402	41.1 ± 5.9	41.1 ± 5.7	0.9701	42.0 ± 5.2	42.5 ± 4.4	0.6615
Function	28.7 ± 3.7	25.5 ± 5.3	0.0027	31.5 ± 2.8	30.6 ± 3.5	0.2371	32.4 ± 1.4	32.6 ± 1.3	0.6626	32.8 ± 0.7	32.4 ± 1.6	0.1301
Total	89.5 ± 8.1	81.4 ± 9.8	0.0001	91.2 ± 9.7	91.4 ± 9.7	0.9317	95.8 ± 7.8	95.9 ± 6.8	0.9680	97.5 ± 5.7	97.3 ± 5.5	0.8700
VAS	1.9 ± 1.2	1.9 ± 1.6	0.9530	1.3 ± 0.5	1.4 ± 1.0	0.4414	1.6 ± 1.5	1.4 ± 1.2	0.4606	1.6 ± 1.4	1.3 ± 0.6	0.1857
6MWT, m	513.7 ± 750.5	344.4 ± 96.7	0.1644	428.4 ± 95.2	402.3 ± 71.9	0.1842						
HOOS												
Symptoms	79.4 ± 12.3	79.9 ± 11.6	0.8631	90 ± 11.5	83.9 ± 11.7	0.0471	90.6 ± 12.7	89.7 ± 8.9	0.7404	92.9 ± 13.2	92.1 ± 8.7	0.7574
Pain	83.5 ± 14.7	79.6 ± 16.7	0.2673	90.8 ± 11.6	8.90 ± 12.5	0.5214	90.7 ± 14.8	92.6 ± 9.6	0.5288	94.3 ± 12.7	93.4 ± 10.6	0.7407
ADL	83.5 ± 13.7	79.0 ± 13.3	0.1341	89.1 ± 12.1	89.7 ± 8.6	0.8122	92.5 ± 12.7	93.3 ± 7.8	0.7521	94.4 ± 11.2	95.4 ± 7.3	0.6518
S&R	60.6 ± 23.6	42.0 ± 23.7	0.0007	67.5 ± 22.3	68.6 ± 23.4	0.8395	72.6 ± 26.5	75.7 ± 19.2	0.5770	82.0 ± 20.2	79.4 ± 18.5	0.5614
QOL	62.6 ± 19.8	54.7 ± 20.5	0.0777	76.3 ± 18.2	67.5 ± 19.8	0.0606	80.3 ± 20.2	82.3 ± 17.0	0.6615	81.3 ± 21.8	85.3 ± 17.5	0.3769

* N (%).

The DAA group had longer operative times, larger wounds and more blood loss. However, the DAA group had significantly shorter hospital stays of 2.28 days versus 3.02 days for PA group (p=0.037). This was matched with the ability of DAA patients to walk further than PA group patients post-operatively from day 1 to discharge. The DAA group also reported lower VAS pain scores and had lower opiate use on the first post-operative day. VAS Pain scores were insignificant at later time points. HHS and HOOS had significant findings favouring the DAA group until 3 months post-operatively. Both groups had no statistical difference after 6 months follow-up.

Minor complications were not significant between both groups. There was no report of LCNT neuropraxia. A single case of revision surgery was performed for the PA group due to recurrent dislocation for prosthesis malposition (Acetabular inclination 59° and acetabular anteversion 58°). One intraoperative complication occurred with the PA group; a calcar crack was noted after stem placement and was treated with a circlage wire. Hip precautions were instituted for the PA group but not the DAA group.

Taunton et al

Taunton et al in 2014 published a randomised controlled trial comparing DAA to MPA. (79) The inclusion criteria were patient's age between 25 to 80 and compliance with study requirements. Patients were excluded if they had previous THA, inflammatory arthritis, chronic narcotic dependence or conditions precluding to a complex hip arthroplasty. Stratified randomisation of 54 patients into DAA or MPA was performed based on age (older than 65years or younger than 65 years) and gender. 27 patients were allocated to each group. The primary end point was the cessation of gait aids. Secondary measures

were assessed with HHS, WOMAC, Short form- 12 (SF-12) at 3 weeks, 6 weeks and 12 months post-operatively. An Orthopaedic table was used for DAA THA. Routine hip precautions were instituted for MPA patients.

Taunton's results indicated that DAA patients ceased gait aids voluntarily earlier than MPA patients. (22 versus 28 days, P =0.04). However, at 3 weeks SF-12 mental scores (60.66 versus 58.43, P=0.01) and WOMAC total scores favoured MPA patients (91.49 versus 87.20, P=0.04). There were no other significant findings between the two approaches reported.

Unlike other clinical studies, there was no mention of operative times, hospital length of stay or analgesic use. Major complications were reported. There was an absent report in the incidence of LCNT neuropraxia.

Christensen et al

Christensen and Jacobs conducted a brief randomised trial comparing very early outcomes. 51 patients with similar inclusion and exclusion criteria to Taunton's study were randomised to DAA and PA groups. Orthopaedic table use during DAA was not discussed. Peri-articular local infiltration analgesia was used. Routine hip precautions were instituted for PA patients. Like Taunton's study, the primary outcome was time to cessation of gait aids. Secondary outcomes were measured using HHS, LEFS, Single Assessment and Numeric Evaluation (SANE), SF-12 questionnaires and the timed up and go (TUG) test.

Christensen's reported a significantly shorter hospital stay for the DAA group (1.4 days versus 2.0 days, P=0.01) with an earlier ability to discontinue use of gait aids (33.0+/- 18 days versus 43.1+/-14.6 days, p=0.03). Christensen also found that DAA patients demonstrated significantly greater pain relief after surgery. No other significant differences were noted. Unlike Barrett's study, there was no difference between groups with distances walked, stairs or function with shoes and socks up to 6 weeks post-operatively.(80)

Further Randomised Trials & Summary of RCT findings

Another two further randomised controlled trials that analyse differences between DAA and other surgical approaches were published in 2015. However, these studies focused on other aspects of DAA surgery such as peri-operative local anaesthetic infiltration and post-operative inflammatory marker changes. These topics are discussed in their sections to follow.

Randomised trials discussed to date have compared gait analysis and clinical outcomes of DAA THA to PA, MPA, LA and the anterolateral approaches. These trials associate DAA THA with earlier cessation of gait aids and better PROMs. Gait analysis suggests that there are more improvements in movement parameters with DAA when compared to the anterolateral approach but not with the PA. 2 RCT's by Barrett and Christensen associate the DAA with earlier discharge times. Differences between the DAA and other surgical approaches appear to be in the early post-operative period of less than 6 months.

Systematic Reviews & Meta- Analysis

2014 and 2015 saw the publications of three level 1 evidence type studies. Higgins, De Geest and Lee conducted a literature review of the current publications comparing the DAA to other surgical approaches. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were utilised by Higgins and De Geest. Lee's detailed the investigators methodology on study retrieval and inclusion. This resulted in analysis of approximately 12,000 patients from a combined pool of randomised, non-randomised, cohort and retrospective trials.

Higgins et al

Higgins in 2014 compared clinical, surgical and clinical outcomes in his analysis. His criteria for inclusion was

1) Was a comparison study
2) Primary THA
3) Single Incision DAA
4) PA THA
5) Quantifiable outcome measure reported

Higgins concluded from his analysis of 17 studies and 2302 patients that the DAA was generally associated with a shorter length of stay in hospital with a weighted mean difference (WMD) of 0.53days (95% CI: 1.01 to 0.04 days) after excluding a Swiss and Japanese study that reported a mean hospital stay of between 7 to 22 days for DAA surgery. Higgins also identified a significant difference in dislocation rates favouring the

DAA. Peto Odds Ratio 0.29% (95% CI: 0.09 to 0.95). Higgins identified little difference between operative times (7.9minutes) and acetabular component placement. Only a single study of the 17 included was a randomised controlled trial.

De Geest et al

De Geest in 2015 analysed 38 studies with 6485 patients and focused on identifying the rates of intra and post-operative complications associated with DAA THA. The inclusion criteria were

1) Primary elective single incision DAA
2) Outcomes reported
3) No restriction to follow-up times
4) All ages and all hip pathology included

De Geest excluded studies in which an estimation of complication rate was not possible. De Geest concluded that there was an increased risk of intra-operative and post-operative with the DAA. A low dislocation rate was also observed with the DAA. A significant risk incidence (RI) of 1.7% was reported for intra-operative complications. The most common intra-operative complications were femoral fractures (RI – 0.5% (95% CI: 0.3-0.9%) and trochanteric fractures (RI 0.8% - 95% CI: 0.4-1.65). The incidence of post-operative complications that needed surgical intervention was 2.9% (95% CI: 1.9-3.7%). The RI for surgery needing device explantation was 2.1% (95% CI: 1.4-2.8%). The RI for dislocation was 0.6% (95% CI: 0.4-0.9%).

Lee & Marconi

The final systematic review in 2015 on DAA THA surgery was from Lee. The focus of Lee's systematic review was to determine the risk of complications of DAA. The inclusion criteria were

1) Publication in English language
2) Primary THA with DAA
3) Complications reported
4) Minimum 50 patients
5) Minimum 12 months follow-up

Non clinical studies were excluded. Lee pooled a total of 11,810 DAA THAs from the 38 studies in the literature. From this Lee reported a complication rate of 2.8% for nerve dysfunction 2.3% for intra-operative fractures and a 1.2% of both wound complications and further revision within 12 months from the index surgery. The large majority of neuropraxias involved the LCNT. Only 11 patients had femoral nerve neuropraxias while 8 had peroneal nerve dysfunction.

Summary Systematic Review Findings

The main findings of the systematic review were an association of shorter hospital stay, lower dislocation rates but higher complications of intra-operative fractures, post-operative revision surgery and nerve injuries with DAA THA.

However, evidence from the systematic reviews although interesting based was potentially biased. The pooled patients accrued through the literature search mainly consisted of those from non-randomised studies. Randomised controlled trial patients made up between 1-4% of the overall number of patients. All three systematic reviews concluded that more evidence was needed in the form of further randomised controlled trials. Articles reviewed by Lee & Marconi were similar to that by De Geest et al. It was no coincidence that DAA complication types and rates reported were similar. Of note, the prevalence of LCNT neuropraxia following DAA was not reported by all studies. This is possibly an under reported complication associated with the procedure. LCNT neuropraxia is discussed in more detail under the complications section of the literature review.

Potential Advantages of DAA THA

To substantiate findings from the randomised trials, systematic reviews and to avoid a reporting bias, clinical outcomes discussed in this section are obtained from other non-randomised DAA THA studies. This section of the thesis focuses on controversial findings which are not elaborated in prior randomised trials or systematic reviews. Advantages associated with DAA THA are listed and discussed below

PROMS

Assessment of outcomes in DAA versus other surgical approaches utilising PROMs can be difficult as studies often utilise varying sets of outcome measures. Some PROMs utilised by studies include the WOMAC, HHS, HOOS, OHS, SF-12, SF-36, LEFS, Forgotten Joint Score and the Merle d'Aubigne and Postel scale. (73-75, 78, 81)

Findings from the literature demonstrate association of worse PROMs with LA when compared to DAA or PA. An example is from a Norwegian study with 1 to 3 year cross section follow up. PROMs utilised were the HOOS, WOMAC and EQ5D. Adjusted HOOS scores for pain, other symptoms, activities of daily living, sport/recreation, and quality of life were significantly worse ($p < 0.001$ to $p = 0.03$) for the LA than for the DAA and the PA approaches (mean differences: 3.2–5.0). These results were related to more patient-reported limping with the LA (25%) than with the DAA (12%) and PA (13%) ($P < 0.01$). Higher self-reported re-operations (4.9%) were also identified in LA compared to PA (1.7%) and DAA groups (1.9%). (82)

When comparing the DAA to PA specifically, results were less clear. Some studies have identified areas of significant differences in scores such as reduced pain and stiffness in the DAA. Other studies identified no significant differences in the pain and stiffness domains. Differences reported were identified to occur within the 6 months of follow-up. Differences between both groups eventually dissipated at later time points. (72, 80, 83-85)

Operative Times & Hospital Stay

Operative time for DAA THA varies in comparison to other approaches. The range reported in the literature for primary elective DAA THA was from a mean of 75.9 minutes to 164 minutes when using a traction table and 56 minutes to 114 minutes when using a standard Orthopaedic table. (75, 86-88). Operative times described for the PA range from 46 minutes to 118 minutes. (89, 90) Generally, for comparison studies with the same surgeon performing all operations, DAA THA generally takes longer to perform when compared to other approaches. Few studies had longer operative times with non DAA

approaches. (90) Surgeon experience, preference in approach or case complexity was not accounted in this range. Also documentation of the definition of surgical time in studies was not always clear.

Much like operative times, reports pertaining to hospital length of stay were varied for DAA THA when compared with other surgical approaches. Some studies report outcomes significantly favouring the DAA whilst others have identified no changes. The range of discharge times for DAA THA is from 1.4 days to 30 days post-operatively. The trends in current reports of comparative studies favour DAA THA over the PA. (74, 80, 85, 91, 92) Reduced costs can be appreciated with shorter hospital stays.(93)

Pain & Analgesia

Pain outcomes measures are reported commonly using PROMs such as the HHS, WOMAC and quality of life questionnaires. However, alternative methods utilise the VAS and quantified opiate analgesic. Opiate usage is converted to morphine equivalents.(91) Outcomes from studies are subjective given a lack of standardisation in analgesic protocol and follow-up. As such it is not surprising to see clinical studies comparing pain and analgesia report varying outcomes.

Reduced opiate narcotic consumption and better VAS scores associated with DAA THA were reported by Spaans and Zawadsky in non-randomised trials. (83, 89) Rodriguez did not identify and difference in analgesic usage between DAA and PA THA whilst Bergin,

Auffarth and Poehling-Monaghan reported better pain outcomes in PA and LA techniques respectively. (76, 84, 85, 90)

Aside from surgical technique, use of local anaesthetic infiltration during THA can address short-term pain and reduce hospital stay.(94). A randomised study looking at the effect of local infiltration analgesia (LIA) in DAA THA did not show any difference between conventional infiltration, reversed infiltration and placebo groups. The study utilised 2mg/ml of ropivocaine and 1µg/ml of adrenaline prepared in a 100ml dilution. (95) Compared to other studies utilising LIA in the literature, the dose of local anaesthetic was lower and did not use steroids or an anti-inflammatory such as Ketorolac. (96, 97)

Soft Tissue Trauma

Arterial & Venous Flow

Recognised alteration or occlusion of blood flow to the operative lower limb can occur during PA and LA THA. The disruption of flow occurs in the femoral artery and vein. (98, 99) Stryker assessed ten patients undergoing primary DAA THA on an Orthopaedic traction table with intra operative Doppler ultrasound. Doppler ultrasound scans were performed at incision, acetabular preparation, femoral preparation and final reduction. Stryker reported that peak vascular flow rates for both the femoral artery and femoral vein were not significantly reduced and that there were no occlusions at any point during surgery.(100)

Inflammatory markers

A novel way of comparing the degree of damage soft tissue trauma is through the use of inflammatory markers. Theoretically given that the DAA utilises intermuscular and internervous intervals, the amount of muscle damage should be minimal. Bergin's 2011 study analysed Creatinine Kinase (CK), C-reactive protein (CRP), interleukin-6 (IL-6), interleukin-1 beta (IL-1β), and tumour necrosis factor alpha (TNF-α) levels in patients two days after undergoing DAA and PA surgery. Bergin found that CK levels in the PA group were 5.5 times higher than the DAA group post-operatively in the post anaesthetic care unit. CK levels were nearly twice as high cumulatively for the PA group compared to the DAA group. As such Bergin drew a conclusion that DAA THA surgery was less invasive than the PA. Interestingly, the PA group in the study had significantly larger incisions and longer operative times. (90) While initial inflammation might be reduced, ongoing rise in inflammatory markers are observed to increase beyond the second post-operative day.

A Norwegian study by Kivle et al randomised 163 patients into DAA and LA THA surgery (83 DAA and 80 LA). The inclusion criteria for the study were end stage osteoarthritis, patient age between 20-80 years and consent. The exclusion criteria were previous hip surgery, BMI>35 and cognitive impairment. CK and CRP levels were recorded up to the fourth post-operative day. CK levels were higher in the DAA group compared to the LA group at all time points, peaking to significance on the fourth post-operative day. In Kivle's study, the DAA group had a statistically significant increase in duration of surgery (15minutes longer 95% CI, 11-19) but had a 4cm smaller wound. (95% CI 3.7-4.3cm) (Mean DAA 9.5cm versus Mean LA 13.5cm). Use of analgesics and pain scores were consistently higher in the LA group when compared with the DAA group despite the CK rise. (101)

Both studies observed similar inflammatory markers of CK and CRP when comparing the DAA with other approaches. The soft tissue traumatised in each approach varies as previously discussed in the surgical technique section. This makes it difficult to draw any firm conclusions. A reporting bias is potentially present in Bergin's study as inflammatory markers had not yet peaked. One could possibly associate the larger wound and longer operative time with increased inflammatory markers. Both studies have demonstrated that inflammatory markers increase with surgical time. The length of the incision seems irrelevant to post-operative CK and CRP levels. As such one can only hypothesise whether CK and CRP as biological markers are indeed a true reflection of muscle damage.

Magnetic Resonance Imaging (MRI)

Bremer in 2011 published a retrospective MRI study comparing muscle damage following DAA and LA THA. This retrospective comparative study case matched 25 clinically similar LA patients to 25 DAA patients 1 year post-operatively. Bremer reported significantly less soft tissue damage in the DAA group compared to the LA group. Soft tissues findings in the DAA group were reduced peri-trochanteric bursal fluid, reduced partial and full thickness abductor tears, reduced detachment of the abductors, less abductor tendinitis and less abductor fatty atrophy. There were no significant differences in the findings regarding TFL between the the DAA and LA. (102)

Hip Function

Multiple methods are available to measure hip function assessment following THA. Methods of assessment include gait analysis, static and dynamic testing. Gait analysis itself whilst able to detect more parameters (step length, stride length, cadence, walking speed,

dynamic base, progression line, foot angle, hip angle) than other methods are difficult to perform, analyse and interpret.

Gait Analysis

With 2 randomised trials that report minor to no benefits associated with DAA THA compared with other approaches, it is without surprise that analysis of the literature for non-randomised arrived a similar conclusion.

Klausemeier reported in her prospective study that there were no differences between the DAA and anterolateral groups. Hip isometric strength together with dynamic gait measures was tested at 6 and 16 weeks.(103)

Lamontagne assessments of stair function between DAA and LA groups 10 months after THA identified gait anomalies in both operative groups when compared to the control. In stair ascent, the DAA group had reduced peak hip extension, peak hip flexion moment, and peak hip power. The LA group had reduced peak hip abduction, hip frontal plane range of motion, and peak hip internal rotation. In stair decent the DAA group had reduced peak hip flexion, peak hip abduction moment, internal rotation, and peak hip power. The lateral group had reduced peak hip flexion, peak knee extension moment, and peak hip power.(104)

Rathod when comparing the DAA to PA identified better improvements in post-operative hip external and internal rotation of with DAA THA. The improvements were recorded at 6 months and 1 year post-operatively. (14˚ DAA versus 9˚PA) There were similar improvements in both groups for other gait parameters. (105)

Dynamic Hip Tests

Dynamic hip testing for osteoarthritis of hip and knee joints can be conducted with 30second chair-stand test, 40metre fast-paced walk test, stair-climb test, the TUG test and the 6-minute walk test. (106) Other measures that can be utilised to assess return of hip function are through observation of the time taken for t cessation of gait aids, time taken to return to work and driving. However, these observations are highly subjective.

When comparing TUG scores utilised in DAA THA matched with other approaches, outcomes reported are varied. Some results favour the DAA in up to 2 weeks while others reporting no difference. (80, 84, 107)

Assessment of hip function through use of gait aids was also conflicting with reports of earlier cessation by Taunton, Zawadsky and Christensen but not Poehling. (79, 80, 83, 85) Poehling's study identified increased gait aid usage in the DAA group at 2 weeks compared to a MPA group. (92% DAA versus 68% MPA: $P<0.01$)

Static Hip Tests

A common screening assessment of hip function performed by clinicians includes Trendelenburg's sign and assessment using the Medical Research Council (MRC) muscle grading scale.(108-110) Alternative assessments of hip function post operatively can be performed with quantified weight muscle strength testing. (111) Only a single study was identified to assess hip strength following DAA THA.

Winther reported in a prospective study of 60 patients that the PA and DAA produced less decrease in muscular strength than the LA following THA. Testing was performed using weights during leg press and hip abduction. The PA and DAA had the least negative effect on abduction and leg press muscular strength in the first post-operative week. 6 weeks post-operatively, the PA group had greater recovery of muscular strength than the LA. At the same time point, the PA group had better hip abduction strength than the DAA group. There were no differences between the groups beyond 3 months of follow-up. (112)

Hip Stability

The general consensus of the literature is that DAA THA has advantages in terms of innate stability. As previously reported, Higgins concluded that DAA THA had an Odds ratio of 0.29 when compared to the PA for dislocations. Sheth reported in 2015 from the Kaiser Permanente Total Joint Replacement Registry lower dislocation rates of 0.8% and 0.4% with DAA and anterolateral for primary THA respectively. This was lower when compared to the PA that had a 1.4% dislocation rate. (4) Other literature reports of dislocations for the PA vary from no dislocations to 3.95%.(20, 39) Benefits of DAA THA for dislocation have been reported in the literature up to 5 years post-operatively. (113)

Potential Disadvantages and Complications of DAA THA

Disadvantages and limitations associated with a surgical technique can present in the form complications or suboptimal clinical outcomes. The type, prevalence and severity of complications associated with a surgical approach are important. A safer less complex approach with fewer complications may be better than a newer procedure with potentially enhanced recovery but a higher complication rate. The Recognised limitations and complications associated with DAA THA can be summarised into categories of (114)

- Neurovascular Injury
- Wound problems and Obesity
- Fractures and Component Malposition
- Learning Curve, Revision & Long Term Survivorship

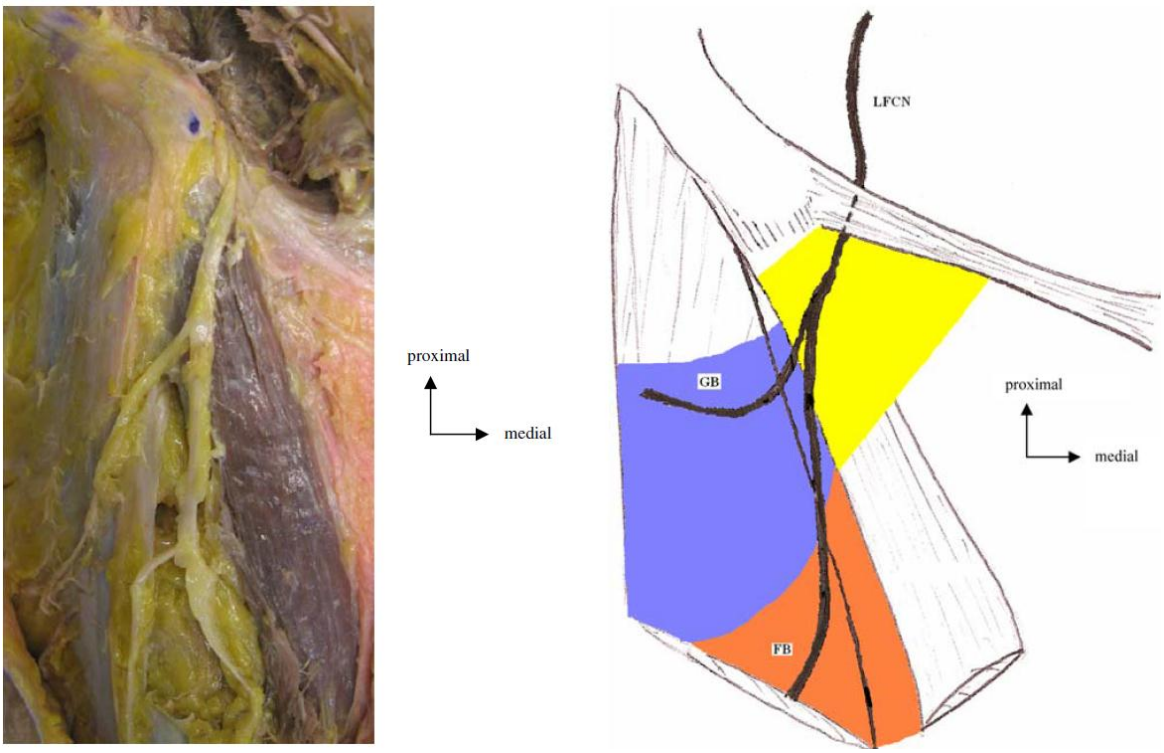
Neurovascular Injury

Nerve Injury

Nerve injuries in THA are rare with an incidence of nerve injuries less than 1%. Nerve damage can be divided broadly into neuropraxias, axonotemesis and neurotemesis. (115, 116) 80% of these injuries were related to the sciatic nerve of which the peroneal division was most affected and associated with poorer recovery. (25) The femoral nerve and superior gluteal nerves are less commonly traumatised during THA. (117-119). Other nerve injuries can also occur from use of an Orthopaedic traction use during DAA THA. The common nerves that are injured with traction table use the pudendal and (Incidence 1.9% to 27.6%) and sciatic nerve.(120, 121)

The LCNT is the nerve that is often reportedly injured during DAA THA due to its anatomy. The LCNT is a sensory nerve. Injury of the LCNT presents as either the absence of or an abnormal sensation along its distribution when compared to the contralateral limb. Anatomically the LCNT arises from the posterior divisions of L2 and L3 of the lumbar plexus. It emerges from the lateral border of iliopsoas (occasionally as a branch of the femoral nerve) and enters the thigh by passing through or under the inguinal ligament. (122) Recognising this, a cadaveric study was published in 2009 focusing on anatomic variations of the LCNT. A map was proposed for use in DAA THA surgery to prevent trauma to the gluteal and femoral branches of the LCNT.(123)

Figure 1.21: Anatomical study of the lateral femoral cutaneous nerve with special reference to minimally invasive anterior approach for total hip replacement (Ropars, Surg Radiol Anat, 2009)



The incidence if LCNT neuropraxia significantly varies in the literature. Lee's systematic review reported in a systematic review a 2.8% incidence of LCNT neuropraxia. However, three other studies by Bhargava, Goulding and Homma focusing of the incidence of LCNT in DAA report a far higher incidence.

Bhargava's analysis of LCNT neuropraxia in his retrospective study of 85 DAA THA patients identified a 14.7% incidence at 6 weeks. No hip had frank numbness and 83.3% resolved by the 2 years post-operative time-point. Impaired sensation did not appear to affect functional outcome or Harris Hip Score.(124)

Goulding published in 2010 reported her findings of LCNT neuropraxia associated with 30 DAA THA and 30 hip resurfacing surgeries. Follow-up was at 6 months and 1 year. The incidence of LCNT neuropraxia was 88.3% at 6 months and 83.3% at 1 year. The incidence of LCNT was greater with hip resurfacing than conventional THA (91% versus 67%). Goulding affirmed Bhargava's findings that LCNT did not affect functional outcomes when assessed with WOMAC and SF-12 questionnaires. (125)

A Japanese study by Homma in 2015 reported the incidence of LCNT in 122 DAA THA surgeries to be 39%. Of this 46.2% was defined as hypo-aesthesia, 28.2% as a tingling or jolt like sensation and pain 25%. He observed a 32% spontaneous recovery in 6.4 months. A finding of significance was identified using the Forgotten Joint Score. Patients having LCNT neuropraxia gave lower scores (12- 50.9+/-25.3) compared to those without LCNT

neuropraxia (64.3+/-25.7) P=0.01. There were no differences in functional WOMAC or HHS results. (81)

From these studies, it can be deduced that the rate of LCNT neuropraxia is between 1% and 67%. Additionally, time of recovery for the LCNT appears to be variable and the presence of LCNT neuropraxia does not seem to affect functional outcomes.

Vessel Injury& Haemorrhage

Vessel injury is rare during primary THA with a reported incidence of less than 0.3%. (126, 127) In revision hip arthroplasty, this risk increases.(128) The vessels that are most commonly injured include the external iliac artery common femoral artery, external iliac vein, medial and lateral circumflex femoral arteries.(129) Uncontrolled haemorrhage is the most obvious sign in which a significant vessel injury has occurred. While major vessel injury is exceedingly rare and can often be avoided with meticulous surgical technique, DAA THA is associated with an increase in blood loss.(78, 87, 89)

In DAA THA, the ascending branch of the lateral circumflex artery is commonly encountered. Associated vessels with the artery are found underneath the deep fascia through Hueters interval. If not properly identified or ligated, excessive haemorrhage and damage to the superior gluteal nerve to the TFL can occur.(114, 130) Although not directly in the surgical field, injuries of the major femoral neurovascular bundle injuries have been described. (24) The femoral neurovascular bundle can be protected by judicious retraction of Sartorius and rectus femoris muscles.

Other sources of bleeding from DAA THA include bony blood loss from the femoral side. This is potentially related to more difficult visualisation of posterior capsular vessels and end branches of the medial circumflex femoral artery at the piriformis fossa. (78)

Wound Problems & Obesity

Obesity is well known to be associated with significant surgical complications. Bamgbade in 2007 reported in a retrospective review a post-operative complications rate of 7.7% in obese patients. Obese patients had a higher prevalence of myocardial infarction ($P < 0.01$), peripheral nerve injury ($P = 0.039$), wound infection ($P < 0.01$), and urinary tract infection ($P < 0.01$). Morbidly obese patients had a higher mortality rate of 2.2% compared with 1.2% for all other patients ($P = 0.034$). Morbidly obese patients also had a higher prevalence of tracheal re-intubation ($P < 0.01$) and cardiac arrest ($P = 0.01$). Obese patients were reported to have higher ASA physical status scores compared with non-obese patients ($P = 0.01$).(131)

Russo compared normal and overweight patients (BMI <30) to a combined group of WHO class I, II, and III obese patients (BMI > 30) who underwent DAA THA. Russo found an 8.8 and 3.6 times increase in major operative and wound complications respectively in the obese group when compared to patients with a BMI less than 30. The obese group also demonstrated increased surgical times ($P < 0.011$), increased length of stay ($P= 0.01$), increased narcotic use ($P= 0.01$) and trended towards rehabilitation for discharge with increased assistive device use at two weeks ($P< 0.01$). Hungerford affirmed in a separate study that a higher BMI was associated with increased operative time during DAA THA. (86, 132)

Supporting the report of difficulties with DAA THA in obese patients, Frye reported that muscle damage was significantly increased with the male gender ($P<0.01$) and increased BMI levels ($P<0.01$). Whilst this contradicts to a degree the philosophy of minimally invasive muscle sparing surgery, Frye identified that this could be mitigated to a degree if a short stem femoral implant was utilised for patients of increased BMI.(133)

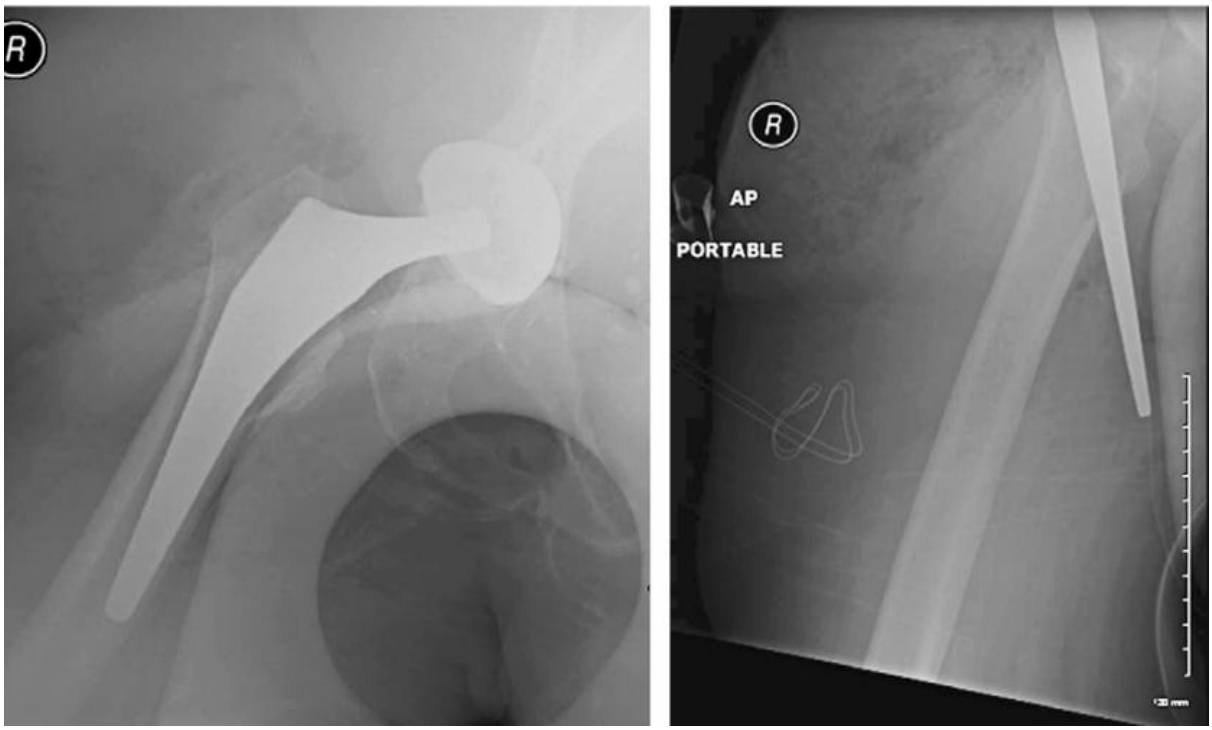
Despite Recognised soft tissue complications in obese patients, studies have reported increased wound complication rates associated with DAA THA in non-obese patient groups. Jewett reported a rate of wound complications of 4.6% in a group of patients with a BMI of 28. The re-operation for wound complications in Jewett's study was 1.6% (134) Christensen affirmed this in his retrospective study that DAA THA was associated with increased re-operation rates for wound complications. Christensen reported this rate to be 1.4% compared to 0.2% for the PA ($P<0.01$) in a group of patients with a BMI of 27.6. (135) The varying properties of skin when comparing anterior, lateral and posterior aspects of the thigh could potentially be a reason for increased wound complications in DAA THA. The anterior skin is noticeably thinner and crosses a flexion crease. This could increase shear forces in the wound during movement. The surgical incision can also be covered by the moist abdominal pannus of patients with a corpulent habitus. (134)

Fractures & Component Malposition

Aside from perineal skin and peripheral neurological complications, reports of fractures have been associated with traction table use. Fractures of the ankle whilst utilising a traction table during DAA THA described by Matta was thought to arise from excessive rotational forces utilised during dislocation and femoral positioning. (57, 120, 136)

Acetabular component malposition can lead to groin pain, instability, premature wear and early revision.(137-141) Femoral component malposition on the other hand can cause implant subsidence, thigh pain, intra-operative perforations and fractures. Fractures associated with DAA THA are trochanteric fractures, femoral calcar fractures and acetabular fractures. Rates of between 8-14% have been reported for fractures in DAA THA. (142-144) The rate of fractures observed is lower for cemented components (0.1-1%) and higher for uncemented components (3-18%). (145, 146) Whilst component malposition can occur in up to 50% of THAs, it can be reduced in DAA THA when combined with fluoroscopy or navigation. (68, 147-149). The use of fluoroscopy comes at the expense of radiation exposure to both the surgical team and patients. (150)

Fig 1.22: Malpositioned Femoral Implant with perforation (Barton ,Orthop Clin North Am, 2009)



Learning Curve, Revision and Long Term Survivorship

Complications seen during DAA THA have been observed during a surgeon's learning curve. Complications can often lead to early revisions. The learning curve described in the literature varies from 20 to 50 cases. This is dependent on technique, mentorship and surgeon volume. (151-154) During this learning curve, high revision rates of between 6-21% at up to 5 years post-operatively can be expected.

Midterm survivorship reports by Muller and DeSteiger affirm that revision rates beyond the learning curve drops to between 2% and 3.2%. This was comparable to a revision rate of 3.1% to 3.5% for primary THA's using an uncemented stem in the Australian National Joint Registry. (58, 151, 153) Reliable long term outcomes following DAA THA surgery have not been published. Despite its historical use since the 1990's, Sariali and Kennon have yet to report their revision rates.(61, 69) Confounders of survivorship results include not only surgical technique, patient factors but also implant design and surgeon experience.

When performing revision THA, the DAA has been reported to offer unique access and challenges to the operator. The creation of accessory incisions in revision THA can form skin bridges and result in wound complications. (155) Good acetabular access can be obtained through the Levine modification of the DAA to approach and address anterior acetabular pathology. (156-158). As such the DAA can be utilised for isolated acetabular or minor revisions safely. (159)

Distal extension can be difficult and there is significant risk to the anterolateral quadriceps neurovasculature during soft tissue dissection. (160) To avert this Kennon and Mast described techniques of extension to a lateral incision, a separate lateral incision or percutaneous incisions depending on the access required femoral component revision. (63, 158) An iliac osteotomy technique was described by Ziran to improve femoral access and prevent proximal soft tissue/bony impingement when introducing long stemmed implants through the DAA. (161).

Rationale for Research

Current literature suggests that there are benefits associated with the DAA when compared to other approaches. The benefits have been identified to be in the early post-operative period of less than 6 months. However, there are also reports of early complications associated with the DAA THA. There are limited randomised controlled trials of which have a favourable perspective towards DAA THA. Other prospective studies report mixed outcomes when evaluating DAA THA to PA THA. The literature review identified no locally published clinical trials when comparing the DAA to the PA for THA. Despite evidence and interest from the general Orthopaedic community, the use of DAA is still approximately 5%. As such one wonders why this number remains low if DAA THA potentially has better outcomes with less soft tissue damage, low dislocation rates, improved PROMs and reduced use of gait aids. Adding to the conundrum, a simple search on the internet for information pertaining to THA identified numerous sources of lay information biased towards DAA THA.(162)

Hence it can be deduced that there is a recognizable contention with the adoption of DAA THA surgery. One conservative stance on DAA THA is aptly summarised by Post in the Journal of the American Academy of Orthopaedic Surgeons. "The DAA for hip arthroplasty has gained popularity as patient demand for less invasive surgical techniques increased. Modern surgical instruments combined with specially designed operating tables have made the technique more accessible to Orthopaedic surgeons. However, the learning curve can be steep and mastery requires hundreds of cases. Although there is literature available to support the use of the DAA, large randomised trials are lacking. Once a

surgeon has mastered the DAA, the technique should be viewed as a viable alternative approach for a highly successful surgical procedure."(163)

The randomised study in this thesis that compares the DAA to the PA is therefore justified. The focus of the study is to determine if there are measurable differences during early recovery between DAA and PA THA. Areas that study investigators aim to analyse are listed below

1) PROM
    a. Hip function
    b. Quality of life

2) Functional Outcomes
    a. Hip range of motion
    b. Hip strength
    c. Walking speed
    d. Gait aids

3) Radiological Outcomes
    a. Prosthesis placement

4) Clinical outcomes
    a. Operative time
    b. Hospital length of stay
    c. Discharge destination
    d. Blood loss
    e. Opiate analgesic usage
    f. Complications

Aims and Research Hypothesis

The study adopts a null hypothesis when comparing the DAA to the PA to avoid bias.

Primary Research Question

- Is there a difference in return to function between the DAA and PA?

Secondary Research Questions

- Does quality of life reported by patients differ between the DAA and PA?
- Is the length of hospital stay different for patients undergoing DAA compared to the PA?
- Is there a difference in patient's analgesic requirements between the DAA and PA?
- Is there radiological evidence that prosthesis placement in DAA differs when compared to the PA?
- Is there a difference in blood loss between the DAA and PA?
- Is there a difference in complications between the DAA and PA?

CHAPTER 2

METHODOLOGY

METHODS

Ethics

Australian New Zealand Clinical Trials Registry (ANZCTR)

'A Prospective Randomised Clinical Trial in Total Hip Arthroplasty – comparing early results between the Direct Anterior Approach and the Posterior Approach' is registered with the ANZCTR. The Trial ID is ACTRN12614000131651. The ANZCTR complies with the requirements of the International Committee of Medical Journal Editors (ICJME).

Ethics Approval

'A Prospective Randomised Clinical Trial in Total Hip Arthroplasty – comparing early results between the Direct Anterior Approach and the Posterior Approach' has obtained ethical approval from the Eastern Health Ethics Committee on 18th December 2013 with the project number EH11-1314.

Funding

The study received external funding totalling approximately $55,000 Australian Dollars. Funding was obtained from the

- Eastern Health Bulley Fellowship $30,000
- Box Hill Golf Club Grant $25,000

Funding was primarily directed towards the research position of the principal investigator. Additional funding for costs involved in the trial was shouldered by the Orthopaedic

Department of Eastern Health through its special purposes fund. Of note, costs were incurred for the licensing and maintenance of a database & use of PROMs.

- Database initial licensing and installation $11,500
- Database yearly license renewal $1,650
- WOMAC® Likert 3.1 English for Australia Index and 1 copy of WOMAC® User Guide X $565.40

There were no other sources of funding from the project. The investigators involved with the study received no other forms of benefits or funding for the trial. The investigators have declared no known conflicts of interests in the undertaking of this study.

Sample Size

An a priori analysis with a power of 80% and a two tailed significance of 5% was conducted. The study aimed to record statistical significance with a 10 point difference in the WOMAC function scores. Assuming a mean and standard deviation of 36.94 and 13 with equal distribution in each group, the number of patients required in each group was determined to be 31. (164) Allowing 10% attrition, the study requires 34 patients in each group to maintain statistical significance. Recruitment targets were adjusted appropriately to a minimum of 70 patients with 35 patients in each group.

TRIAL DESIGN

Inclusion and Exclusion Criteria

To achieve results that were relevant, this study adopted similar demographics and implant preferences reflected in the Australian Joint Registry. This was also influenced by prior randomised trials discussed in the previous chapter.

The inclusion criteria for the study are listed below:

- Unilateral symptomatic hip osteoarthritis
- Suitability for uncemented femoral prosthesis (Dorr's femur classification A and B)
- American Society of Anaesthesiologists (ASA) Score ≤ 3
- Body Mass Index (BMI) ≤ 35
- Aged between 40 and 75 years of age

Potential patients were excluded if they:

- Had Dorr's femur classification C
- Had previous surgery to the hip excluding hip arthroscopy
- Had complex primary hip arthroplasty requiring major bone grafting – eg: Coxa Profunda, Crowe III, IV hip dysplasia
- Had previous joint arthroplasty – eg: contralateral hip & knee
- Were unwilling to accept randomisation and blinding
- Had severe pathology that would affect post-operative participation such as neurologic, psychiatric or other confounding pre-existing musculoskeletal disorders (eg: symptomatic back pain, knee arthritis)

Patients with asymptomatic or minimally symptomatic osteoarthritis despite radiographic evidence in other joints were not excluded from the study.

Recruitment

A single cohort of patients was recruited through the Osteoarthritis Knee & Hip Services (OAKHS) and outpatient clinics at Eastern Health. Suitable patients on the Eastern Health THA waitlist were also contacted and offered an opportunity to participate in the study. From February 2014 to November 2014, the principal investigator contacted eligible patients through telephone to organise an outpatient appointment with specialist hip surgeons.

On review in outpatient clinic, a full medical history was taken and a physical examination was performed. Investigations and patient clinical information were crossed checked against the study's criteria. Eligible patients were then reviewed together with a specialist hip surgeon to confirm suitability for the study. An extensive discussion about treatment options available for hip arthritis was held with the study being an option for THA. Patients were presented with a summary sheet with relevant information on the study together with a Patient Information and Consent Form (PICF) to assist in the decision making process. The PICF detailed the study structure, participation information and risks. The PICF included contact details of the principal investigator.

Further phone conversations were held with patients to address questions and concerns regarding the study. Patients who agreed to participate were consented for both the study

and THA at a separate outpatient review. The consent process was documented electronically and a signed copy of the signed PICF with version number and dates was retained by the principal investigator.

Randomisation & Blinding

For the purposes of the study, simple and block styled randomisations were not suitable as this does not address potential systematic differences in the analysed groups. Hence the investigators of the study opted to stratify randomisation in order to minimise the risk of selection bias in each group. Patients were randomised using computer software into the DAA and PA groups with stratifications made for surgeon and age.

Surgeon

Two surgeons were involved in the study. Each surgeon was exclusive to a single site. The sites for randomisation were Box Hill Hospital and Maroondah Hospital. This was to account for minor inter-campus variations and subtle surgical differences that cannot be accounted for by trial protocol alone.

Patient Age

Age was determined to be a significant predictor in patient recovery and thus was included in the randomisation algorithm. The mean age for conventional primary THA in Australia is 69 years old for females and 66.4 years old for males.(59) The combined mean for both sexes is 67.9 years old. Factoring in the inclusion criteria of patients aged between 40 and

75 years old, the study investigators determined that age can be stratified into two groups of less than 65 years old and 65 years old and above.

Other factors

Other factors assessed by the study investigators to not require stratification during randomisation were gender and BMI. Unlike surgeon and age, gender and BMI were not thought to have a significant impact on early results given the study's criteria.

Randomisation

The randomisation of the study was managed by an independent investigator who had no contact with trial patients during recruitment or assessment. The randomisation sequence was prepared in permuted blocks of 6 stratified for site and age. A web based random number generator from www.randomization.com was utilised. The seed for the random number generator is obtained from the clock of the local computer and is printed at the bottom of the randomisation plan. If a seed is included in the request, it overrides the value obtained from the clock and can be used to reproduce or verify a particular plan. (165, 166) The four categories receiving DAA and PA group randomisations were

- Box Hill Hospital less than 65 years old
- Box Hill Hospital 65 years old and above
- Maroondah Hospital less than 65 years old
- Maroondah Hospital 65 years old and above

Written informed consent was obtained for both DAA and PA THA approaches from patients. Patients were blinded from the pre-operative period to the point of surgery to avoid selection bias. Patients who were unwilling to receive either the DAA or PA were excluded.

Blinding of the surgical team was not possible for operative procedures. Both surgeons remained blinded until the routine weekly pre-operative orthopaedic meetings prior to surgery. Each surgeon was presented with sealed opaque and sequenced envelopes that contained the assigned approach (either DAA or PA) one week prior to surgery. At this stage, the patient who was due for surgery had already completed the pre-operative assessments. The principal investigator who was in attendance of the weekly meetings then had knowledge of the patient allocation into the DAA or PA groups.

Physiotherapists, nursing and other staff involved in the routine pre-operative assessment of patients were blinded to the approach allocated to the patient. However, none of the clinical staff involved in the post-operative care of the patient were blinded. The ethical and logistical complexity of blinding both clinical staff and patients to the surgical approach received throughout the duration of the trial was a limitation of the study.

Pre-operative Protocol

Clinical staff involved in care of trial patients were informed of the trial protocol prior to commencement in February 2014. This involved briefing anaesthetists, the acute pain service, junior orthopaedic doctors managing the ward, nursing staff and allied health

personnel (physiotherapists, occupational therapists and radiographers). Copies of the trial protocol were also made available to the various departments involved.

All trial patients were reviewed routinely at Eastern Health pre-admission clinics. As per Eastern Health Joint Arthroplasty Protocol, patients were subjected to a basic physical assessment. Patients were also screened by junior doctors, nursing staff and a senior anaesthetist. Medical issues that could compromise surgical care were flagged and treated prior to surgery.

Pre-operative templating of radiographs were performed by the principal investigator using IMPAX Orthopaedic Tools 2.52 (AFGA Healthcare© NV, Belgium). The acetabular component templating aimed to achieve 40°+/-10°of inclination with maintenance of the native hip joint centre in accordance with Lewinnek's safe zone.(139) The femoral component template aimed to maintain a neutral alignment within the femoral canal. Patients with coxa varus and coxa valga deformities had template neck cuts and implant positions accommodate a suitable prosthesis and maintain the planned hip joint centre.

Intervention & Peri-operative Protocol

All surgeries were performed by one of two experienced surgeons. Both surgeons had extensive experience with DAA and PA surgeries, performing both approaches for the study. Surgeries were conducted at Eastern Health facilities from March 2014 to March 2015. Equipment and implants used were standardised for all procedures across both centres. Choice of implant and weight bearing surface were based on surgeon preferences.

The implant used in the study was the uncemented R3 cup and Anthology stem. (Smith & Nephew, Memphis, Tennessee). The weight bearing surface utilised was an oxinium head on a highly cross-linked ultra-high molecular weight polyethylene surface for individuals over 65 years of age and a ceramic head on ceramic cup weight bearing surface for individuals aged 65 years or younger. Femoral head sizes of >32 mm were used to reduce the risk of dislocation. Intra-operative implantation of components was guided by templating and patient anatomy. Conventional instrumentation was employed for this. Both surgeons had goals of positioning acetabular components within 40°+/-10° of inclination and 15°+/-10° of anteversion. For the femoral component, surgeons aimed to achieve a neutral orientation in the canal with 0-20° of anteversion. In scenarios where this was not achievable, the positioning of components outside the range was guided by stability, soft tissue balance and leg length.

Autologous bone grafting from acetabular reamings and the femoral head were used in scenarios that required minor bone grafting. No operative cases required major bone grafting.

Post-operative analgesia was standardised with the infiltration of local anaesthetic peri-operatively and on wound closure. All patients received intra-operative prophylactic antibiotics of 2g intravenous Cephazolin. Tranexamic acid (TXa) was not routinely utilised in surgery and its use was anaesthetist-dependent. All candidates in the study received an intra-capsular infusion of local anaesthetic into hip joint capsule for 24 hours via dedicated delivery system that was inserted prior to closure.

Surgical Technique: The Direct Anterior Approach (DAA)

The patient is firstly positioned supine on an orthopaedic traction table (Maquet GmbH & Co.KG, Rastatt, Germany- Extension Set for MIS Hip Interventions). The non-operative leg is then placed in a neutral position whilst the operative leg is put into a 5-10° of internal rotation to enhance the bulge of tensor fascia lata.

An incision is made starting 2cm-3cm posterior and distal to the ASIS over TFL. The incision is extended distally. The approximate length of the incision is 10cm. If continued, the line of incision should intersect the lateral border of the patella. When the fascia is encountered, Hueter's interval between Sartorius and TFL is identified and developed. The lateral branch of the LCNT is sometimes encountered. If present, it is identified and protected. TFL is then retracted laterally while sartorius is retracted medially. The incision is further deepened through the interval between rectus femoris and gluteus medius to the posterior fascia surrounding these muscles. Following dissection through this fascia, the ascending branches of the lateral circumflex vessels of the thigh are identified in the inferior third of the wound and ligated. The surrounding pericapsular fat pad is removed and the anterior hip capsule can be visualised. Surgeons in the study utilised Beckman's, Norfolk Norwich or a mini Charnley retractors. Iliopsoas and rectus femoris are gently elevated and retracted medially to complete the exposure of the hip capsule.

A "V" shaped capsulotomy is then performed and a capsular flap raised, the capsulotomy has its borders extending from along the lateral border of iliopsoas and along the intertrochanteric line. To facilitate this, the hip can be internally rotated to access the lateral portion of the hip joint capsule and externally rotated to access the medial portion of

the hip capsule. The capsulotomy flap is then tagged with suture and retracted laterally. The femoral neck is now exposed. Retractors are repositioned intra-articularly along the superior and inferior borders of the femoral neck.

Gentle traction is introduced. The femoral neck is then cut at the planned level and femoral head delivered with a corkscrew. A double neck osteotomy may be used if difficulty is encountered with retrieval of the femoral head. Traction is then released and the femur externally rotated to 45° to facilitate acetabular exposure. Precautions are taken during external rotation to prevent fractures. A Charnley retractor is applied with its body placed inferiorly, the medial arm under the medial capsule and lateral arm on the capsular flap raised laterally Placement of the retractor on the sturdy hip capsule avoids damage to the anterior hip musculature. Preparation of the acetabulum can now occur. Reaming is done under direct vision. Acetabular component trialling is done with offset instruments and radiographic guidance. The definitive acetabular prosthesis is inserted. Supplementary fixation with acetabular dome screws is used when required. Local anaesthetic is then applied to the soft tissue surrounding the acetabulum in accordance with the trials analgesic protocol.

On completion of the acetabular portion of surgery, a tri-radiate posterior capsular release is performed to allow the sufficient mobilisation of the femur. A specialised retractor is placed under the GT and a medial retractor use to deliver the femur anteriorly and laterally. The surgeon aims to achieve external rotation of 90°, hip adduction of 20° and hyperextension of 30° to 40° of the lower limb. Should there be inadequate exposure of the

femur, further staged soft tissue release is undertaken in the sequence of the superior hip capsule, obturator internus and piriformis tendon.

Once exposure is adequate, the femur is then breached with a box cut and broached. Broaching is undertaken carefully to prevent proximal femur fractures, cortical perforation and excessive anteversion. Broaching is completed when the size matches that of the preoperative template. This is also guided by feel, depth and final broach size. The femoral component is then trialled.

The hip is reduced with traction, flexion and internal rotation. Leg length, offset and stability are checked clinically and with fluoroscopic assistance. On meeting adequate operative parameters of stability and component placement, femoral trial components are removed. The definitive femoral prosthesis is inserted. The hip is then reduced. An intra-articular catheter for peri-operative infusion of local anaesthetic is introduced. The capsular incision is now repaired. Haemostasis with diathermy is performed. Local anaesthetic infusion into the joint and soft tissues is achieved prior to closure of the soft tissue and skin. The fascia lata is repaired cautiously to avoid accidental incorporation of the LCNT into the suture line.

Surgical Technique: The Posterior Approach (PA)

The patient is placed in the lateral position on a standard orthopaedic table. A 10 to 20 cm curvilinear incision is made beginning approximately a hands breath inferior to the posterior superior iliac spine, extending over the posterior third of the GT and ending a in line with the femur a hands breath inferior to GT. The gluteal fascia is split and the fibres

of gluteus maximus are dissected to expose the short external rotators of the hip. The piriformis muscle is identified and the sciatic nerve palpated and protected. The hip joint capsule is then exposed through the incision and reflection of the short external rotators of the hip. A capsulotomy is performed and the capsular tendinous flap tagged with suture for later repair.

The hip is then dislocated through hip flexion and internal rotation. The femoral neck cut is performed at the templated level and the femoral head is retrieved. Acetabular preparation commences with retractor placement in the in periacetabular region. Charnley, Norwich and Hohmann retractors are utilised in this step. The labrum and redundant soft tissue are removed from the acetabulum prior to reaming. Reaming is done under direct vision and considered complete upon reaching good bone stock. Acetabular components are then trialled and fitted. Dome screw fixation is utilised to obtain adequate acetabular implant fixation where necessary. Similar to the DAA, local anaesthetic is applied to the soft tissue surrounding the acetabulum.

Upon completion of the acetabular component of surgery, femoral preparation begins. The operative leg is positioned by the surgical assistant in flexion, adduction and internal rotation. Breaching and broaching of the femur is done under direct vision. Broaching again is considered complete when operative parameters are met. The femoral components are trialled and the hip reduced. Leg length, offset and stability are checked. Once satisfactory, trial components are removed and the prosthesis proper inserted. An intra-capsular wound infusion catheter is introduced. The remaining local anaesthetic is administered. The posterior capsule and short rotators are repaired with intaosseous sutures

to reduce the risk of post-operative dislocation. Haemostasis is obtained prior to closure of the fascia, subcutaneous tissue and skin.

Intra-operative Analgesic Protocol

Similar intra-operative local anaesthetic protocols were used in both the DAA and PA groups. The anaesthetist was instructed not to provide supplementary pain management with regional blocks or intra-thecal morphine. A concoction of – 0.2% ropivocaine with 30mg ketorolac and 1% adrenaline (200ml unless limited by patient factors eg: weight, renal impairment) was employed. Ketorolac was not utilised in patients with evidence of renal impairment. Local anaesthetic was administered in three stages. The injections were administered in a fan shaped from the surgical wound and with the moving needle technique.

The first followed implantation of the acetabular component, the local anaesthetic was injected into the surrounding peri-acetabular tissue. The second followed femoral prosthesis implantation. The gluteal tendons, ITB and short external rotators are injected with local anaesthetic. The third stage was prior to skin closure with the local anaesthetic administered into the surrounding subcutaneous tissues.

The intra-capsular infusion catheter was placed in inferior and lateral to the skin incision through the ITB for patients having DAA THA surgery. For PA THA surgery, the wound infusion catheter was placed lateral to the skin incision and passed through the ITB before being directed into the joint capsule.

The wound infusion system delivered constantly of 0.2% ropivocaine, ketorolac and 1% adrenaline at a rate of 5millilitres/hour. After 24 hours the wound infusion catheters were removed. Unlike the technique described by Kerr and Kohan, no top up boluses were administered on the ward. (96)

Post-operative Protocol

Following surgery, the patients were managed by the hospital orthopaedic team. On the first post-operative day, routine post-operative bloods were taken. Patients were reviewed medically and if safe, mobilised by physiotherapists using appropriate gait aids. Patients from both groups received standardised post-operative physiotherapy as per Eastern Health protocol. Daily assessment and measurements by physiotherapist with activities of daily living such as distance walked, use of walking aids, transfers in and out of bed or chair, stair climbing, ability to dress independently were performed. Patients in the PA group were taught hip precautions to minimise the risk of dislocation. Instructions given avoided movements that resulted in hip flexion of more than 90°, hip adduction and hip internal rotation past neutral.

Post-operative patients with haemoglobin of less than 80g/L or less than 100g/L with symptoms of anaemia received the blood transfusions. Details of each transfusion were recorded. Wound infusion catheters inserted operatively together with any drain tubes were removed 24 hours post operatively for all patients. Post-operative radiographs according to the standardised trial imaging protocol were obtained when patients attained clearance from physiotherapists to independently mobilise. This commonly occurred on the second or third post-operative day. Deep vein thrombosis prophylaxis was standardised for both

DAA and PA groups in accordance with Eastern Health Joint Recovery Protocols. Patients were prescribed and educated to self-administer subcutaneous Dalteparin Sodium 5000units daily for 6 weeks post-operatively.

The hospitals aimed for the discharge of patients on the third post-operative day with the Eastern Health Sub Acute Care Service. Discharge requirements were based on three criteria. Firstly, the patient must be medically well. Secondly, the patient must have attained adequate mobility to achieve semi-independent care. Thirdly the patient must have regained the ability to perform personal ADLs. These criteria were assessed clinically, with pathology results and with allied health assessments. Physiotherapy assessment for discharge criteria was the ability to transfer perform transfers with minimal assistance, walk 50 metres safely with an appropriate gait aid and to successfully navigate up and down a set of three steps.

Individuals who were either clinically suspected to exceed usual hospital stay length or unsuitable for discharge home were assessed by a rehabilitation physician. Patients who qualified for rehabilitation were discharged to one of several facilities in Eastern Health. Eastern Health Campuses that provided inpatient geriatric and rehabilitation services were Peter James Centre, Angliss Hospital and Maroondah Hospital. Copies of the Trial protocol were provided in the hospital transfer notes and made available to rehabilitation teams. Patients in rehabilitation were discharged home once goals were met. All discharged patients received ongoing physiotherapy through a community rehabilitation program at Eastern Health.

Post-operative analgesia

All trial patients were given the following medications unless contraindicated or refused. This was managed in part by the acute pain service team.

Basic analgesia

- Oral Paracetamol 1g four times daily
- Oral Celecoxib 100-200mg twice daily

Opiate Analgesia

- Oral Oxycontin or Targin (oxycodone/naloxone) – between 5-20mg twice daily equivalent dose of oxycodone
- Oral Endone (oxycodone) – 5mg four times daily as needed
- Intravenous patient controlled analgesia– morphine (1mg/ml) and fentanyl (10mcg/ml)
- Subcutaneous Morphine between 5-10mg four times daily as needed

Other medications commenced by the acute pain service or anaesthetist where appropriate

- Intravenous patient controlled analgesia – oxycodone (1mg/ml)
- Oral Tramadol slow release between 100-200mg twice daily
- Oral Tramadol between 50-100mg four times daily as needed
- Intravenous Ketamine infusion

Patients were discharged on medications required during the last 24 hours of hospital stay. Clinical paperwork related to each patient's hospital stay was stored electronically on secure hospital servers.

Primary Outcome Measures

To address the primary research question on patient return to function following THA, the study investigators determined that it was best measured using serial administration of PROMs. PROMs utilised were the WOMAC, OHS and EQ-5D. All outcome measures used were licensed for use by the Orthopaedic Department at Eastern Health.

Western Ontario and McMaster universities Osteoarthritis Index (WOMAC)

The WOMAC is a validated patient reported outcome questionnaire in people with osteoarthritis of the lower limbs.(167) It assesses three domains of pain, stiffness and functional status. The 5-item pain scale is scored from 0 (best) to 20(worst). The stiffness sub scale is assessed with 2 questions and scored from 0 (best) to 8 (worst). The 17-item functional status scale is scored form 0 (best) to 68 (worst). The 3 domain scores can be totalled and scored out of 96 points to evaluate the severity of hip osteoarthritis. The format used for the trial was the English Likert 3.1.

Oxford Hip Score

The Oxford Hip Score (OHS) is a validated patient reported outcome questionnaire that scores function and pain in hip osteoarthritis. (168) The OHS is quick to perform and has 12 items that scores patients symptoms from 0 (very bad) to 48 (excellent). The OHS correlates well with other outcome measures such as the SF-12, WOMAC and EQ-5D

Secondary Outcome Measures

To supplement investigation of functional outcomes and address secondary research questions, the following secondary outcome measures were utilised.

EuroQol (EQ-5D) questionnaire and the EQ-VAS

The EuroQol (EQ-5D) questionnaire and the EQ-VAS is used to measure the patient's quality of life, covering the domains of mobility; self-care; usual activities; pain/discomfort; and anxiety/depression and overall health state (EQ-VAS). (169, 170) The EQ-5D is a standardised instrument for measuring health related quality of life and provides a single index of utility. The EQ-5D has been used for a range of conditions. Changes in the EQ-5D are significantly correlated with changes in condition-specific measures over three months. (171) The EQ-5D is validated in its use as a patient reported outcome questionnaire in hip osteoarthritis and THA. The EQ-5D has good correlation with the WOMAC.(172, 173)

Short Form 12

The Short Form 12 (SF-12) is a multipurpose short survey with 12 questions selected from the SF-36 Health Survey. The questions were combined, scored, and weighted to create two scales that provide insight into mental and physical functioning and overall health-related-quality of life.

The SF-12 was developed to provide a shorter, yet valid alternative to the longer SF-36. Physical and Mental Health Composite Scores are measured using the scores of twelve questions and range from 0 to 100. A zero score indicates the lowest level of health measured and 100 indicates the highest level of health.(174)

Use of the SF-12 Questionnaire was discontinued in February 2014 as there was limited funding in obtaining a license for the study. The investigators of the study determined that both physical and mental domains assessed by the SF-12 were adequately covered by the EQ-5D-3L and EQ-VAS.

10 Metre Walk Test

Hip function is measured using walking speed with the 10 metre walk test. Patients are instructed to walk as quickly as possible over a 10m walkway. The time taken to walk the middle 6 m measured. The test has been applied to a wide variety of health conditions and demonstrated evidence of reliability and validity (175-177) Alternative tests for assessment

of mobility were considered such as the timed up and go test (TUG) and the 6 minute walk test recommended by the Osteoarthritis Research Society International (OARSI) group.

Radiographic Evaluation of Uncemented Hip Prosthesis

Radiological assessment undertaken utilised standardised weight bearing posterior to anterior hips radiographs with a 27mm metal templating ball and a fixed focus distance of 120cm that centred on the pubic symphysis. In order to facilitate standardised rotational profiles of hip radiographs, pre-fixed lines were placed parallel to the radiographic imaging plate. In addition, two perpendicular lines 7.5cm apart from the centre of the plate were placed to assist in the positioning of patient's feet. Radiographers were instructed to align patient's feet in a manner such that the both heels were parallel in line to the imaging plate and the second toes of patient's feet placed on the perpendicular lines. Lateral views of the hip and pelvis were obtained in the standard cross table manner.

All cases were independently reviewed and graded using an abbreviated Johnston's Hip Replacement Evaluation Criteria. Radiographs obtained six weeks post-operatively were used for radiographic evaluation of prosthetic placement and alignment. (178) Primary assessment of acetabular alignment included cup inclination and anteversion whilst femoral component is assessed in terms of its varus, neutral or valgus orientation.

Clinical Data

Demographics

Patient age and gender data were retrieved through the hospitals' registration system. The age reported by the trial indicates the patient's age at time of surgery. Patient height and weight were recorded by the principal investigator during the study's pre-operative assessment. Height was measured in centimetres (cm) using a fixed tape measure attached to the wall while weight was measured in kilograms (kg) using an electronic scale.

Hospital Length of Stay

As per the National Health Performance Authority, hospital 'stay' is defined in the report as a period of care in a hospital for a single type of care. For example, acute care, rehabilitation or palliative care is categorised separately. If a patient changes from one type of care to another, or transfers hospital, this would be two episodes of care. Hence 'stay' is calculated as the period a patient remains in care of the operating hospital until discharge home or to a rehabilitation facility.

Discharge Destination

Discharge destinations recorded for patients were listed as either

- Home
- Rehabilitation

Peri-Operative Data

Surgical Time

- Surgical Time in the study was calculated from surgical preparation skin until post-operative dressings were applied.

American Society of Anaesthesiologist's (ASA) Physical Health Score(179)

- The ASA status is determined by the treating anaesthetist during the pre-operative review.

Mode of Anaesthesia

The mode of anaesthetic used during the course of the surgery was anaesthetist dependent. Patients received either one of the following combinations of anaesthetic:

- General Anaesthetic
- Spinal Anaesthetic
- Combined General & Spinal Anaesthetic

Estimated blood loss

- Blood loss was estimated through comparison of pre-operative haemoglobin levels with day one post-operative haemoglobin.

Opiate Use

Opiate use by trial patients were recorded from surgery until the first post-operative review (2 weeks). Patients were requested to bring in their remaining analgesic medications to facilitate accurate calculation of medication use. Additional opiate medication prescribed by the local doctor was included in calculations.

Complications

All peri-operative, early complications and adverse outcomes reported by the clinical and research team were documented. Complications observed during THA included dislocations, peri-prosthetic fractures, unexpected return to theatre, femoral component subsidence, leg length discrepancies greater than 2cm, revision surgery, LCNT neuropraxia, deep infections and infections requiring re-operations.

Hip Function and Range of Motion

Hip function was measured using the straight leg raise power, abduction power and Trendelenburg sign. Hip range of motion was recorded in the parameters of flexion, extension, abduction, adduction, external rotation and internal rotation. Pre and post-operative leg length discrepancies and fixed flexion deformities were also documented.

Gait aids

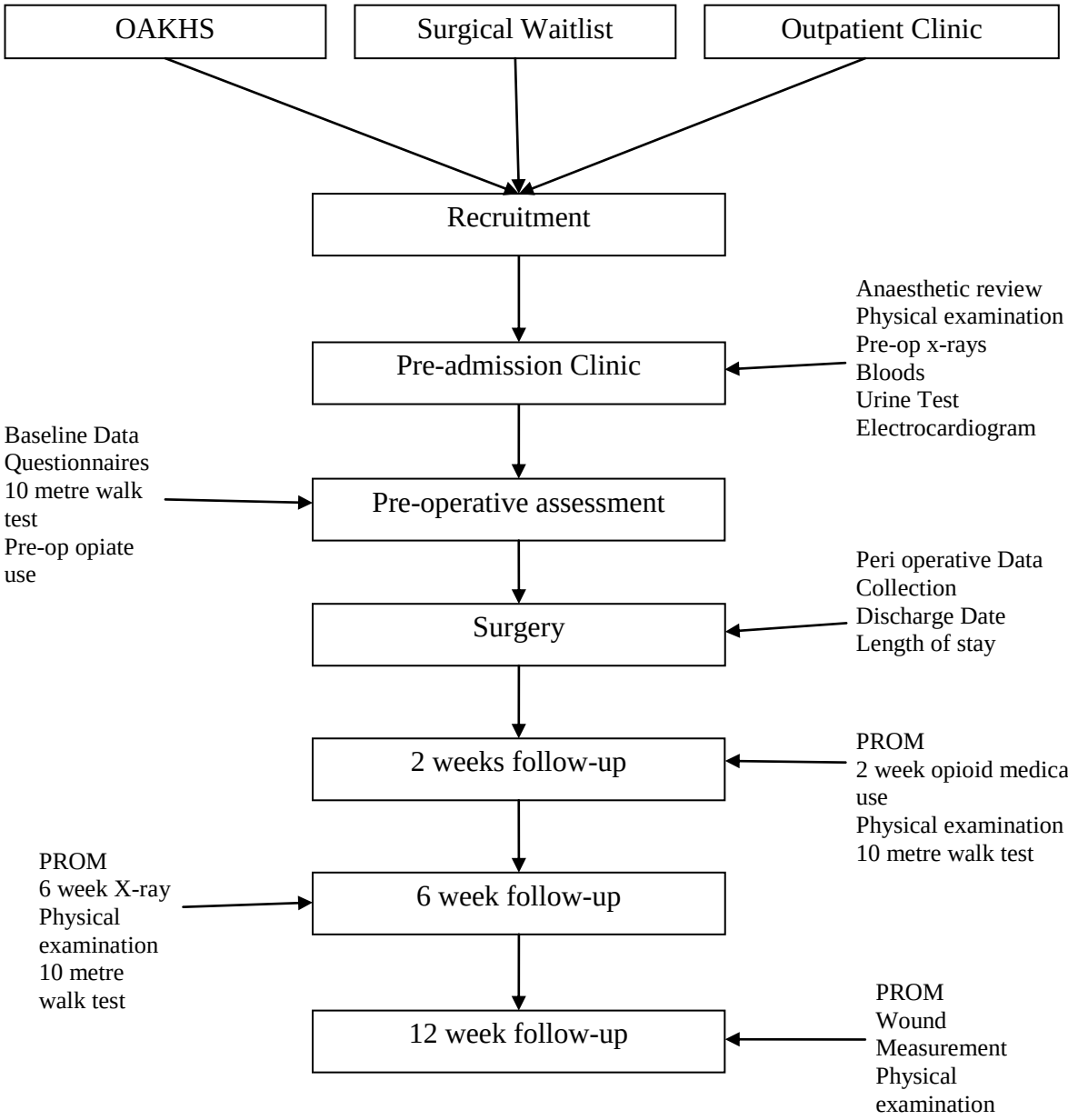
Gait aids used at each of the follow-up time points were recorded for comparisons.

Common gait aids used by trial patients were:

- None
- Single Point Stick
- Fixed Arm Crutch
- Fixed Arm Crutch x2
- Pick Up Frame
- 4 Wheel Frame

Patient Flow in Trial

Fig 2.1: Patient Flow Diagram



As shown in the Fig 2.1, patients were assessed at a preoperative, 2 week, 6 week and 12 weeks post-operative time points.

Pre-operative assessment

Patients were reviewed prior to their date of surgery. The assessment occurred within three months of surgery. The principal investigator provided patients with study PROMs (OHS, WOMAC, EQ-5D) to be completed on the day.

Patient parameters, demographics and clinical measures were recorded. The parameters collected at this time point were patient height, weight, BMI and gait aids used. Pre-operative hip range of motion, straight leg raise and abduction power, Trendelenburg's sign were assessed for the operative limb. The amount of opiate analgesia used routinely by patients was documented. Finally, the 10 metre walk test was performed.

2 weeks post-operative assessment

Patients were reviewed at approximately two weeks post operatively to assess recovery and the surgical wound. Trial PROMs (OHS, WOMAC, EQ-5D) provided pre-operatively were repeated and completed on the day.

Hip straight leg raise, abduction power and Trendelenburg's sign were repeated for the operative limb. The total amount of analgesia used since discharge was recorded.

Post-operative DAA patients were further assessed for LCNT neuropraxia. The 10 metre walk test was repeated. Gait aids utilised during the test were documented.

6 weeks post-operative assessment

At the six week post-operative review, all parameters and PROMs completed during the two week review were repeated. Additionally, post-operative radiographs were taken on the day for comparison.

12 weeks post-operative assessment

At the twelve week review, all pre-operative measurements, tests and PROMs were repeated with the addition of wound length measurement. Patient height, weight and BMI were not recorded again.

Data Collection

Pre-operative and post-operative assessments were conducted mainly by the principal investigator. Meticulous notes were kept in both hard and digital copies. Digital notes were accessed from the Eastern Health server through clinical patient folders. Hard copy notes were stored in patient folders in the secured Eastern Health Clinical School.

Data collection of primary outcome measures and most secondary outcome measures was performed by the principal investigator. Collected data points were entered into a local secure database (Socrates, Ortholink, Pyremont, New South Wales) located on the Eastern Health Servers. This database was routinely backed up on auxiliary servers.

Patient Reported Outcome Measures (PROM)

[OHS/WOMAC/EQ-5D]

PROMs used in the study were provided to patients in a printed paper format with English as the medium of communication. Patients were presented the PROMs at outpatient clinic appointments to complete at each of the review time points.

Each completed questionnaire was reviewed by the principal investigator with the patient to ensure its satisfactory completion of all data points.

10 Metre Walk Test

The 10 metre walk test is conducted along a long secluded corridor to ensure minimal interruption of testing. Marks are placed at the 0, 2, 8 and 10 metre points. Patient times are recorded as the leading foot crosses the 2 and 8 metre marks. Patients are requested to walk at two difference paces, one being self-selected and the other as quickly as possible. Gait aids used during the walk tests are documented. The walk test is repeated 3 times for each variation in pace (self-selected and fast).

The 10 metre walk tests were performed by one of two individuals, the principal investigator and a senior musculoskeletal physiotherapist who is not associated with the study. The 10 metre walk tests were recorded at each of the study review time points.

Demographics

Height

Patient height was recorded in the pre-operative assessment clinic using a standardised tape measure. Patient shoes were removed prior to height measurements. Patient height was recorded in centimetres and rounded to the nearest 0.5 centimetre.

Weight

Patient weight was recorded in the pre-operative assessment clinic using a digital weighing scale with a maximum limit of 150 kg. Patients were weighed with their clothes on but without footwear. The recorded weight was documented and rounded to the nearest kilogram.

Age

The definition of age in the study was the age of the patient at the time of surgery. Age was recorded in years.

Hip Range of Movement

The range of movement of the operative hip was measured by the principal investigator pre-operatively and at 12 weeks post operatively. All hip range of motion parameters were measured with a universal goniometer. Passive range of motion was measured rather than active range of motion in order to isolate hip joint movement. Examination of the hip joint involved gentle manipulation until firm end point was felt. In a scenario where range of

motion caused significant discomfort to the patient, the joint was only assessed up to a point of tolerable discomfort.

Flexion

Flexion was measured with the patient in the supine position on a flat examination table without a pillow. To eliminate pelvic flexion, the patient was examined with the lumbar lordosis eliminated much like when performing Thomas's Test. If the patient was unable to eliminate the lordosis, the examiner stabilises the pelvis whilst flexing the patient's hip. A goniometer was centred on the GT and the axis of the proximal arm placed in line with femur aiming for the lateral condyle. The distal arm was placed in line with the patient parallel to the bed. The angle formed between the two arms was recorded as the hip flexion angle.

Extension

Hip extension was measured in one of two ways, either with the patient prone or standing. For the prone position, the patient was instructed to lie on the flat examination table in the face down position. The examiner then extended the hip passively with the knee joint flexed whilst stabilising the patient's pelvis. A goniometer was centred on the GT and the axis of the proximal arm placed in line with femur aiming for the lateral condyle. The distal arm was placed in line with the patient parallel to the bed. The angle formed between the two arms formed the hip extension angle.

The standing position was adopted for patients who are unable to lie prone due to body habitus. The patient was positioned 10 centimetres facing towards a wall with a relaxed stance. The patient is instructed to brace themselves by placing both hands against the wall with the spine straight. With stability attained, the patient was instructed to adopt a single leg stance on the non-operative leg with the operative knee flexed. The examiner was then able to passively extend the hip joint whilst stabilising the pelvis and spine. A goniometer was used in a similar fashion as with the prone position.

Abduction & Adduction

Hip abduction was measured with the patient in a supine position on the examination table. The patient was positioned with both lower limbs in a neutral position. The lower limbs paralleled the anterior axillary line. The examiner then abducted the operative leg whilst maintaining pelvic stability. A goniometer was centred on the ASIS and the axis of the proximal arm placed in a line parallel to the anterior axillry line. The distal arm was placed in line with the femur, aiming towards the centre of the patella. The angle formed between the two arms was recorded as the hip abduction angle.

Hip adduction of the hip joint adopted the similar parameters and position used in abduction. However, to facilitate unhindered adduction of the hip joint, the patient was positioned with the operative leg in a neutral position and the non-operative leg in an abducted position.

Internal Rotation & External Rotation

Hip rotation can be measured with the patient in a supine or sitting position on the examination table. For the supine position, the patient was positioned with both lower limbs in a neutral position. The operative leg was flexed to 90° at the hip joint and knee joint. The examiner then internally rotates the hip joint. A goniometer was centred over the knee joint with the proximal arm in parallel to the anterior axillary line and the distal arm aiming towards a point halfway between both malleoli. The angle formed between the two arms was recorded as the hip internal rotation angle.

The sitting position was used for patients who had difficulty attaining 90° of hip flexion. The patient was seated at the edge of the examination table with the knee flexed to 90° and foot dangling above the ground. The hip joint was internally rotated and a goniometer placed centrally over the knee joint with the proximal arm in perpendicular to the floor parallel to the anterior axillary line. The distal arm was aimed towards a point halfway between both malleoli. The angle formed between the two arms was recorded as the hip internal rotation angle.

External rotation of the hip joint adopted similar parameters and positions. However, a slight variation was needed in the sitting position. The non-operative leg was placed on a stool with the hip flexed and knee extended. This allowed for unobstructed external rotation of the operative limb.

Hip Muscle Strength

To evaluate the post-operative trauma associated with DAA and PA THA, muscle groups involved in the surgery were assessed using simple functional tests as listed below. The tests were conducted by the principal investigator at all assessment time points. Pre-assessment analgesia was not used or provided.

Straight Leg Raise (Quadriceps Muscle Group)

The straight leg raise test was performed with the patient supine on the examination table. The patient was then asked to actively flex the operated hip whilst maintaining full knee extension. Patients who are unable to straight leg raise against gravity were repositioned to a lateral position with the non-operative side on the table.

Hip Abduction Strength (Hip Abductors)

The hip abduction strength test was performed with the patient lying in a lateral position on the examination table with the operated side pointing towards the ceiling. The patient was then asked to actively abduct the operated hip whilst maintaining full knee extension. Patients who were unable to abduct against gravity were repositioned to a supine position and the test repeated. The hip abduction strength test was not performed with the patient standing in order to avoid a false result from spinal or contralateral hip abduction.

The strength of the quadriceps and abductor muscle groups were assessed using the Medical Research Council (MRC) Musculoskeletal Grading Scale as listed below(180)

0 – No visible or palpable contraction

1 – Visible and palpable contraction but no movement

2 – Full Range of Motion with gravity eliminated.

3 – Full Range of Motion with gravity

4 – Full Range of Motion with moderate resistance

5 – Full Range of Motion with maximum resistance

Trendelenburg Sign

The Trendelenburg sign was another examination that assessed hip abductor function. The test was performed with the patient standing on both legs in front of and facing away from the examiner. The examiner placed both hands on the patient's iliac crests. The patient was then instructed to stand on one leg. The test was positive if the contralateral pelvis sags down. The test was then repeated on the other hip.

If a patient was unable to perform the standard test due suspected non-abductor associated pathology, a modified test was performed. The patient was assessed standing up on both legs in front of but facing the examiner. The examiner then places his hands in front of the patient at the level of the waist and in supination. The patient was instructed to place their hands on the examiners hands to obtain additional balance. Following this, the patient was instructed to stand on one leg. With additional support from the examiners hands, the

patient should be able to stand on one leg without losing balance. Pressure was felt through the examiners hand on the contralateral side of the leg being tested if it was positive for abductor weakness. (Right abductor weakness results in the patient leaning to the left and pressure being felt through the examiners right hand)

Gait Aids

Gait aids used by patients were recorded by the principal investigator at each presentation. A note is made of the type of gait aid used during clinic and during the 10 metre walk test.

Peri-operative Data

Hospital length of stay, discharge destination, surgical time, ASA score, mode of anaesthesia were retrieved from electronic patient records. Hospital length of stay was recorded and rounded to the nearest hour. The surgical time routinely recorded by the scout nurse was recorded in minutes. ASA and mode of anaesthesia received by patients were recorded on the peir-operative anaesthetic documents. Discharge destination is defined as the destination patients are discharged to from acute inpatient orthopaedic care. Patients were generally discharged home or to rehabilitation.

Pre and Post-Operative Haemoglobin

Pre-operative haemoglobin was determined by the most recent haemoglobin value recorded prior to surgery. This occurred routinely at pre-admission assessment. Post-operative haemoglobin was determined by the haemoglobin value closets to the 24 hours

post-operatively. Haemoglobin values were retrieved for each patient from the electronic pathology reporting system.

Wound Length

Wound length was recorded at the 12 week post-operative follow-up time point. This was done using a flexible tape measure. Lengths were recorded up to the nearest centimetre.

Post-Operative Opiate Analgesia Use

Post-operative opiate analgesia use is defined as the total amount of opiate analgesia consumed by patients post operatively. All forms of opiate medication administered or consumed by patients are converted to oral morphine equivalents. Inpatient opiate medication use was recorded on inpatient drug charts, anaesthetic charts and patient controlled analgesia forms. Opiate medication ingested by patients following discharge was calculated from the remaining opiate medications prescribed to patients attending the 2 week outpatient follow-up. The total amount of opiate analgesia used was then tabulated to reflect opiate analgesic usage in the first two weeks following THA surgery. The sum of all opiate analgesics was then converted to oral morphine based on an opiate conversion chart. (181)

Fig 2.2: Opioid Conversion Chart Calvary Health Care Bethlehem (2007) Opioid Conversion Chart)

Oral to Oral		Ratio	
Morphine	Tramadol	1:5	Morphine 10mg = Tramadol 50mg
Morphine	Codiene	1:8	Morphine 10mg = Codeine 80mg
Morphine	Oxycodone	1:1.5	Morphine 10mg = Oxycodone 15mg
Subcutaneous to Oral		Ratio	
Oral Morphine	Subcutaneous Morphine	2-3:1	Oral Morphine 20-30mg = Subcutaneous Morphine 10mg
Oral Oxycodone	Subcutaneous Oxycodone	2:1	Oral Oxycodone 20mg = Subcutaneous Oxycodone 10mg
Oral Morphine	Subcutaneous Fentanyl	1:0.03125	Oral Morphine 1mg = Subcutaneous Fentanyl 31.25mcg

Lateral Cutaneous Nerve of Thigh Neuropraxia

Patients who were randomised for DAA THA were assessed for LCNT neuropraxia at all post-operative assessment time points. A positive LCNT neuropraxia was defined as any neurosensory deficit along the anterolateral thigh. Sensory deficiency, numbness together with associated with size and distribution was documented. Reduced or altered sensation indicated neuropraxia. Normal sensation indicated the absence of a neuropraxia. Meralgia paresthetica was documented if present.

Radiological Analysis

Radiographic measures of acetabular inclination, acetabular anteversion and femoral stem orientation were analysed by two blinded independent consultant radiologists using computer software and digital radiographs. IMPAX Orthopaedic Tools 2.52 (AFGA Healthcare© NV, Belgium) & TraumaCad (Voyant Health, Petach-Tikva, Israel) Implant subsidence was also recorded by comparing interval imaging. Acetabular implant position dichotomised for safe zone position. (139)

Statistical Methods and Analysis

Principles of Analysis

1. Analysis were conducted using the intention to treat principle
2. Repeated measurements were analysed using linear mixed effects models and the restricted maximum likelihood method. All available data were used in these analyses.
3. Statistical tests were two sided with a statistical significance (α) level of 5%.
4. Estimates of treatment effects are presented with 95% confidence intervals
5. No adjustments for multiple testing were made.

Primary Analysis

The primary analysis was performed on primary outcome measures of the WOMAC and OHS score collected 2 weeks pre-operatively, 2, 6, and 12 weeks post-operatively.

The primary analysis utilised linear mixed effects model with WOMAC & OHS score as the dependent variable and Treatment group, Time, and a (Treatment x Time) interaction as the predictor variables. Treatment group and Time were fixed effects (both categorical) and patients and assessments within patients were random effects. The linear mixed model allows for the correlated structure of data that results from having study patients with repeated measurements over time. The most suitable correlation structure was determined from the data using Akaike's Information Criterion. The F-test for the Treatment x Time interaction is to be reported together with pairwise comparisons between the treatment groups at each time point.

Stratification variables, site and age group, were included in the model with site treated as a random effect and age as a fixed effect. The software package Stata 12 (StataCorp LP, College Station, TX) was used to analyse the data.

Secondary Analysis

The following secondary outcomes were analysed in the same way as the primary outcomes:

- EQ-5D (United Kingdom Weights)(182)
- EQ-VAS
- 10 metre walk test velocity

Each secondary outcome was the dependent variable in a linear mixed model, with Treatment, Time and a (Treatment x Time) interaction as the predictor variables. Time points were identical to the primary analysis. Additional secondary analysis considered the effect of covariates, gender, BMI, ASA Score, and mode of anaesthesia.

Ancillary Analysis

For categorical data collected at the same time points, the outcome were dichotomised and logistic regression used. Repeated measures for categorical data were allowed for by using a generalised estimating equation approach. The variables considered here are based on:

- Trendelenburg sign
- Abductor and Quadriceps Power measures
- Gait aids (Dichotomised – as with or without gait aids)

Outcome measures based on radiographs post-operatively and 6 weeks were analysed using analysis of covariance separately at each time point. This facilitated comparison of mean differences in the outcome between the treatment groups while adjusting for baseline levels of the outcome measure.

Other outcomes such as: operative time; wound length; length of stay in hospital; length of rehabilitation; post-operative haemoglobin drop; and 2 week opiate analgesic usage were summarised by treatment group using medians and interquartile ranges and compared using Wilcoxon's rank-sum test. Discharge destinations were compared between groups using Fisher's Exact test. No corrections were made for multiple analyses.

Sensitivity Analysis

A sensitivity analysis was performed on the primary outcomes WOMAC and OHS. The models used for the primary analysis were adjusted for the stratification variables site and age group. Interactions of age with the other fixed effects factors (time and treatment) were assessed via F-tests.

Subgroup Analysis

A subgroup analysis by site and patient age was conducted on the two primary outcomes and relevant secondary outcomes. The effect of hip precautions was investigated by analysing specific WOMAC and OHS responses.

Complications

The incidence of the following types of complications were reported in each treatment group

- LCNT neuropraxia – exclusive to DAA
- Dislocations
- Implant migration
- Unplanned return to surgery
- Wound complication
- Blood transfusions
- Fracture
- Heterotopic ossification
- Bursitis
- Iliopsoas impingement

Risk ratios and 95% confidence intervals were calculated where possible. Fisher's Exact test was be used to compare the incidences between the two groups.

Additional Analysis

For the purposes of publication, the study investigators are continuing to review patients up to one year after surgery. Ethics approval for one year follow-up has been obtained.

CHAPTER 3

RESULTS

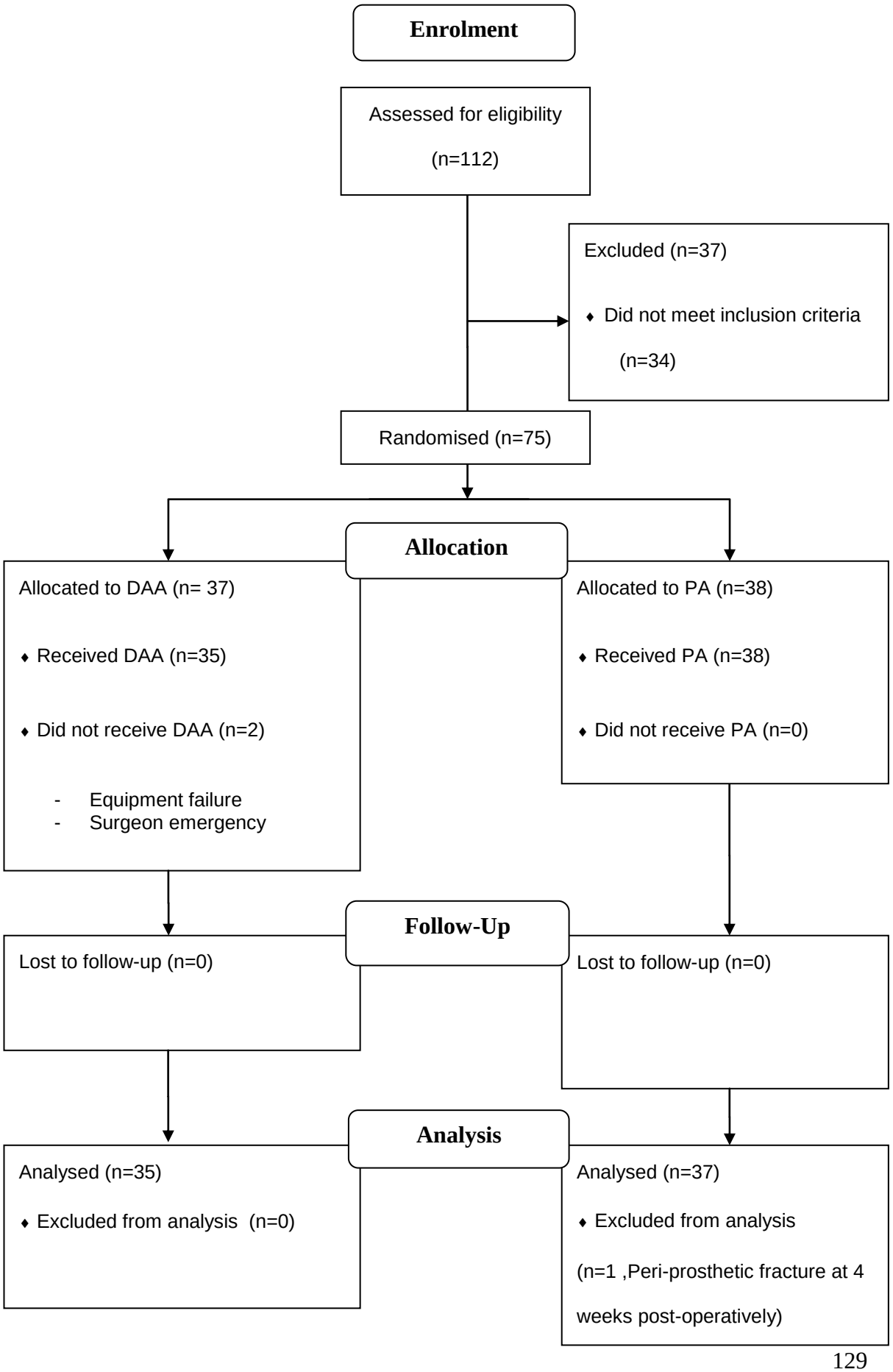
RESULTS

Recruitment

In total 112 patients were contacted to participate in the trial. 36 patients out of 112 were excluded as they did not meet the inclusion criteria. 3 patients declined to participate as they had a preference for surgical approach. In total 75 patients were recruited and consented to participate in the trial. Participants were then randomised into DAA and PA groups and stratified according to age and site. The 75 participants were randomised into the 2 surgical approaches for both surgeons. 37 were randomised into the DAA group and 38 were randomised into the PA group. In the DAA group, 2 participants failed to receive the allocated intervention due to an emergency and an episode of DAA specific equipment failure requiring conversion to PA. Both of these failures occurred for the same surgeon. The affected participants were excluded from analysis.

In the PA group all participants received their allocated surgical intervention. However a single participant in the PA group sustained a peri-prosthetic fracture of the femur 4 weeks post-operatively after a fall during a seizure. The participant required revision surgery and violated the study's protocol. The investigators determined that results prior to this time point for this participant were still suitable for analysis whilst results after this time-point were excluded. No participants were lost to follow-up. The number of remaining participants in each group that were suitable for complete analysis was 35 for the DAA and 37 for the PA. The recruitment process for this study is reflected in the Consolidated Standards of Reporting Trials **(**CONSORT) Flow Diagram below

CONSORT Flow Diagram of Participants



General Clinical Data

Participant Characteristics

The DAA group had 15/35 (43%) males and 20/35 (57%) females. The PA group had 18/38 (47%) males compared to females 20/38 (53%). The median age of participants when surgery was performed was 59 years for the DAA group and 62.5 years for the PA group. The median BMI of participants for the DAA and PA groups were 27.7 and 28.3 respectively. There were no statistically significant differences between each group for gender, age and BMI.

Clinical Outcomes

Anaesthetic

The ASA rating for each group was similar with most participants given a score of 2 (80% DAA, 63% PA) by anaesthetists. The modality of anaesthesia used did not differ statistically between both groups. For the DAA group, 49% received a general anaesthetic, 29% received a spinal anaesthetic and 23% received a combined anaesthetic. For the PA group, 45% received a general anaesthetic, 45% received a spinal anaesthetic and 11% received a combined anaesthetic.

Surgical Characteristics

Surgical characteristics utilised for participants were also similar for both groups. 57% and 63% of right hips were operated on in the DAA and PA groups respectively. Participants in the DAA group had longer operative times than PA group. This was statistically significant.

(125mins versus 100mins P<0.001) The DAA group had statistically smaller surgical wounds compared to the PA group (107mm versus 135mm P<0.001). The DAA group also had a slightly higher drop in haemoglobin post-operatively than the PA group. This was statically significant (DAA 35g/L versus PA 31g/L: P=0.04). 90% of participants did not require a transfusion post-operatively. 3 participants from each group required blood transfusions for anaemia. One participant from the DAA group required a single blood transfusion of 1 unit. 2 participants from the DAA and PA groups required 2 units each. A single participant from the PA group required 3 units of blood for transfusion.

Length of Stay & Discharge Destination

In the domains of hospital length of stay, the DAA group when compared with the PA group had a shorter length of stay in the acute hospital that was not statistically significant (DAA 77hours versus PA 95 hours: P= 0.15). Discharge destinations for the DAA group was home 29/35 (83%) and rehabilitation 6/35 (17%). Fewer participants from the PA group were discharged home 28/38 (74%) and 10/38 (26%) were discharged to rehabilitation. However, the difference was not statistically significant (P=0.4). DAA and PA participants that required rehabilitation stayed a mean of 154.5 and 166 hours respectively (P=0.48). The total length of hospital stay including duration of stay at rehabilitation favoured the DAA group slightly. The mean total length of stay for the DAA group was 96 hours versus 100 hours for the PA group (P=0.15).

Analgesic Usage

Post-operative analgesic usage is reported in oral equivalents of oral morphine. 2 week total opiate analgesic usage was lower in the DAA group when compared to the PA group

(263.7mg versus 405.6mg: P=0.04). Net opiate analgesic usage factors in the 2 weekly doses of opiate analgesics utilised by some participants pre-operatively. The net 2 weekly opiate dose calculated for the DAA and PA groups was 240mg and 328mg respectively (P=0.19). Results can be found in tables 3.1a, 3.1b and 3.1c below.

Table 3.1a: Demographic characteristics of the participants by treatment group.

Characteristic	DAA Median(IQR)	PA Median(IQR)
Gender[1]		
Male	15 (43%)	18 (47%)
Female	20 (57%)	20 (53%)
Age at surgery (years)	59 (54, 69)	62.5 (55, 69)
PreOp Height (cm)	170 (162, 177)	166 (162, 174.5)
PreOp Weight(kg)	81 (71, 87)	81.5 (67, 91)
PreOp BMI	27.7 (25.8, 30)	28.3 (24.8, 31.1)

[1]Frequency(%)

Table 3.1b: Surgical characteristics of the participants by treatment group.

Characteristic	DAA Frequency (%)	PA Frequency (%)	P-value[1]
Side operated on			
Right	20 (57%)	24 (63%)	0.6
Left	15 (43%)	14 (37%)	
Anaesthetic			
General	17 (49%)	17 (45%)	0.3
Spinal	10 (29%)	17 (45%)	
General, Spinal	8 (22%)	4 (10%)	
Anaesthetic rating			
1	5 (14%)	9 (24%)	0.3
2	28 (80%)	24 (63%)	
3	2 (6%)	5 (13%)	
Transfusion (No. packs)			
0	32 (91%)	35 (92%)	0.9
1	1 (3%)	0 (0%)	
2	2 (6%)	2 (5%)	
3	0 (0%)	1 (3%)	

[1]P-value based on Fisher's Exact test.

Table 3.1c: Summary of clinical parameter outcomes by treatment group

Clinical Parameters	DAA Median(IQR)	PA Median(IQR)	P-value[1]
Operative time(mins)	125 (111, 138)	100 (93, 113)	<0.001
Wound length (mm)	107 (88, 120)	135 (127, 155)	<0.001
Haemoglobin Drop (g/L)	35 (29, 45)	31.0 (24, 37)	0.04
Length of stay in hospital (hours)	77 (73, 118)	95 (76, 120)	0.15
Total hospital stay (hours)	96 (74, 127)	100 (76, 190)	0.15
PostOp analgesia (morphine/mg) TOTAL	263.7 (192.5, 476.2)	405.6 (275, 565)	0.04
PostOp analgesia (morphine/mg) NET	240 (175, 415)	328 (195, 512.5)	0.19
Discharge to[3] rehabilitation Home Rehab Centre	 29 (83%) 6 (17%)	 28 (74%) 10 (26%)	 0.4
Rehab stay duration (hours)	154.5 (72, 169)	166 (95, 211)	0.48

[1]P-value based on Wilcoxon rank-sum test
[2]P-value based on Fisher's Exact test.
[3]Frequency(%)

Primary Outcomes

WOMAC Scores

Total Score

WOMAC scores analysed were reported in the total, pain, motion and function scores. The WOMAC total score is the sum of the pain, motion and function scores. A lower score translates to better symptoms. The mean WOMAC scores for the DAA group at baseline, 2 weeks, 6 weeks and 12 weeks were 62.97, 40.34, 19.23 and 9.11 respectively. The PA group at similar time points gave a total score of 71.18, 44.47, 21.98 and 12.80 respectively. A statistically significant difference was observed between the DAA group and PA group at baseline (P= 0.02). Although the DAA group had better mean total scores than the PA group at all time points, there were no other statistically significant differences.

Pain Score

The DAA group had a pain score of 13.06 at baseline, 7.46 at 2 weeks, 3.83 at 6 weeks and 1.74 at 12 weeks. The PA group at equal time points scored 14.63, 7.53, 3.69 and 2.33 respectively. Analysis of pain scores at each time point did not differ statistically between the two groups at all time points.

Motion Score

Motion scores favoured the DAA group at all time points except at 6 weeks. The DAA group at the 4 study time points reported a motion score of 5.43, 3.34, 2.37 and 1.40 respectively. Similar scores of 6.11, 3.55, 2.04 and 1.83 were also reported by the PA

group in this category. Differences between both groups at all time points were not statistically significant.

Function Score

The statistical difference between the DAA and PA groups at baseline in the total WOMAC score is accounted for in the functional score. The DAA group scored 44.49 versus 50.45 in the PA group (P=0.02). However, at further post-operative time points despite the DAA having better mean scores, no significant differences were observed between the two groups. At 2, 6 and 12 weeks the DAA group 29.54, 13.03 and 5.97 respectively. For the PA group at equal time points the scores reported were 33.39, 16.25 and 8.65. Tables & graphs detailing the comparison of WOMAC results are found below (Tables 3.2, 3.2a, 3.2b, and 3.2c, Graphs 3.2, 3.2a, 3.2b, 3.2c)

Table 3.2: Primary outcome results: A two-way table of predicted WOMAC means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Total score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	62.97	(2.59)	71.18	(2.48)	8.21	1.07	15.36	0.02
2 weeks	40.34[2]	(3.01)	44.47[3]	(2.89)	4.13	-4.19	12.45	0.33
6 weeks	19.23[2]	(2.47)	21.98[3]	(2.40)	2.75	-4.12	9.61	0.43
12 weeks	9.11[2]	(2.05)	12.80[3]	(1.99)	3.69	-2.02	9.39	0.20
(time x treatment interaction)								0.70[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.2a: WOMAC Pain Score

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Pain score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	13.06	(0.60)	14.63	(0.57)	1.57	-0.07	3.22	0.06
2 weeks	7.46[2]	(0.71)	7.53[3]	(0.68)	0.07	-1.88	2.02	0.94
6 weeks	3.83[2]	(0.56)	3.69[3]	(0.55)	-0.14	-1.70	1.43	0.86
12 weeks	1.74[2]	(0.46)	2.33[3]	(0.45)	0.58	-0.70	1.86	0.33
(time x treatment interaction)								0.35[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.2b: WOMAC Motion Score

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Motion score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	5.43	(0.29)	6.11	(0.28)	0.68	-0.13	1.49	0.10
2 weeks	3.34[2]	(0.33)	3.55[3]	(0.31)	0.21	-0.69	1.11	0.64
6 weeks	2.37[2]	(0.28)	2.04[3]	(0.27)	-0.33	-1.10	0.44	0.39
12 weeks	1.40[2]	(0.28)	1.83[3]	(0.27)	0.43	-0.34	1.19	0.27
(time x treatment interaction)								0.11[1]

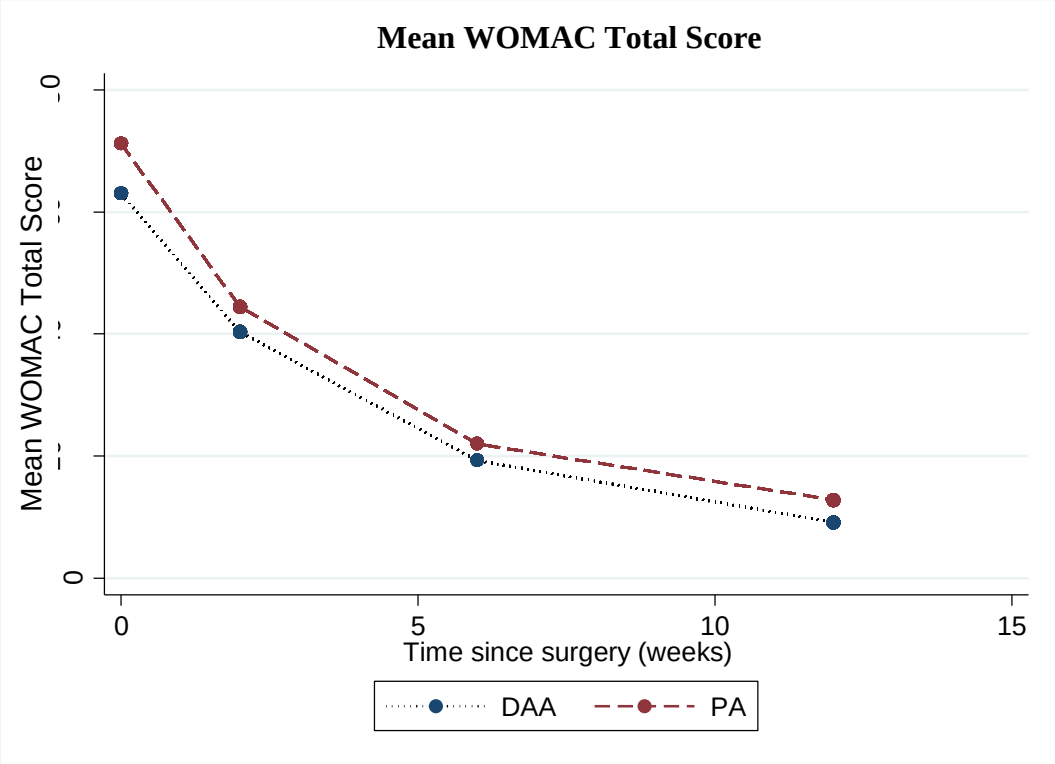
[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.2c: WOMAC Function Score

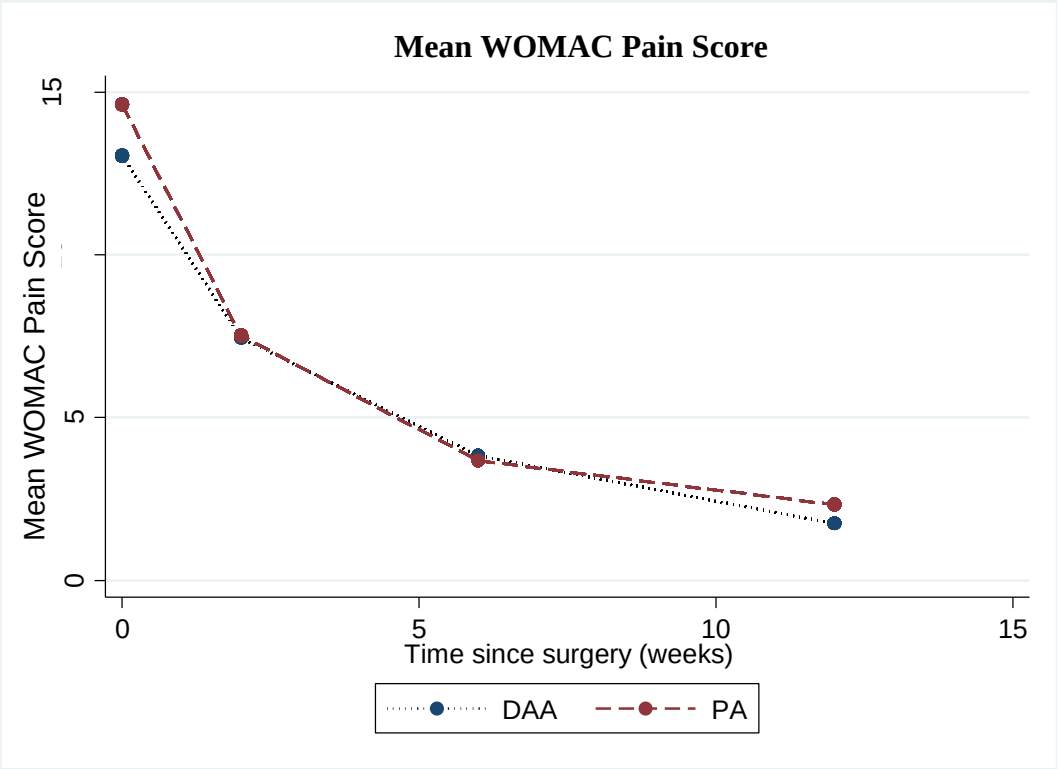
Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Function score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	44.49	(1.86)	50.45	(1.78)	5.96	0.82	11.10	0.02
2 weeks	29.54[2]	(2.16)	33.39[3]	(2.08)	3.85	-2.13	9.83	0.20
6 weeks	13.03[2]	(1.78)	16.25[3]	(1.72)	3.22	-1.71	8.16	0.20
12 weeks	5.97[2]	(1.40)	8.65[3]	(1.36)	2.68	-1.21	6.57	0.17
(time x treatment interaction)								0.76[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

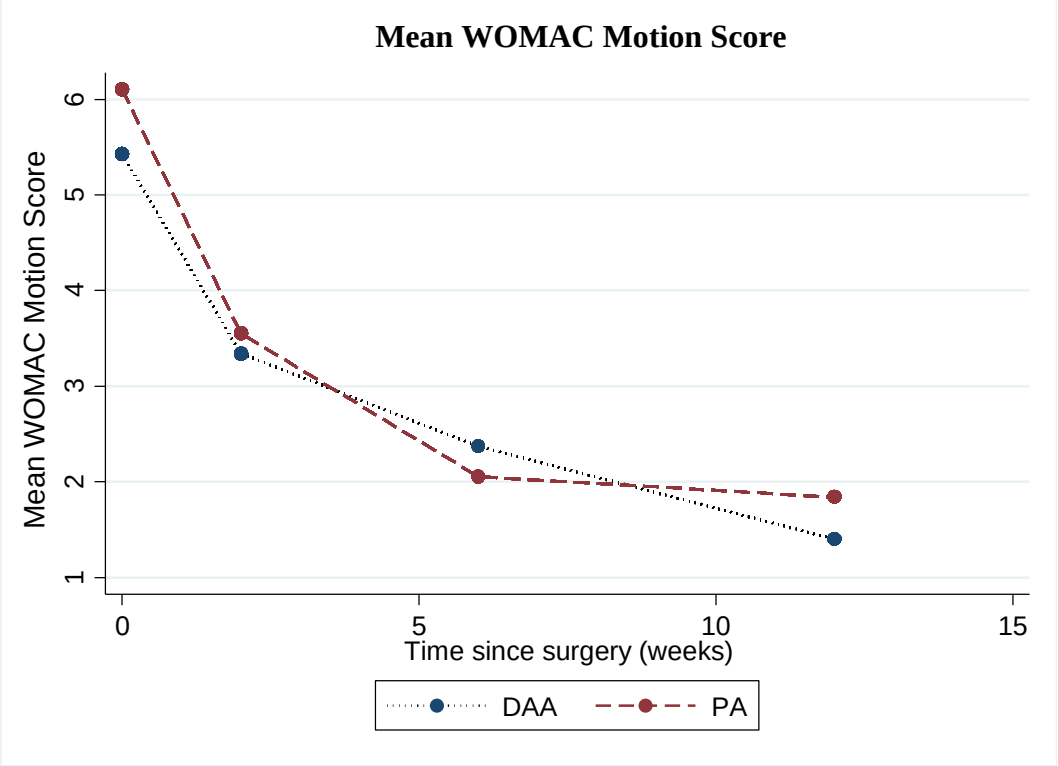
Graph 3.2: Mean WOMAC Total score between DAA and PA groups



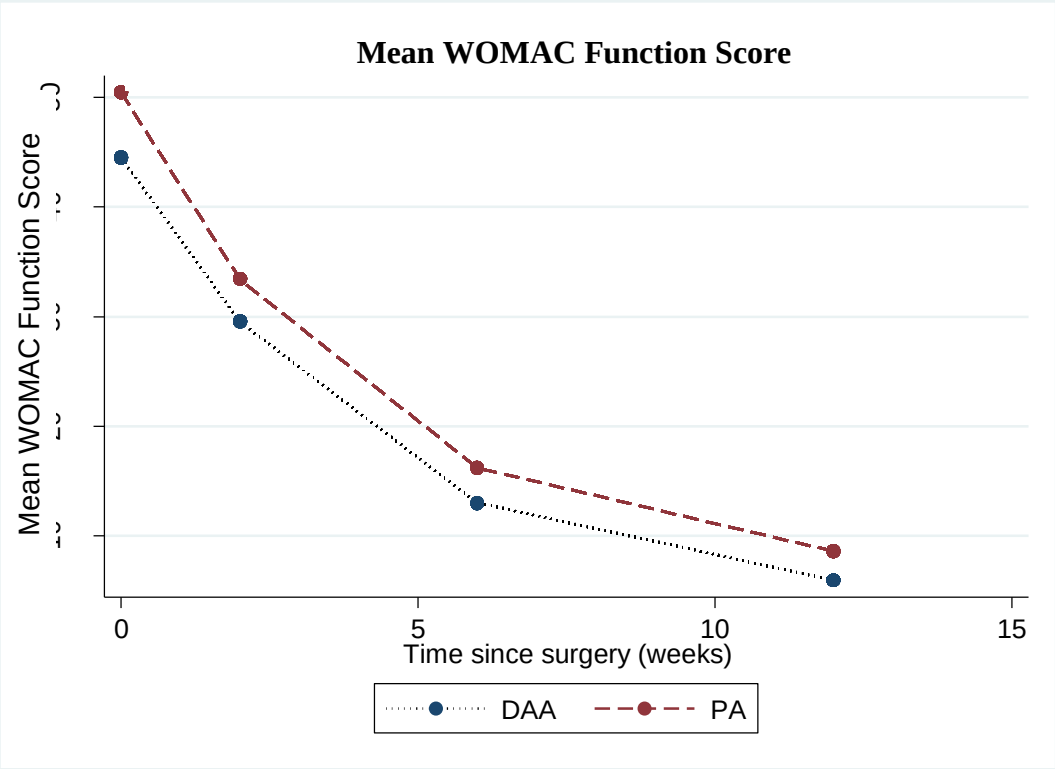
Graph 3.2a: Mean WOMAC Pain score between DAA and PA groups



Graph 3.2b: Mean WOMAC Motion score between DAA and PA groups



Graph 3.2c: Mean WOMAC Function score between DAA and PA groups



Oxford Hip Score

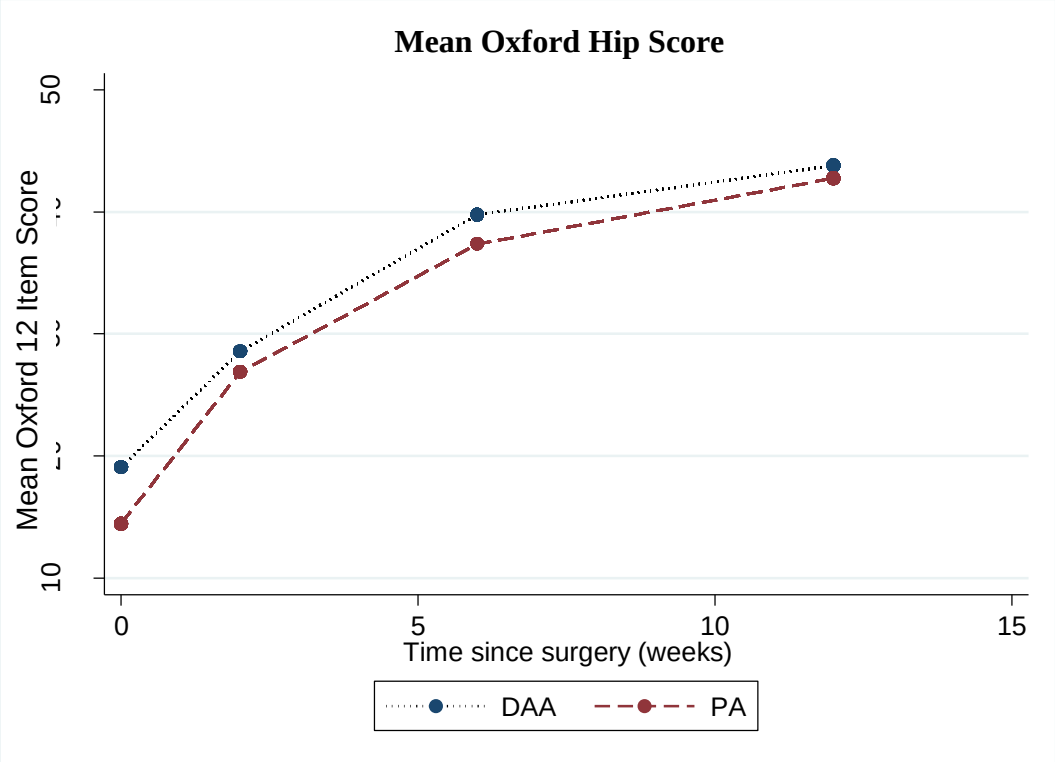
For the Oxford Hip Score, a higher score translates to fewer symptoms. The DAA group reported at baseline, 2 weeks, 6 weeks and 12 weeks a score of 19.06, 28.54, 39.77 and 43.80 respectively. The PA group reported similar improvements in scores of 14.45, 26.84, 37.32 and 42.75 from baseline to 12 weeks. Like the WOMAC scores, a statistically significant difference was observed between the DAA and PA groups at baseline. Further differences did not attain statistical significance at post-operative time points. Tabulated and graphical results are found below in Table 3.3 and Graph 3.3.

Table 3.3: Primary outcome results: A two-way table of predicted OHS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Oxford12 Item Score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	19.06	(1.13)	14.45	(1.08)	-4.61	-7.73	-1.49	0.004
2 weeks	28.54[2]	(1.56)	26.84[3]	(1.50)	-1.70	-6.02	2.62	0.44
6 weeks	39.77[2]	(1.05)	37.32[3]	(1.01)	-2.45	-5.35	0.45	0.10
12 weeks	43.80[2]	(0.87)	42.75[3]	(0.84)	-1.05	-3.46	1.37	0.39
(time x treatment interaction)								0.14[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Graph 3.3: Mean OHS score between DAA and PA groups



Secondary Outcomes

EQ-5D

EQ-5D Utility Scores

EQ-5D scores were calculated utilising UK weights. A higher score translates to better quality of life. At all study time points similar scores were reported by both DAA and PA groups. The DAA group reported at baseline, 2 weeks, 6 weeks and 12 weeks a score of 0.36, 0.6, 0.8 and 0.9 respectively. Matching this, the PA group reported scores of 0.33, 0.52, 0.80 and 0.88. There were no statistically significant differences between both groups at all time points.

EQ-5D VAS

The EQ-5D VAS score is interpreted in a similar way to the utility scores. A higher score translates to the perception of better quality of life by participants. The DAA group reported at baseline, 2 weeks, 6 weeks and 12 weeks a score of 61.23, 74.03, 86.57 and 91.57 respectively. The PA group reported matching scores of 59.08, 74.13, 87.04 and 91.86. There were no statistically significant differences between both groups at all time points. Tabulated and graphical results are found below in Tables 3.4a, 3.4b and Graphs 3.4a and 3.4b

Table 3.4a: A two-way table of predicted EQ5D utility* score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
EQ5D Utility	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	0.36	(0.05)	0.33	(0.05)	-0.03	-0.18	0.11	0.64
2 weeks	0.60[2]	(0.04)	0.52[3]	(0.04)	-0.08	-0.20	0.03	0.16
6 weeks	0.80[2]	(0.03)	0.80[3]	(0.03)	0.01	-0.07	0.09	0.86
12 weeks	0.90[2]	(0.02)	0.88[3]	(0.02)	-0.02	-0.09	0.05	0.57
(time x treatment interaction)								0.53[1]

* calculated using UK weights

[1]P-value for the F-test of the time by treatment interaction

[2] Means are significantly different from baseline ($p \leq 0.001$) within DAA group

[3] Means are significantly different from baseline ($p \leq 0.001$) within PA group

Table 3.4b: A two-way table of predicted EQ5D3LVAS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

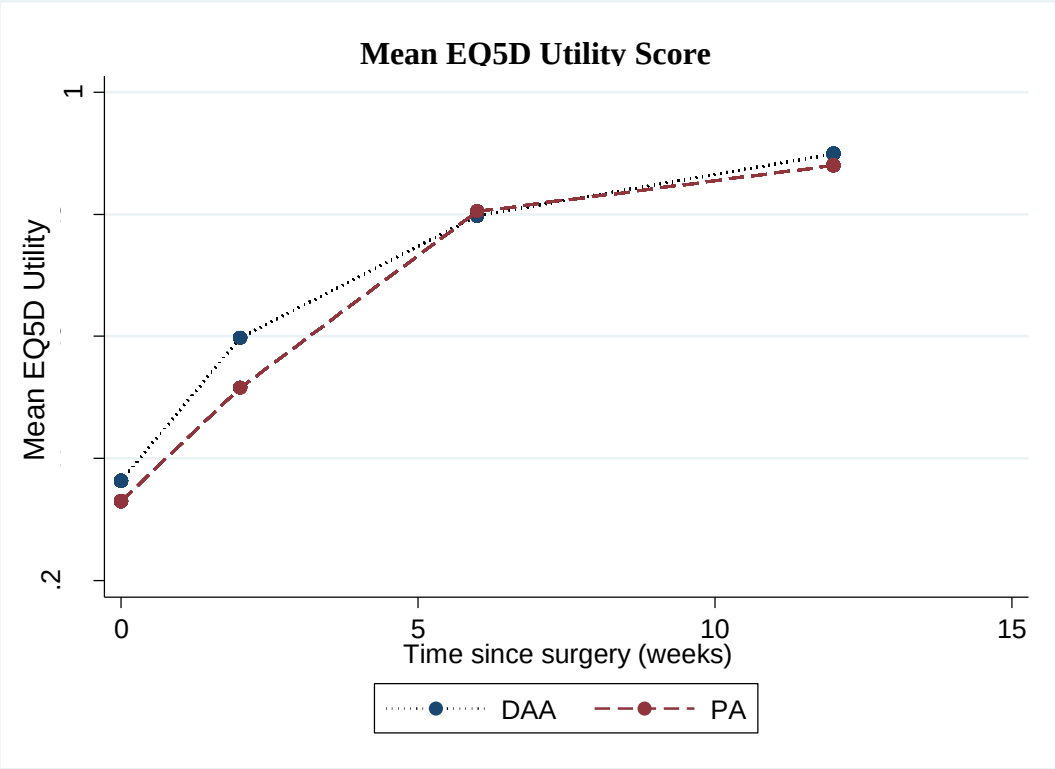
Endpoint	DAA		PA		Difference (PA-DAA)			
EQ5D-3L-VAS	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	61.23	(3.29)	59.08	(3.16)	-2.15	-11.25	6.95	0.64
2 weeks	74.03[2]	(2.70)	74.13[3]	(2.59)	0.10	-7.36	7.56	0.98
6 weeks	86.57[2]	(1.63)	87.04[3]	(1.58)	0.47	-4.05	4.98	0.84
12 weeks	91.57[2]	(1.31)	91.86[3]	(1.27)	0.29	-3.33	3.92	0.87
(time x treatment interaction)								0.95[1]

[1]P-value for the F-test of the time by treatment interaction

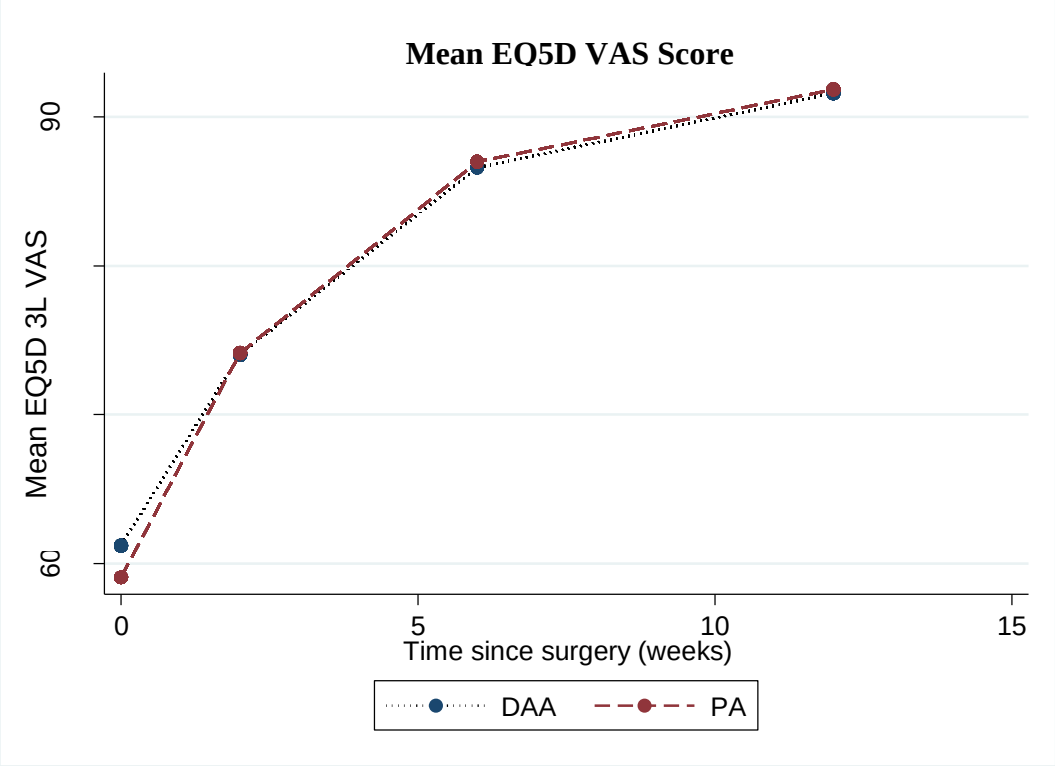
[2] Means are significantly different from baseline $p \leq 0.001$) within DAA group

[3] Means are significantly different from baseline ($p \leq 0.001$) within PA group

Graph 3.4a: Mean EQ-5D Utility Weights between DAA and PA groups



Graph 3.4b: Mean EQ-5D VAS between DAA and PA groups



10 Metre Walk Test

10 Metre Walk Test – Self-Selected

The results of the 10 metre walk test (10mwt) are reported in mean speed/velocity. At a self-selected pace, the DAA group walked at baseline, 2 weeks, 6 weeks and 12 weeks with speeds of 1.12m/s, 0.86m/s, 1.19m/s and 1.28m/s respectively. At matching time points, the PA group walked with speeds of 1.05m/s, 0.82m/s, 1.16m/s and 1.27m/s. There were no statistically significant differences between both groups at all time points.

10 Metre Walk Test - Fast Paced

At the fast pace, the DAA group walked at baseline, 2 weeks, 6 weeks and 12 weeks with speeds of 1.47m/s, 1.14m/s, 1.56m/s and 1.74m/s respectively. The PA group walked with speeds of 1.41m/s, 1.09m/s, 1.55m/s and 1.72m/s at similar time points. Again there were no statistically significant differences between both groups at all time points. Results comparing both groups at each time point can be found below in Tables 3.5a, 3.5b, Graphs 3.5a and 3.5b.

Table 3.5a: A two-way table of predicted self- selected pace 10m walking test score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DA		PA		Difference (PA-DAA)			
10mwt Self Selected	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	1.12	(0.04)	1.05	(0.04)	-0.07	-0.18	0.04	0.19
2 weeks	0.86[2]	(0.04)	0.82[3]	(0.04)	-0.04	-0.15	0.07	0.45
6 weeks	1.19[2]	(0.04)	1.16[3]	(0.04)	-0.03	-0.14	0.08	0.55
12 weeks	1.28[2]	(0.03)	1.27[3]	(0.03)	-0.01	-0.10	0.08	0.85
(time x treatment interaction)								0.50[1]

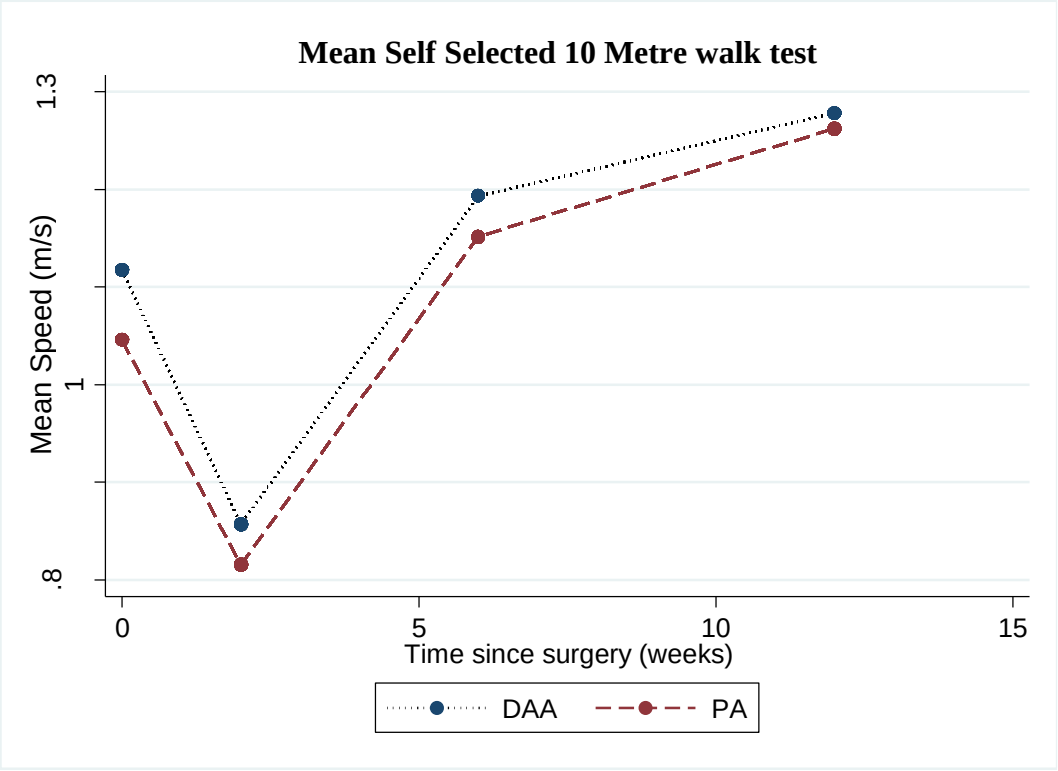
[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.03$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.001$) within PA group

Table 3.5b: A two-way table of predicted fast paced 10m walking test score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

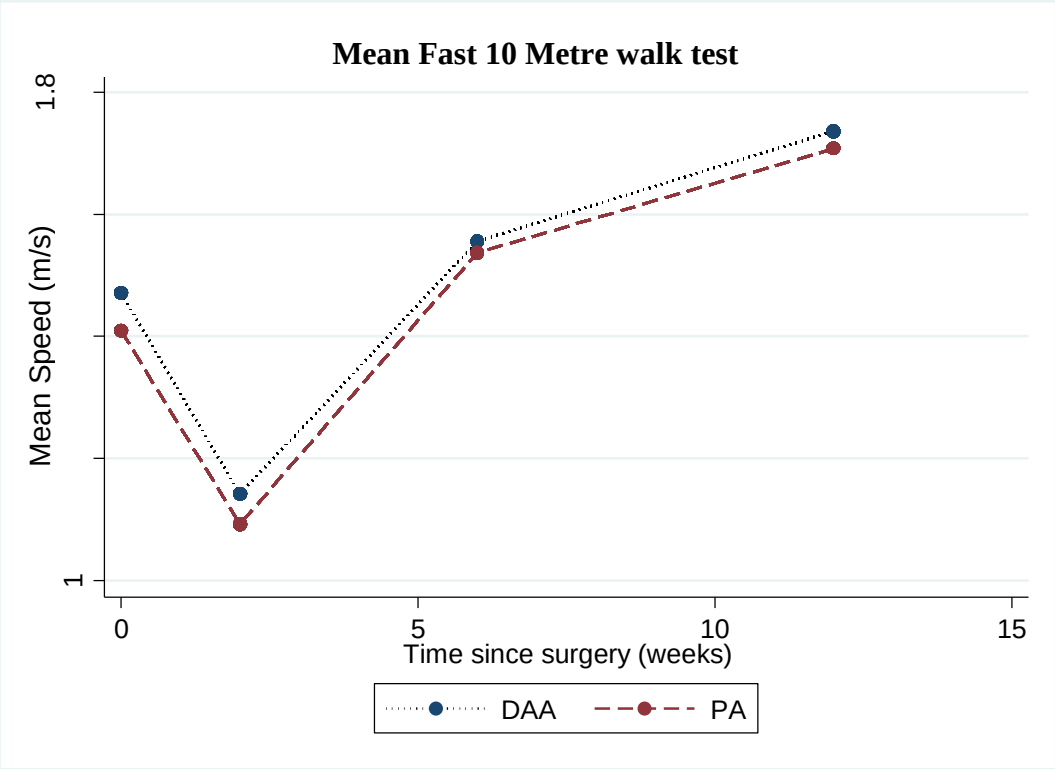
Endpoint	DA		PA		Difference (PA-DAA)			
10mwt Fast Paced	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	1.47	(0.06)	1.41	(0.06)	-0.06	-0.22	0.10	0.44
2 weeks	1.14[2]	(0.05)	1.09[3]	(0.05)	-0.05	-0.19	0.09	0.48
6 weeks	1.56[2]	(0.04)	1.55[3]	(0.04)	-0.01	-0.12	0.11	0.90
12 weeks	1.74[2]	(0.04)	1.72[3]	(0.04)	-0.02	-0.14	0.11	0.78
(time x treatment interaction)								0.75[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.05$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.001$) within PA group

Graph 3.5a: Mean Self Selected 10metre walk test speeds between DAA and PA groups



Graph 3.5b: Mean Fast Speed 10metre walk test speeds between DAA and PA groups



Hip Function

Hip Range of Movement

Hip range of movement recorded for both groups showed improvements between pre-operative and 12 week data. There was no clear difference in hip range of motion that achieved statistical significance for all parameters of range of motion.

The mean hip flexion at baseline for the DAA and PA groups was 82.9° and 77.9° respectively. This improved to 101.2° and 99.2° at the 12 week mark. Parameters reported for the remaining hip range of movements for each motion at each time point follows the pattern established in the description of hip flexion. Hip extension DAA and PA baseline 8.2° and 9.7° improved to 12.4° and 11.9° at 12 weeks. Hip abduction was recorded at

22.0° and 23.5° improving to 26.3° and 28.5°. Hip adduction measured 14.8° and 14.6° at baseline and increased to 20.5° and 22.1°. Hip internal rotation was recorded at 5.8° and 7.0° at baseline, improving to 17.5° and 16.9° 12 weeks post-operatively. Hip external rotation was assessed to be 19.3° in both DAA and PA groups at baseline. This increased to 31.1° and 27.6°.

The top 3 improvements observed was in domains of hip flexion in PA group with a mean improvement of 21.8°, hip flexion in the DAA group with a mean improvement of 18.3° and hip external rotation in the DAA group with an improvement of 11.9°.

Straight Leg Raise

Straight legs raise measurements results were reported following continuous and ordinal analysis. Both the DAA and PA groups had similar means of 3.63 at baseline. The DAA group at 2 week, 6 weeks and 12 weeks recorded a mean score of 2.83, 3.86 and 4.54 respectively. The PA group had less post-operative decline in straight leg raise function with recorded means at 2 weeks, 6 weeks and 12 weeks of 3.29, 4.32 and 4.67. There were statistically significant differences between both groups at 2 weeks and 6 weeks post-operatively (2 weeks - DAA 2.83 versus PA 3.29: P=0.03) (6 weeks – DAA 3.86 versus PA 4.32: P=0.01)

Ordinal analysis found an odds ratio (OR) of 2.74 (P= 0.02) and 3.23 (P=0.01) in favour of having a higher straight leg raise score with the PA.

Hip Abduction

Hip abduction was measured by means of a Trendelenburg's sign as well as the MRC grading scale. At baseline a similar proportion of participants were Trendelenburg's positive in the both the DAA group (9/35 -26%) and in the PA groups (10/38 -26%). 2 weeks post-operatively, the number of participants who had a positive Trendelenburg's sign were again similar in both groups (DAA 21, PA 22: P=0.86). The number of participants with a positive Trendelenburg's sign reduced to 4 in each group at 6 weeks post-operatively. At 12 weeks only 1(3%) participant in the DAA group and 3(8%) in the PA group still tested positive for Trendelenburg's sign (P=0.37)

An OR and Relative Risk (RR) of approximately 1 was found for Trendelenburg's sign between both DAA and PA groups from baseline to 6 weeks. At 12 weeks the PA group had non-significant increase in an OR 2.92 and RR 2.77 for being Trendelenburg's positive (P=0.37).

The mean MRC grades for hip abduction for both groups were similar throughout all time points. The DAA at baseline, 2 weeks, 6 weeks and 12 weeks were 3.86, 3.23, 4.06 and 4.74 respectively. For the PA group, the scores were 3.76, 3.26, 4.27 and 4.65. The PA group had a non-significant increase in OR of 1.8 for higher hip abduction scores at 6 weeks post-operatively when compared to the DAA. Tables for all hip function values are found in Tables 3.6a to 3.6g

Table 3.6a: Summary of the Hip Range of motion data at baseline and 12 weeks

	Mean (SD) at each time						Baseline change PA and DAA groups[1]	
Outcome	Baseline		12 weeks		Change		Difference (95%CI)	P-value
	DAA	PA	DAA	PA	DAA	PA		
Hip Flexion	82.9 (15.0)	77.9 (19.8)	101.2 (13.2)	99.2 (10.0)	18.3 (13.7)	21.8 (15.8)	0.0 (-5.2, 5.2)	0.99
Hip Extension	8.2 (5.9)	9.7 (5.9)	12.4 (5.5)	11.9 (4.2)	4.2 (5.4)	2.0 (7.0)	-1.0 (-3.2, 1.3)	0.4
Hip Abduction	22.0 (9.6)	23.5 (6.5)	26.3 (5.6)	28.5 (7.5)	4.3 (10.6)	5.2 (8.9)	2.1 (-1.0, 5.1)	0.18
Hip Adduction	14.8 (4.6)	14.6 (4.7)	20.5 (4.4)	22.1 (5.0)	5.6 (6.4)	7.5 (7.2)	1.7 (-0.6, 3.9)	0.14
Hip Internal Rotation	5.8 (8.4)	7.0 (7.1)	17.5 (7.2)	16.9 (7.0)	11.7 (10.7)	9.7 (7.9)	-0.9 (-4.2, 2.3)	0.57
Hip External Rotation	19.3 (12.8)	19.3 (8.9)	31.1 (10.1)	27.6 (9.8)	11.9 (13.1)	8.3 (12.1)	-3.5 (-8.1, 1.0)	0.13

[1]Analysis of Covariance was used to compare the change from baseline to 12 weeks between the groups after adjusting for baseline values

Table 3.6b: A two-way table of straight leg raise means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Straight Leg Raise	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	3.63	(0.14)	3.63	(0.14)	0.00	-0.39	0.40	0.99
2 weeks	2.83[2]	(0.15)	3.29[3]	(0.14)	0.46	0.06	0.86	0.03
6 weeks	3.86	(0.13)	4.32[3]	(0.13)	0.47	0.10	0.83	0.01
12 weeks	4.54[2]	(0.09)	4.76[3]	(0.09)	0.22	-0.03	0.47	0.08
(time x treatment interaction)								0.18[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.04$) within PA group

Table 3.6c: A two-way table of Odds Ratios (ORs), 95%CIs and p-values to compare treatment arms at each time point. The ORs are obtained ordered logistic regression adjusting for "clustering" of repeated measures. The ORs are a common OR across the categories of the outcome estimating the odds of being graded at a higher level compared to a lower level.

Endpoint	Common odds ratio of having a higher grade compared to a lower grade and comparing the PA group to the DAA group			
Straight Leg Raise	OR	95%CI_LL	95%CI_UL	P-value
Baseline	1.02	0.42	2.46	0.97
2 weeks	2.74	1.15	6.52	0.02
6 weeks	3.23	1.26	8.23	0.01
12 weeks	2.16	0.80	5.81	0.13
(time x treatment interaction)				0.19

[1]P-value for the chi-square test of the time by treatment interaction

Table 3.6d: A two-way table of the number (%) of participants with Trendelenburg's Positive test in each treatment arm at each time point. Odds ratios (ORs) obtained from logistic regression (using generalised estimating equations) are used to compare the PA group to the DAA group at each time point, along with 95% confidence intervals and p-values.

Endpoint	DAA		PA		Odds Ratio (PA to DAA)			
Trendelenburg's +ve	n	(%)	n	(%)	OR	95%CI_LL	95%CI_UL	P-value
Baseline	9	(26)	10	(26)	1.03	0.36	2.96	0.95
2 weeks	21	(60)	22	(58)	0.92	0.36	2.35	0.86
6 weeks	4	(11)	4	(11)	0.92	0.21	4.07	0.91
12 weeks	1	(3)	3	(8)	2.92	0.28	30.33	0.37
(time x treatment interaction)								0.74[1]

[1]P-value for the Chi-square-test of the time by treatment interaction

Table 3.6e: A two-way table of the number (%) of participants with Trendelenburg's Positive test in each treatment arm at each time point. Risk ratios (RRs) obtained from binomial regression (using generalised estimating equations) is used to compare the PA group to the DAA group at each time point, along with 95% confidence intervals and p-values.

Endpoint	DAA		PA		Risk Ratio (PA to DAA)			
Trendelenburg's +ve	N	(%)	n	(%)	RR	95%CI_LL	95%CI_UL	P-value
Baseline	9	(26)	10	(26)	1.02	0.47	2.23	0.95
2 weeks	21	(60)	22	(58)	0.96	0.66	1.42	0.86
6 weeks	4	(11)	4	(11)	0.93	0.25	3.49	0.91
12 weeks	1	(3)	3	(8)	2.77	0.29	26.07	0.37
(time x treatment interaction)								0.76[1]

[1]P-value for the Chi-square-test of the time by treatment interaction

Table 3.6f: A two-way table of hip abductor power means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Hip Abduction Power	Mean	SEM	Mean	SEM	Difference	95%CI_LL	95%CI_UL	P-value
Baseline	3.86	(0.13)	3.76	(0.12)	-0.09	-0.44	0.25	0.59
2 weeks	3.23[2]	(0.14)	3.26[3]	(0.14)	0.03	-0.36	0.42	0.86
6 weeks	4.06	(0.12)	4.27[3]	(0.11)	0.21	-0.11	0.53	0.20
12 weeks	4.74[2]	(0.10)	4.65[3]	(0.09)	-0.09	-0.36	0.18	0.49
(time x treatment interaction)								0.12[1]

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.001$) within PA group

Table 3.6g: A two-way table of Odds Ratios (ORs), 95%CIs and p-values to compare treatment arms at each time point. The ORs are obtained using ordered logistic regression adjusting for "clustering" of repeated measures. The ORs are a common OR across the categories of the outcome estimating the odds of being graded at a higher level compared to a lower level.

Endpoint	Common odds ratio of having a higher grade compared to a lower grade and comparing the PA group to the DAA group			
Hip Abduction Power	OR	95%CI_LL	95%CI_UL	P-value
Baseline	0.78	0.34	1.76	0.55
2 weeks	1.15	0.47	2.83	0.76
6 weeks	1.80	0.71	4.55	0.22
12 weeks	0.75	0.25	2.29	0.61
(time x treatment interaction)				0.19

[1]P-value for the chi-square test of the time by treatment interaction

Gait Aids

94% of participants in the DAA group and 84% in the PA group did not require use of gait aids at baseline. This decreased to 14% and 18% 2 weeks post-operatively for the both the DAA and PA groups respectively. Gait aids used at this time were mostly Crutches x1 (DAA 40% and PA 45%) followed by Crutches x2 (DAA 37% and PA 29%). 6 weeks post-operatively 89% of the DAA group and 87% of the PA group did not require gait aids. Finally, at 12 weeks 97% of the DAA group and 100% of the PA group did not require gait aids. A single participant from the DAA group at 12 weeks still used a single crutch due to an episode of hip dislocation.

The OR of participants in the PA group requiring gait aids at baseline was 2 (P=0.36). At 2 weeks and 6 weeks this decreased to 0.74 (P=0.64) and 0.94 (P=0.93) respectively. The RR of participants in the PA group requiring gait aids was similar to that of the OR. There

were no statistically significant differences. Results showing utilisation of gait aids are found in Tables 3.8, 3.8a and 3.8b.

Table 3.8: A cross-tabulation of the types of gait aid used by treatment group, at each time point (frequencies and percentages will be given).

Timepoint	Groups	None	Single point stick	Crutchesx1	Crutches x2	Pick up frame	4 Wheel frame
Baseline	DAA	32(91%)	3 (9%)	0	0	0	0
	PA	32 (84%)	2 (5%)	0	2 (5%)	0	2 (5%)
2 weeks	DAA	5 (14%)	2 (6%)	14 (40%)	13 (37%)	1 (3%)	0
	PA	7 (18%)	0	17 (45%)	11 (29%)	2 (5%)	1 (3%)
6 weeks	DAA	31 (89%)	1 (3%)	3 (9%)	0	0	0
	PA	33 (87%)	0	3 (8%)	1 (3%)	0	1 (3%)
12 weeks	DAA	34 (97%)	1 (3%)	0	0	0	0
	PA	38 (100%)	0	0	0	0	0

Table 3.8a: Ancillary results: A two-way table of the number (%) of participants using Gait aids in each treatment arm at each time point. Odds ratios (ORs) obtained from logistic regression (using generalised estimating equations) are used to compare the PA group to the DAA group at each time point, along with 95% confidence intervals and p-values.

Endpoint	DAA		PA		Odds Ratio (PA to DAA)			
Use of Gait aids	n	(%)	n	(%)	OR	95%CI_LL	95%CI_UL	P-value
Baseline	3	(9)	6	(16)	2.00	0.46	8.79	0.36
2 weeks	30	(86)	31	(82)	0.74	0.21	2.61	0.64
6 weeks	4	(11)	4	(11)	0.94	0.21	4.11	0.93
12 weeks	1	(3)	0	(0)				
(time x treatment interaction)								<0.001[1]

[1]P-value for the Chi-squared test of the time by treatment interaction

Table 3.8b: Ancillary results: A two-way table of the number (%) of participants using Gait aids in each treatment arm at each time point. Risk ratios (RRs) obtained from binomial regression (using generalised estimating equations) are used to compare the PA group to the DAA group at each time point, along with 95% confidence intervals and p-values.

Endpoint	DAA		PA		Risk Ratio (PA to DAA)			
Use of Gait aids	n	(%)	n	(%)	RR	95%CI_LL	95%CI_UL	P-value
Baseline	3	(9)	6	(16)	1.84	0.49	6.87	0.36
2 weeks	30	(86)	31	(82)	0.95	0.78	1.17	0.64
6 weeks	4	(11)	4	(11)	0.94	0.25	3.51	0.93
12 weeks	1	(3)	0	(0)				
(time x treatment interaction)								<0.001[1]

[1]P-value for the Chi-squared test of the time by treatment interaction

Radiological Analysis

The mean acetabular inclination and anteversion of participants was 46° and 22.4°respectively. The mean acetabular inclination for the DAA group was 46.07° and for the PA group 45.86°. Mean acetabular anteversion was greater at 24.57° for the DAA group when compared to 20.34° for the PA group. This trended towards but did not achieve statistical significance. (P=0.06) The DAA group had 20(57%) outside of Lewinnek's safe zone versus 13(34%) for the PA group (P=0.06)

The mean femoral stem position was 1.37° varus. Post-operatively, femoral stem position was 1.09° and 1.62° varus for the DAA and PA groups respectively. At 6 weeks, the mean femoral stem position progressed to 1.43° and 2.04° for both DAA and PA groups. 10(29%) of stems in the DAA group and 11(30%) in the PA group was greater than 3° of varus. 5/35 (14%) of the DAA femoral stems had radiological evidence of subsidence of >3mm compared to 1/38 (3%) for the PA group (P=0.1). Analysis of stem subsidence identified 4/6(66%) of subsided stems were performed by Surgeon 2 in the DAA group. For Surgeon

1, one subsidence occurred in both groups. 4 out of 6 participants with stem subsidence were male. Patients with femoral stem subsidence were monitored closely. All subsiding stems stabilized and did not require revision. Overall there were no statistically significant results in radiological positioning of implants between the DAA and PA group. Radiological results are found in Tables 3.9a to 3.9c and Scatter Plots 3.9a to 3.9i below.

Table 3.9a: Radiological Analysis immediately after surgery and 6 weeks post-operatively

Radiological Analysis	DAA		PA		Risk Ratio (PA to DAA)			
	n	(%)[2]	n	(%)[3]	RR	95%CI_LL	95%CI_UL	P-value[1]
Acetabular Implant Inclination <30° or >50° Just after surgery	9	26	9	24	0.92	0.41	2.05	1.0
Acetabular Implant Inclination <30° or >50° At 6 weeks	11	31	8	22	0.69	0.31	1.51	0.43
Femoral Implant Alignment >3°varus Just after surgery	5	14	9	24	1.66	0.61	4.47	0.38
Femoral Implant Alignment >3°varus At 6 weeks	10	29	11	30	1.04	0.51	2.14	1.0
Acetabular Implants Outside Lewinnek Safe Zone At 6 weeks	20	57	13	34	0.60	0.35	1.01	0.06
0-6 week Stem Subsidence >3mm	5	14	1	3	0.19	0.02	1.54	0.10

[1]P-value based on Fisher's Exact test.
[2]Denominator is number in DAA group=35
[3]Denominator is number in PA group=38

Table 3.9b: Radiological Analysis just after surgery and at 6 weeks post-operative: continuous data

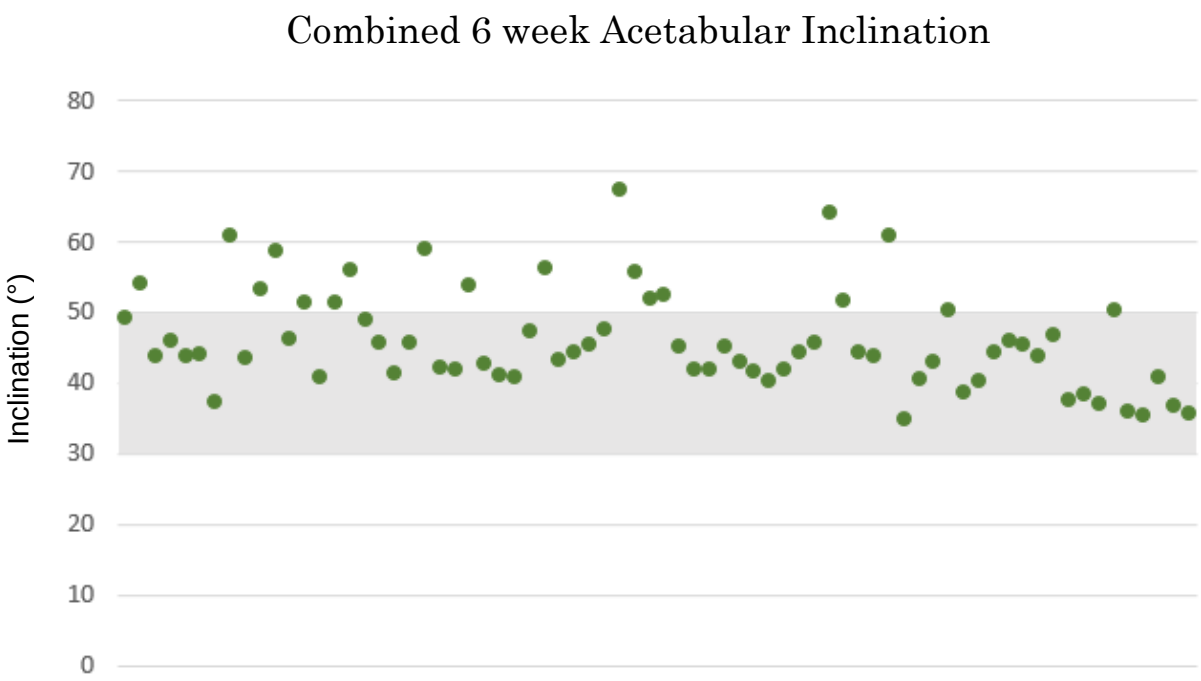
	DAA		PA		Difference (PA-DAA)			
	Mean	SD	Mean	SD	Difference	95%CI _LL	95%CI _UL	P-value[1]
Acetabular Inclination (°)	46.07	5.91	45.86	7.52	-0.20	-3.37	2.97	0.90
6 week Acetabular Inclination (°)	46.18	6.05	45.88	7.96	-0.30	-3.64	3.03	0.86
Femoral Stem Postion (Varus) (°)	-1.09	1.79	-1.62	2.38	-0.53	-1.52	0.46	0.29
6 week Femoral Stem Postion (°)	-1.43	2.55	-2.04	2.44	-0.61	-1.78	0.56	0.30
6 week Acetabular Anteversion (°)	24.57	8.78	20.34	10.17	-4.23	-8.68	0.22	0.06
Stem subsidence 6 weeks in mm[2]	0	(0,1)	0	(0,1)				0.26[3]

[1]P-value based on two sample t-test
[2] Median and Interquartile range given
[3] P-value based on Wilcoxon rank sum test

Table 3.9c: Femoral Stem Subsidence Data

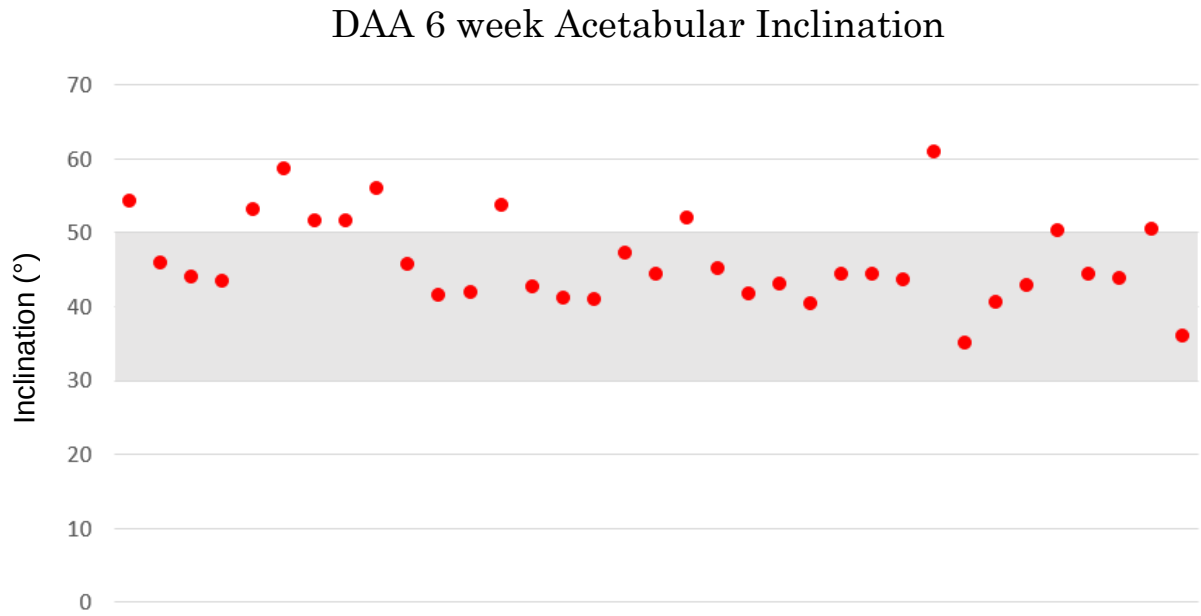
No of participants with femoral stem subsidence>3mm	Surgical Approach	Gender	Surgeon
1	DAA	Male	2
2	DAA	Female	2
3	DAA	Male	2
4	DAA	Female	2
5	PA	Male	1
6	DAA	Male	1

Scatter Plot 3.9a: Combined 6 week Acetabular Inclination



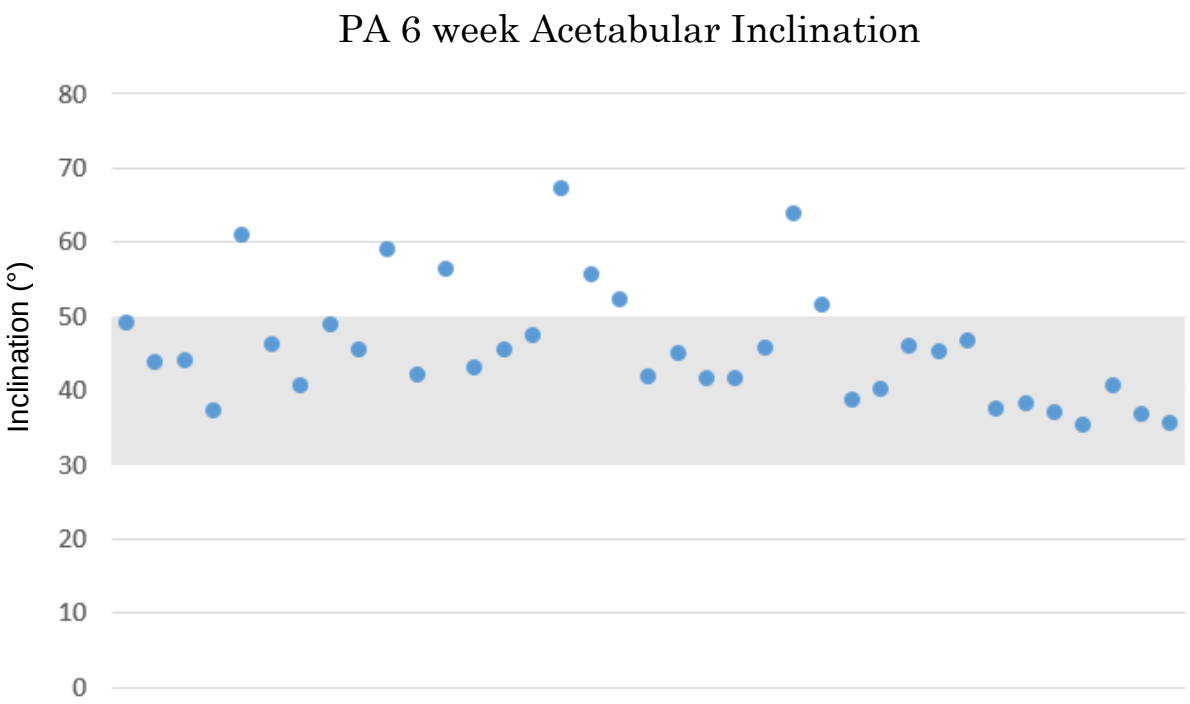
Grey area highlights Lewinnek's safe zone of 30° to 50° for acetabular inclination

Scatter Plot 3.9b: DAA 6 week Acetabular Inclination



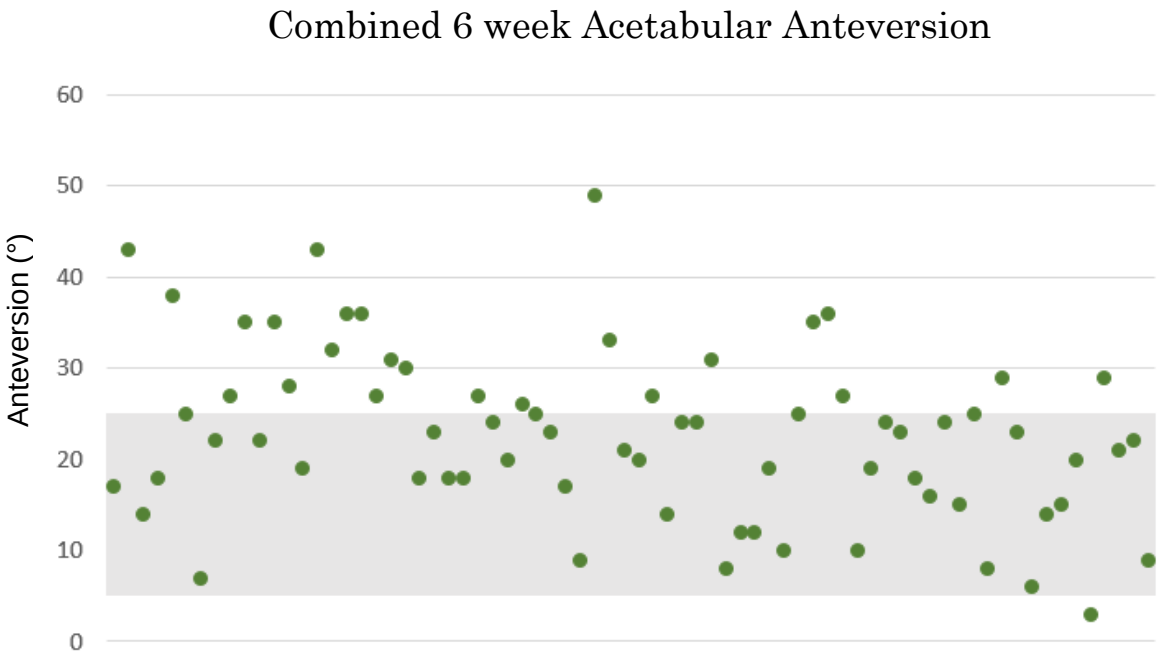
Grey area highlights Lewinnek's safe zone of 30° to 50° for acetabular inclination

Scatter Plot 3.9c: PA 6 week Acetabular Inclination



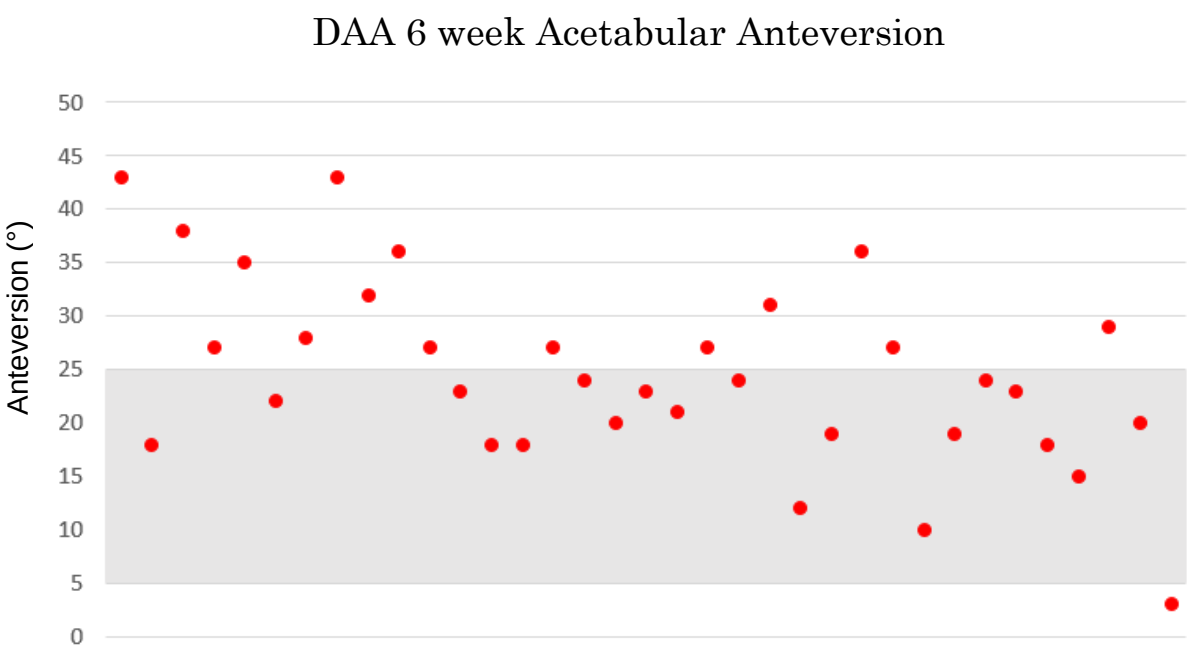
Grey area highlights Lewinnek's safe zone of 30° to 50° for acetabular inclination

Scatter Plot 3.9d: Combined 6 week Acetabular Anteversion



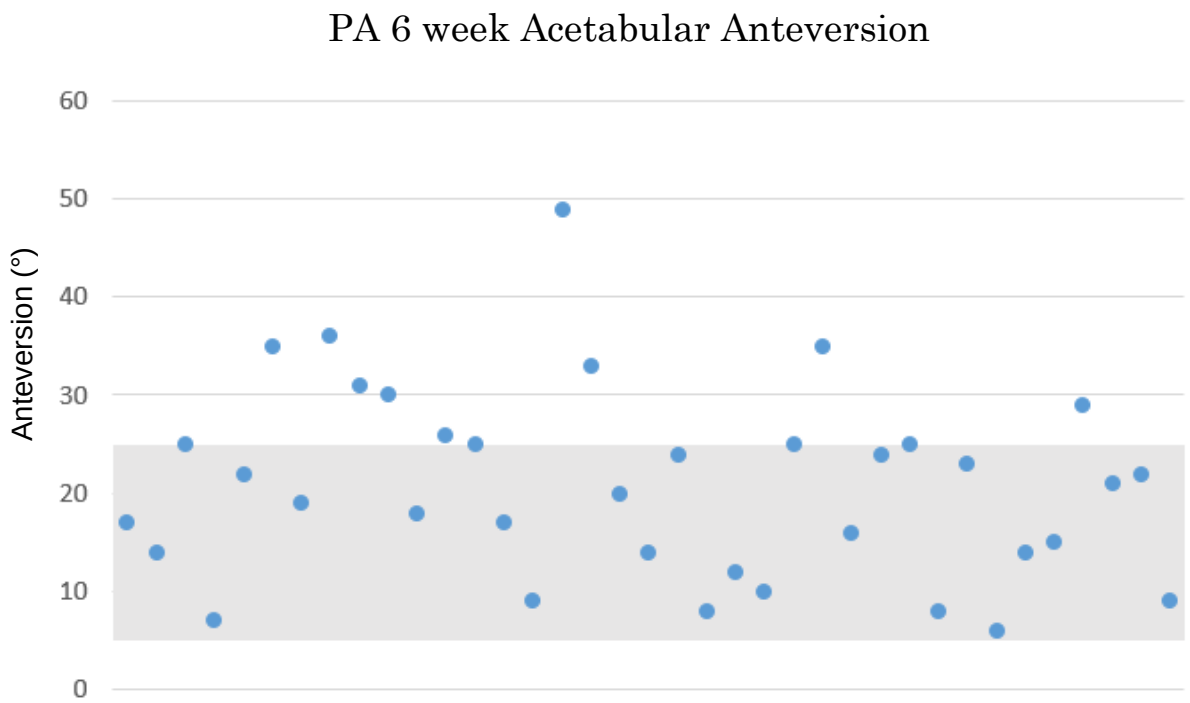
Grey area highlights Lewinnek's safe zone of 5° to 25° for acetabular anteversion

Scatter Plot 3.9e: DAA 6 week Acetabular Anteversion



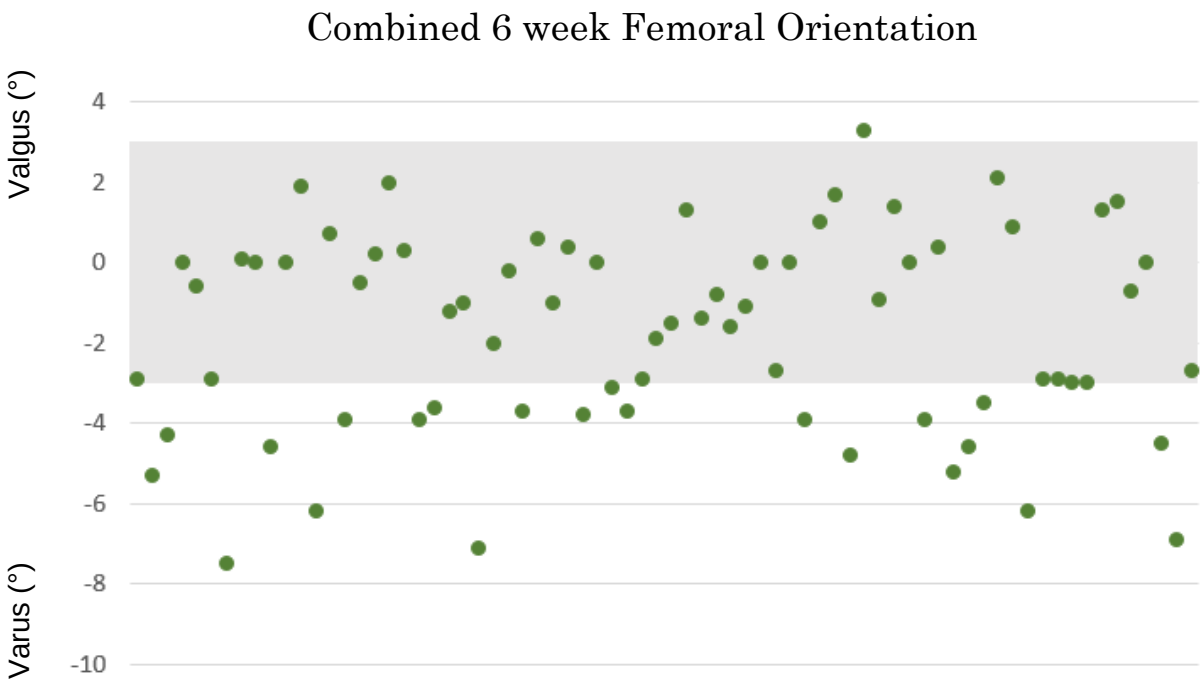
Grey area highlights Lewinnek's safe zone of 5° to 25° for acetabular anteversion

Scatter Plot 3.9f: PA 6 week Acetabular Anteversion



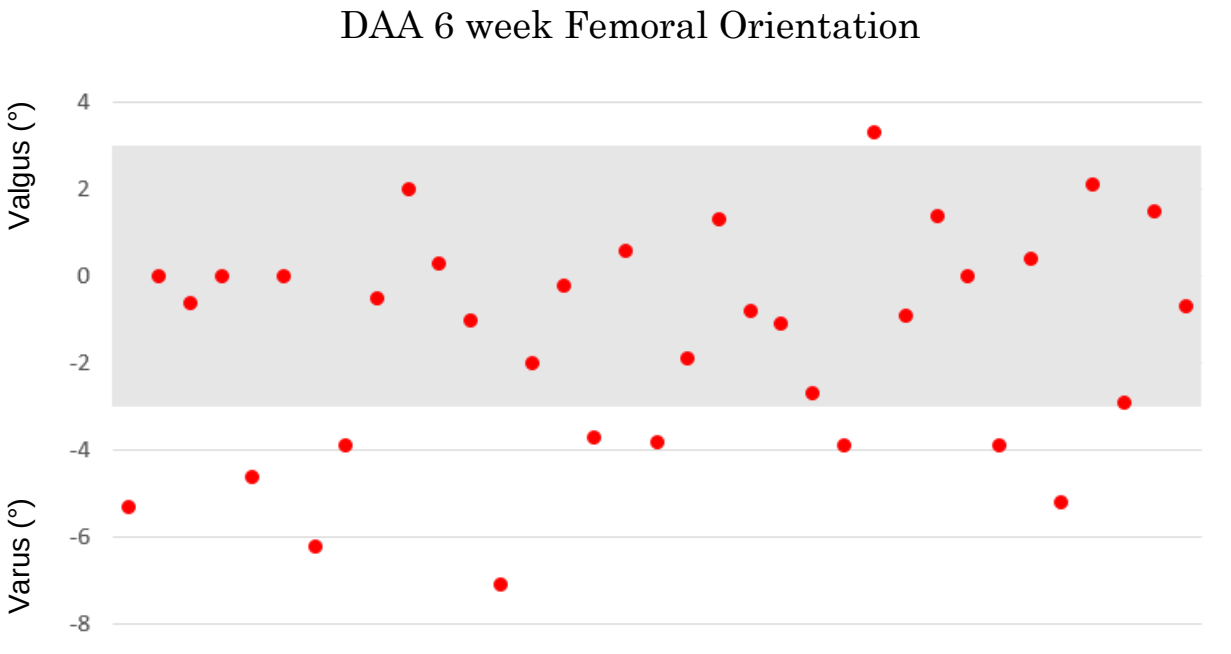
Grey area highlights Lewinnek's safe zone of 5° to 25° for acetabular anteversion

Scatter Plot 3.9g: Combined 6 week Femoral Orientation



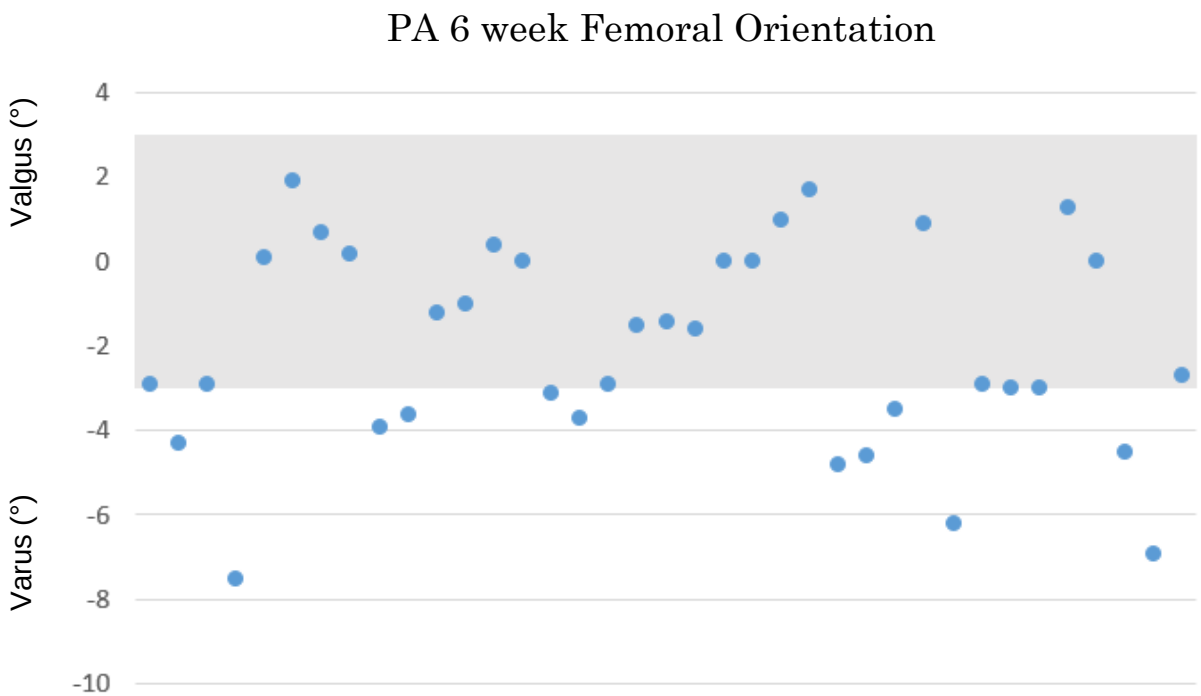
Grey area highlights the range of 3° varus to 3° valgus for the femoral stem relative to the canal

Scatter Plot 3.9h: DAA 6 week Femoral Orientation



Grey area highlights the range of 3° varus to 3° valgus for the femoral stem relative to the canal

Scatter Plot 3.9i: PA 6 week Femoral Orientation



Grey area highlights the range of 3° varus to 3° valgus for the femoral stem relative to the canal

Complications

Complications including LCNT Neuropraxia were significantly higher with the DAA group when compared to the PA group (86% versus 21% P<0.001). Without factoring in LCNT Neuropraxia, the complication rate was reduced to 11/35 (31%) compared to the PA 8/38 (21%) P=0.42) LCNT Neuropraxia was observed to occur in 83% of participants DAA group. A single dislocation occurred in both groups. Both dislocations were treated with closed reduction with no sequelae. 2 fractures were identified in the DAA group. The first was a Recognised intra-operative femoral perforation on broaching that was managed conservatively. The second was an asymptomatic partial fracture of the greater trochanter post-operatively at identified 6 weeks which was also managed conservatively. A single fracture occurred in the PA group. The participant sustained a Vancouver B2 peri-prosthetic femoral fracture as a result of a fall following a seizure 4 weeks post-operatively. This was revised to a long diaphyseal fitting stem.

A single participant in the DAA group had an unexpected return to theatre on the first post-operative day to correct a leg length discrepancy of 3cm. 3 participants from each group had wound problems that did not require surgical intervention. A single case of below knee DVT was recorded in the PA group. 5 cases (14%) of stem subsidence was reported in the DAA group compared to 1 in the PA group (P=0.1). One episode of trochanteric bursitis was identified in the PA group and treated with a cortisone injection. Two cases of iliopsoas tendonitis were documented in the follow up of the DAA group. There were no complications of heterotopic ossification or post-operative haematoma. A table summarising the complications is found below.

Table 3.10: Summary of Complications by treatment groups at 12 weeks.

Complication[4]	DAA		PA		Risk Ratio (PA to DAA)			
	n	(%)[2]	n	(%)[3]	RR	95%CI _LL	95%CI _UL	P-value[1]
Any complication	30	86	8	21	0.25	0.13	0.46	<0.001
Any Non-LCNT complication	11	31	8	21	0.67	0.31	1.47	0.42
Dislocation	1	3	1	3	0.92	0.06	14.17	>0.9
Fracture	2	6	1	3	0.46	0.04	4.86	0.60
Unplanned return to surgery	1	3	0	0	0			0.48
Non-operative wound	3	9	3	8	0.92	0.2	4.27	>0.9
LCNT	29	83	n/a					
DVT	0	0	1	3				>0.9
Implant migration	5	14	1	3	0.18	0.02	1.5	0.10
Bursitis	0	0	1	3				>0.9
Iliopsoas Tendonitis	2	6	0	0	0			0.23

[1]P-value based on Fisher's Exact test.
[2]Denominator is number in DAA group=35
[3]Denominator is number in PA group=38
[4]There were no complications of: heterotopic ossification, post-op fracture or haematoma.

Subgroup Analysis

Subgroup analysis was performed for primary and selected outcomes based on Surgeon (Site) and Age group (<65 and ≥65).

Surgeon 1

Surgeon 1 performed both DAA and PA THA on 54/73 (74%) of participants in the study at Site 1. 26/54(48%) of participants and 28/54 (52%) received both DAA THA and PA THA from Surgeon 1 respectively. Demographic data were similar for both DAA and PA groups. There was an equal proportion of males and females in each group (DAA 46% & PA 50% Male). The mean age of participants having THA surgery was 60.5years for the DAA group versus 62.5 years for the PA group. (P=0.74). The mean BMI for the DAA group was 27.5 versus 28.6 for the PA group (P=0.65).

There were minor but not statistically differences in ASA ratings and modalities of anaesthesia between both groups for Surgeon 1. The majority of participants in both groups were rated as ASA 1 or 2. The PA group had a higher number of ASA 3 participants compared to the DAA group (DAA 1 versus PA 5: P=0.22). In the DAA group, 54% of participants had a general anaesthetic, 19% had spinal anaesthetic and 27% had a combined anaesthetic. For the PA group 47% of participants had a general anaesthetic, 39% had a spinal anaesthetic and 14% had a combined anaesthetic (P=0.24).

Clinical parameters for Surgeon 1 shows that the DAA was associated with an increased operative time (119.5min versus 98.5min: P<0.001), smaller wound length (110.5mm versus 148mm: P<0.001) and higher blood loss (34.5g/L versus 30.0g/L: P=0.03). 3 participants from each group for Surgeon 1 required blood transfusions. For Surgeon 1, length of stay in hospital favoured the DAA group but unlike the combined results, this was statistically significant (DAA 76.5hours versus PA 100.5hours: P=0.04). 77% of the DAA group and 68% of the PA group were discharged home. The remaining participants were discharged to a rehabilitation facility following THA surgery. The duration of rehabilitation for DAA and PA groups were similar for Surgeon 1 (DAA 154.5hours versus PA 166: P=0.68). Factoring this in, the total length of stay in hospital was 98.5hours for the DAA group versus 104.5 hours for the PA group (P=0.11). Total and net analgesic usage was reduced in the DAA group compared to the PA group but unlike the combined surgeon results this was not significant (P=0.15 and P=0.44).

The WOMAC total scores remained similar to that of the combined total score. There was a statistical difference at baseline between the DAA and PA groups (63.15 versus 72.29: P=0.02). The DAA group had better scores than PA group at 2 week, 6 week and 12 week time points. However, this was not significant.

WOMAC pain scores reflected the statistically significant differences at baseline. DAA group participants gave a score of 12.96 compared with 14.86 for the PA group at baseline (P=0.05). Pain scores were similar at the 2 week time point (DAA 7.42 versus PA 7.89 P=0.70) and favoured the DAA at the 6 week (DAA 3.35 versus PA 4.06: P=0.42) and 12

week time points (DAA 1.62 versus PA 2.5: P=0.24). There were no statistical differences beyond baseline between both groups.

WOMAC motion scores for Surgeon 1 were similar at all time points between the DAA and PA groups. There were no statistically significant results.

WOMAC function scores reflected the total WOMAC scores for Surgeon 1. At baseline the DAA group had better function that was statistically significant (DAA 44.85 versus PA 51.39: P=0.02). At 2 weeks, the mean WOMAC function score favoured the DAA group but did not achieve statistical significance. (DAA 30.81 versus PA 35.79: P=0.17). At 6 weeks the DAA group continued to have better scores than the PA group that trended toward but did not achieve statistical significance (DAA 11.27 versus PA 16.48: P=0.07). At 12 weeks the differences of the mean between WOMAC function scores decreased to 3.7 between the DAA and PA groups. There were no statistical differences at this time point.

The Oxford Hip Scores affirms WOMAC results with the DAA group having better scores at baseline, 2 weeks, 6 weeks and 12 week time points with the only statistical significance observed at baseline (DAA 18.46 versus PA 14.07: P=0.01). Tables 3.11a to 3.11h of Surgeon 1's analysis is found below

Table 3.11a: Demographic characteristics of the participants by treatment group (Surgeon 1)

Characteristic	DAA Median(IQR)	PA Median(IQR)	P-value[3]
Gender[1] Male Female	 12 (46%) 14 (54%)	 14 (50%) 14 (50%)	0.79[2]
Age at surgery (years)	60.5 (55, 72)	62.5 (56.5, 68.5)	0.77
PreOp Height (cm)	170 (162, 177)	166 (163, 174)	0.40
PreOp Weight(kg)	81 (72, 87)	80.5 (65.5, 89)	0.94
PreOp BMI	27.5 (25.7, 29.9)	28.6 (23.8, 31.9)	0.65

[1]Frequency(%)
[2]P-value based on Fisher's Exact test.
[3]P-value based on Wilcoxon rank-sum test

Table 3.11b: Surgical characteristics of the participants by treatment group (Surgeon 1)

Characteristic	DAA Frequency (%)	PA Frequency (%)	P-value[1]
Side operated on Right Left	 15 (58%) 11 (42%)	 17 (61%) 11 (39%)	1.00
Anaesthetic General Spinal General, Spinal	 14 (54%) 5 (19%) 7 (27%)	 13 (47%) 11 (39%) 4 (14%)	0.24
Anaesthetic rating 1 2 3	 4 (15%) 21 (81%) 1 (4%)	 6 (21%) 17 (61%) 5 (18%)	0.22
Transfusion (No. packs) 0 1 2 3	 23 (88%) 1 (4%) 2 (8%) 0 (0%)	 25 (89%) 0 (0%) 2 (7%) 1 (4%)	0.9

[1]P-value based on Fisher's Exact test.

Table 3.11c: Summary of other safety outcomes by treatment group (Surgeon 1)

Clinical Parameters	DAA Median(IQR) (n=26)	PA Median(IQR) (n=28)	P-value[1]
Operative time(min)	119.5 (110.0, 133.0)	98.5 (89.5, 110.0)	<0.001
Wound length (mm)	110.5 (104.0, 125.0)	148.0 (132.0, 161.5)	<0.001
Haemoglobin Drop (g/L)	34.5 (29.0, 45.0)	30.0 (23.0, 36.0)	0.03
Length of stay in hospital (hours)	76.5 (73.0, 118.0)	100.5 (77.5, 121.0)	0.04
Total hospital stay (hours)	98.5 (74.0, 147.0)	102.5 (77.5, 206.0)	0.11
PostOp analgesia (morphine/mg) TOTAL	256.8 (218.3, 476.2)	353.8 (271.3, 543.8)	0.15
PostOp analgesia (morphine/mg) NET	241.3 (190.0, 415.0)	303.3 (187.5, 436.9)	0.44
Discharge to[3] rehabilitation Home Rehab Centre	 20 (77%) 6 (23%)	 19 (68%) 9 (32%)	 0.55
Rehab stay duration (hours)	154.5 (72.0, 169.0)	166.0 (95.0, 189.0)	0.68

[1]P-value based on Wilcoxon rank-sum test
[2]P-value based on Fisher's Exact test.
[3]Frequency(%)

Table 3.11d: Primary outcome results: A two-way table of predicted WOMAC means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 1) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Total score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	63.15	(2.84)	72.29	(2.74)	9.13	1.21	17.05	0.02
2 weeks	41.69[2]	(3.68)	47.46[3]	(3.54)	5.77	-4.47	16.01	0.26
6 weeks	16.77[2]	(2.77)	22.66[3]	(2.70)	5.89	-1.88	13.67	0.13
12 weeks	8.04[2]	(2.38)	13.09[3]	(2.32)	5.05	-1.63	11.73	0.14
(time x treatment interaction)								0.84

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.11e: A two-way table of predicted WOMAC Pain score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 1) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Pain score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	12.96	(0.68)	14.86	(0.65)	1.9	0.01	3.78	0.05
2 weeks	7.42[2]	(0.89)	7.89[3]	(0.85)	0.47	-2.00	2.94	0.70
6 weeks	3.35[2]	(0.64)	4.06[3]	(0.62)	0.72	-1.06	2.50	0.42
12 weeks	1.62[2]	(0.54)	2.50[3]	(0.52)	0.88	-0.62	2.39	0.24
(time x treatment interaction)								0.73

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.11f: A two-way table of predicted WOMAC Motion score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 1) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Motion score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	5.35	(0.36)	6.04	(0.35)	0.69	-0.32	1.70	0.18
2 weeks	3.46[2]	(0.41)	3.79[3]	(0.39)	0.32	-0.81	1.46	0.57
6 weeks	2.15[2]	(0.32)	2.12[3]	(0.31)	-0.03	-0.93	0.87	0.94
12 weeks	1.27[2]	(0.30)	1.72[3]	(0.30)	0.45	-0.40	1.30	0.29
(time x treatment interaction)								0.51

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.11g: A two-way table of predicted WOMAC Function score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 1) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Function score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	44.85	(2.03)	51.39	(1.96)	6.55	0.88	12.21	0.02
2 weeks	30.81[2]	(2.60)	35.79[3]	(2.51)	4.98	-2.27	12.22	0.17
6 weeks	11.27[2]	(2.01)	16.48[3]	(1.96)	5.21	-0.42	10.85	0.07
12 weeks	5.15[2]	(1.63)	8.85[3]	(1.59)	3.70	-0.86	8.25	0.11
(time x treatment interaction)								0.70

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.11h: Primary outcome results: A two-way table of predicted OHS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 1) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Oxford12 Item Score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	18.46	(1.22)	14.07	(1.18)	-4.39	-7.79	-0.99	0.01
2 weeks	27.27[2]	(1.96)	25.93[3]	(1.89)	-1.34	-6.81	4.12	0.62
6 weeks	40.31[2]	(1.31)	37.12[3]	(1.28)	-3.19	-6.87	0.48	0.09
12 weeks	44.50[2]	(0.97)	42.87[3]	(0.95)	-1.63	-4.35	1.09	0.24
(time x treatment interaction)								0.17

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Surgeon 2

Surgeon 2 performed both DAA and PA THA on 19/73 (26%) of participants in the study at Site 2. 9/19(47%) of participants and 10/19 (53%) received both DAA THA and PA THA from Surgeon 2 respectively. The gender and BMI demographics for both DAA and PA group participants were similar for Surgeon 2. Approximately 60% of participants in both groups were female and the mean BMI was 28 (P=1 & 0.81 respectively). Participants in the DAA group were younger than the PA group (DAA 55 years versus PA 61 years: P=0.75). The ASA rating and mode of anaesthesia was similar between both groups. Approximately 60% of participants from both groups had THA surgery performed under spinal anaesthetic and 40% under general anaesthetic. Only a single participant in the DAA group received a combined anaesthetic. Most participants for Surgeon 2 had an ASA of 2 (7 in DAA and PA groups). One participant in the DAA group had an ASA rating of 1 and 3 each while 3 participants had an ASA rating of 1 in the PA group. There were no participants who was rated ASA 3 in the PA group.

Clinical parameters for Surgeon 2 shows that the DAA group had increased operative time (135min versus 114min: P=0.054) but this was not statistically significant. The only significant clinical parameter was a smaller wound length (79mm versus 125mm: P<0.001). Blood loss was similar between both groups (DAA 35g/L versus PA 35.5g/L: P=0.84). No participants for Surgeon 2 required blood transfusions. Length of stay in hospital favoured the PA group slightly (PA 76.5hours versus DAA 80hours: P=0.25). 100% of the DAA group and 90% of the PA group were discharged home with a single PA participant discharged to a rehabilitation facility following THA surgery. Counting the single participant's rehabilitation stay, the total length of stay in hospital was 80hours for

the DAA group versus 77 hours for the PA group (P=0.57). Total and net analgesic usage was reduced in the DAA group compared to the PA group. The DAA group utilised a total mean of 325mg of oral morphine in 2 weeks compared to 530mg in the PA group (P=0.072). The net usage of opiate analgesics was similar and not statistically significant.

The WOMAC total scores unlike the combined surgeon score did not demonstrate statistical significance at baseline (DAA 62.44 versus PA 68.1: P=0.42). The DAA group had comparable scores with the PA group at 2 week and 12 week time points. At the 6 week time point, the PA group reported better total WOMAC scores than the DAA group but this was not significant (PA 20.3 versus DAA 26.3: P=0.39)

WOMAC pain scores were similar at baseline, 2 weeks and 12 week time points. At baseline the DAA group scored 13.3 and the PA group scored 14 (P=0.67). At the 2 week time point the DAA group scored 7.56 and the PA group scored 6.5 (P=0.49). At the 12 week time point the DAA group scored 2.11 against PA group score of 1.9 (P=0.89). At the 6 week time point PA group participants reported better pain scores that were not statistically significant (PA2.8 versus DAA 5.22: P= 0.12) There were no statistical differences at any time point between both groups.

WOMAC motion scores for Surgeon 2 were similar at all time points between the DAA and PA groups. There were no statistically significant results.

WOMAC function scores were mildly better at baseline for the DAA group (DAA 43.44 versus PA 47.8: P=0.38). At 2 weeks and 12 weeks, the mean WOMAC function scores were similar between both groups. (2 weeks - DAA 25.89 versus PA 26.7: P=0.87, 12 weeks – DAA 8.33 versus PA 8.2: P=0.98). At 6 weeks the PA group had better scores than the DAA group that was not statistically significant (PA 15.7 versus DAA 18.11: P=0.63).

The Oxford Hip Scores for Surgeon 2 bears the closest resemblance to the combined results. OHS scores were better for the DAA group at baseline and 2 weeks post-operatively (Baseline – DAA 20.78 versus 15.5: P=0.07, 2 weeks DAA 32.22 versus PA 29.4: P=0.33). 6 weeks and 12 week results were comparable between DAA and PA groups. There were no statistically significant differences in the OHS domain. Tables 3.12a to 3.12h of Surgeon 2's analysis is found below

Table 3.12a: Demographic characteristics of the participants by treatment group (Surgeon 2)

Characteristic	DAA Median(IQR)	PA Median(IQR)	P-value[3]
Gender[1] Male Female	 3 (33%) 6 (67%)	 4 (40%) 6 (60%)	 1.00[2]
Age at surgery (years)	55.0 (50, 66)	61 (47, 69)	0.75
PreOp Height (cm)	167 (159.5, 172)	164 (160, 177)	0.8
PreOp Weight(kg)	80 (71, 86)	82.5 (69, 95)	0.54
PreOp BMI	28 (26.1, 30.0)	27.8 (25.9, 30.3)	0.81

[1]Frequency(%)
[2]P-value based on Fisher's Exact test.
[3]P-value based on Wilcoxon rank-sum test

Table 3.12b: Surgical characteristics of the participants by treatment group (Surgeon 2)

Characteristic	DAA Frequency (%)	PA Frequency (%)	P-value[1]
Side operated on Right Left	 5 (56%) 4 (44%)	 7 (70%) 3 (30%)	 0.65
Anaesthetic General Spinal General, Spinal	 3 (33%) 5 (56%) 1 (11%)	 4 (40%) 6 (60%) 0 (0%)	 1.00
Anaesthetic rating 1 2 3	 1 (11%) 7 (78%) 1 (11%)	 3 (30%) 7 (70%) 0 (0%)	 0.58
Transfusion (No. packs) 0 1 2 3	 9 (100%) 0 (0%) 0 (0%) 0 (0%)	 10 (100%) 0 (0%) 0 (0%) 0 (0%)	

[1]P-value based on Fisher's Exact test.

Table 3.12c: Summary of other safety outcomes by treatment group (Surgeon 2)

Clinical Parameters	DAA Median(IQR) (n=9)	PA Median(IQR) (n=10)	P-value[1]
Operative time(min)	135.0 (125.0, 145.0)	114.0 (100.0, 135.0)	0.054
Wound length (mm)	79.0 (74.0, 90.0)	125.0 (114.0, 135.0)	<0.001
Haemoglobin Drop (g/L)	35.0 (31.0, 37.0)	35.5 (27.0, 37.0)	0.84
Length of stay in hospital (hours)	80.0 (76.0, 100.0)	76.5 (75.0, 77.0)	0.25
Total hospital stay (hours)	80.0 (76.0, 100.0)	77.0 (75.0, 79.0)	0.57
PostOp analgesia (morphine/mg) TOTAL	325.0 (180.0, 385.0)	530.0 (477.5, 667.5)	0.072
PostOp analgesia (morphine/mg) NET	185.0 (175.0, 385.0)	500.0 (195.0, 565.0)	0.19
Discharge to[3] rehabilitation Home Rehab Centre	 9 (100%) (0%)	 9 (90%) 1 (10%)	 1.00

[1]P-value based on Wilcoxon rank-sum test
[2]P-value based on Fisher's Exact test.
[3]Frequency(%)

Table 3.12d: Primary outcome results: A two-way table of predicted WOMAC means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 2) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Total score	Mean	SEM	Mean	SEM	Difference	95%CI_LL	95%CI_UL	P-value
Baseline	62.44	(5.02)	68.1	(4.77)	5.66	-8.24	19.56	0.42
2 weeks	36.44[2]	(5.02)	36.1[3]	(4.77)	-0.34	-14.24	13.56	0.96
6 weeks	26.33[2]	(5.02)	20.3[3]	(4.77)	-6.03	-19.93	7.87	0.39
12 weeks	12.22[2]	(5.02)	12.2[3]	(4.77)	-0.02	-13.92	13.88	0.99
(time x treatment interaction)								0.63

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0002$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.12e: A two-way table of predicted WOMAC Pain score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 2) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Pain score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	13.33	(1.11)	14	(1.05)	0.67	-2.41	3.74	0.67
2 weeks	7.56[2]	(1.11)	6.5[3]	(1.05)	-1.06	-4.13	2.02	0.49
6 weeks	5.22[2]	(1.11)	2.8[3]	(1.05)	-2.42	-5.50	0.65	0.12
12 weeks	2.11[2]	(1.11)	1.9[3]	(1.05)	-0.21	-3.29	2.86	0.89
(time x treatment interaction)								0.46

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.12f: A two-way table of predicted WOMAC Motion score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 2) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Motion score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	5.67	(0.54)	6.30	(0.51)	0.63	-0.86	2.12	0.40
2 weeks	3.00[2]	(0.54)	2.90[3]	(0.51)	-0.10	-1.59	1.39	0.89
6 weeks	3.00[2]	(0.54)	1.80[3]	(0.51)	-1.20	-2.69	0.29	0.11
12 weeks	1.78[2]	(0.54)	2.10[3]	(0.51)	0.32	-1.17	1.81	0.67
(time x treatment interaction)								0.29

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.12g: A two-way table of predicted WOMAC Function score means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 2) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Function score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	43.44	(3.59)	47.8	(3.41)	4.36	-5.58	14.30	0.38
2 weeks	25.89[2]	(3.59)	26.7[3]	(3.41)	0.81	-9.13	10.75	0.87
6 weeks	18.11[2]	(3.59)	15.7[3]	(3.41)	-2.41	-12.35	7.53	0.63
12 weeks	8.33[2]	(3.59)	8.20[3]	(3.41)	-0.13	-10.07	9.81	0.98
(time x treatment interaction)								0.75

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.12h: Primary outcome results: A two-way table of predicted OHS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. (Surgeon 2) Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Oxford12 Item Score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	20.78	(2.07)	15.5	(1.97)	-5.28	-11.02	0.46	0.07
2 weeks	32.22[2]	(2.07)	29.4[3]	(1.97)	-2.82	-8.56	2.92	0.33
6 weeks	38.22[2]	(2.07)	37.8[3]	(1.97)	-0.42	-6.16	5.32	0.88
12 weeks	41.78[2]	(2.07)	42.4[3]	(1.97)	0.62	-5.12	6.36	0.83
(time x treatment interaction)								0.42

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Age <65 years

44 participants were younger than 65 years at time of DAA and PA THA surgery. Surgeon 1 performed 16 DAA and PA surgeries (n=32) on participants under 65 years of age. Surgeon 2 performed 6 DAA and PA surgeries (n=12) on participants under 65 years of age. All 44 participants under 65 years of age were randomised equally into DAA and PA groups.

The DAA group had a slightly higher proportion of males than females 59% versus 50% for PA (P=0.76). The mean age & BMI were similar between both groups (Age - DAA 55 versus PA 56.5: P=0.42, BMI- DAA 27.7 versus PA 28.3: P=0.78). Participants under 65 years of age had similar ASA ratings in both groups. Approximately 75% had an ASA rating of 2, 20% had an ASA rating of 1 and 5% had an ASA rating of 3. The mode of anaesthesia differed slightly between both groups with more participants having a combined anaesthetic in the DAA group. For participants in the DAA group, 50% received general anaesthetic, 23% received a spinal and 27% received a combined anaesthetic. 45% of PA group participants had a general anaesthetic, 45% had a spinal anaesthetic and 10% received a combined anaesthetic (P=0.16).

Surgical time was significantly longer for DAA group (DAA 134min versus PA 111.5min: P=0.002). The DAA group also had significantly smaller wound length than the PA group (DAA 110mm versus 132mm: P<0.001). The PA group had less operative bleeding than the DAA group that trended towards but was not statistically significant (DAA 36g/L versus PA 31g/L: P=0.051). Two participants from each group received blood transfusions. Length of hospital stay and total length of stay were similar for both groups. Analgesic

usage in oral morphine equivalents was less in the DAA group but this was not significant (DAA 332.5mg versus PA 376.3: P=0.20). The number of participants and duration of rehabilitation between both groups had no statistical difference. Two (9%) DAA group participants and four (18%) PA group participants under 65 years of age required rehabilitation (P=0.66). Length of stay in rehabilitation was longer for DAA participants compared with PA participants (DAA 214.5hours versus 166hours: P=0.35)

For participants under 65 years of age, WOMAC total scores at baseline and 2 weeks favoured the DAA group minimally with no statistical differences observed (DAA 65.09 versus PA 68.77: P=0.42 at baseline, DAA 43.27 versus PA 45.77: P=0.63 at 2 weeks). At 6 and 12 weeks, the DAA group reported lower WOMAC scores with a larger difference compared with the PA group. However, results were not statistically significant. (DAA 17.45 versus PA 22.73: P=0.20 at 6 weeks, DAA 7.09 versus PA 12.47: P=0.15 at 12 weeks).

Pain and motion domain scores were similar for both DAA and PA groups for participants under 65 years of age at all time points. There were no specific trends favouring either group. WOMAC function scores for the DAA group under 65 years of age were generally better than that of the PA group at all time points. Although there were no statistically significant results, the biggest difference was observed at the 6week time point with the DAA group mean score of 11.32 versus the PA group 16.71 (P=0.07).

OHS means scores of the DAA group was generally better at all time points by approximately 2 points. There were no statistically significant findings between both DAA and PA groups for participants under 65 years of age. Tables 3.13a to 3.13h containing the analysis for participants <65 years can be found below

Table 3.13a: Demographic characteristics of the participants by treatment group (<65 years)

Characteristic	DAA Median(IQR)	PA Median(IQR)	P-value[3]
Gender[1] Male Female	 13 (59%) 9 (41%)	 11 (50%) 11 (50%)	0.76[2]
Age at surgery (years)	55.0 (50, 59)	56.5 (51, 61)	0.42
PreOp Height (cm)	172 (167, 177)	170 (162, 176)	0.65
PreOp Weight(kg)	82 (74, 90)	80.5 (69, 95)	0.92
PreOp BMI	27.7 (26.1, 30.3)	28.3 (25.9, 30.9)	0.78

[1]Frequency(%)
[2]P-value based on Fisher's Exact test.
[3]P-value based on Wilcoxon rank-sum test

Table 3.13b: Surgical characteristics of the participants by treatment group (<65 years)

Characteristic	DAA Frequency (%)	PA Frequency (%)	P-value[1]
Side operated on Right Left	 8 (36%) 14 (64%)	 13 (59%) 9 (41%)	0.23
Anaesthetic General Spinal General, Spinal	 11 (50%) 5 (23%) 6 (27%)	 10 (45%) 10 (45%) 2 (10%)	0.16
Anaesthetic rating 1 2 3	 4 (18%) 17 (77%) 1 (5%)	 5 (23%) 16 (73%) 1 (5%)	1.00
Transfusion (No. packs) 0 1 2 3	 20 (91%) 0 (0%) 2 (9%) 0 (0%)	 20 (91%) 0 (0%) 2 (9%) 0 (0%)	1.00

[1]P-value based on Fisher's Exact test.

Table 3.13c: Summary of other safety outcomes by treatment group (<65 years)

Clinical Parameters	DAA Median(IQR)	PA Median(IQR)	P-value[1]
Operative time(mins)	134 (118, 145)	111.5 (94, 124)	0.002
Wound length (mm)	110 (88, 115)	132 (125, 150)	<0.001
Haemoglobin Drop (g/L)	36 (29, 45)	31 (25, 37)	0.051
Length of stay in hospital (hours)	76.5 (73, 119)	79 (76, 102)	0.28
Total hospital stay (hours)	86 (73, 122)	88 (76, 151)	0.21
PostOp analgesia (morphine/mg) TOTAL	332.5 (218.3, 480)	376.3 (286, 565)	0.20
PostOp analgesia (morphine/mg) NET	253.1 (185, 385)	328 (202.5, 552.5)	0.34
Discharge to[3] rehabilitation Home Rehab Centre	 20 (91%) 2 (9%)	 18 (82%) 4 (18%)	 0.66
Rehab stay duration (hours)	214.5 (169, 260)	166 (129.5, 215)	0.35

[2]P-value based on Fisher's Exact test.
[3]Frequency(%)

Table 3.13d: A two-way table of predicted WOMAC means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point <65 years. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Total score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	65.09	3.26	68.77	3.26	3.68	-5.35	12.72	0.42
2 weeks	43.27	3.67	45.77	3.67	2.50	-7.69	12.69	0.63
6 weeks	17.45	2.88	22.73	2.93	5.27	-2.78	13.33	0.20
12 weeks	7.09	2.61	12.47	2.67	5.38	-1.94	12.69	0.15
(time x treatment interaction)								0.95

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Table 3.13e: WOMAC Pain score <65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Pain score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	13.45	0.77	13.95	0.77	0.50	-1.64	2.64	0.65
2 weeks	8.23	0.86	7.68	0.86	-0.55	-2.94	1.85	0.66
6 weeks	4.05	0.66	3.71	0.67	-0.34	-2.17	1.50	0.72
12 weeks	1.36	0.54	2.23	0.55	0.87	-0.65	2.38	0.26
(time x treatment interaction)								0.49

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.13f: WOMAC Motion score <65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Motion score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	5.73	0.37	5.95	0.37	0.23	-0.79	1.24	0.66
2 weeks	3.55	0.37	3.86	0.37	0.32	-0.69	1.33	0.54
6 weeks	2.09	0.37	2.35	0.37	0.26	-0.77	1.28	0.62
12 weeks	1.14	0.37	1.92	0.37	0.78	-0.24	1.81	0.13
(time x treatment interaction)								0.78

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.13g: WOMAC Function score <65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Function score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	45.91	2.32	48.86	2.32	2.95	-3.47	9.38	0.37
2 weeks	31.50	2.66	34.23	2.66	2.73	-4.65	10.11	0.47
6 weeks	11.32	2.07	16.71	2.11	5.39	-0.41	11.19	0.07
12 weeks	4.59	1.82	8.31	1.85	3.72	-1.37	8.81	0.15
(time x treatment interaction)								0.80

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.13h: OHS <65 years Primary outcome results: A two-way table of predicted OHS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Oxford12 Item Score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	17.45	1.35	14.95	1.35	-2.50	-6.24	1.24	0.19
2 weeks	27.32	2.06	25.73	2.06	-1.59	-7.29	4.11	0.58
6 weeks	39.73	1.24	37.12	1.27	-2.60	-6.08	0.87	0.14
12 weeks	44.05	1.12	42.62	1.15	-1.42	-4.57	1.72	0.38
(time x treatment interaction)								0.81

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline ($p \leq 0.0001$) within DAA group
[3] Means are significantly different from baseline ($p \leq 0.0001$) within PA group

Age ≥ 65 years

29 participants were older than 65 years at the time of DAA and PA THA surgery. Surgeon 1 performed 10 DAA surgeries and 12 PA surgeries on participants over 65 years of age. Surgeon 2 performed 3 DAA surgeries and 4 PA surgeries on participants over 65 years of age. A total of 13 and 16 participants over 65 years of age received DAA and PA surgery respectively.

For participants over 65 years of age, the DAA group had a higher proportion of female participants 85% versus 56% (P=0.13). DAA group participants were slightly older than PA participants. (Age - DAA 72years versus PA 69.5: P=0.38). BMI characteristics were similar between both groups (DAA 27.3 versus PA 28.3: P=0.69).

The modality of anaesthesia was similar between both groups. Between 84 and 90% of participants received either a general or spinal anaesthetic. 2 participants from each group had combined anaesthetics for THA surgery. The PA group had more participants with ASA ratings of 1 and 3 compared to the DAA group. Participants in the DAA group were rated to have an ASA of 1(8%), 2(88%) and 3(8%) while the PA group was rated to have an ASA of 1(25%), 2(50%) and 3(25%) (P=0.22).

Mean operative time was significantly longer for the DAA group than the PA group (DAA 119min versus PA 110mins: P<0.001). Wound length was significantly smaller for the DAA group than the PA group (DAA 104mm versus 146.5mm: P<0.001). Participants in the DAA group had a haemoglobin drop of 33g/L versus the PA group 29g/L (P=0.54). One participant from each group required a blood transfusion. Length of stay favoured the DAA group but this was not significant (DAA 80hours versus PA 100hours: P=0.24) The DAA group had less total post-operative opiate analgesic usage than the PA group. This trended towards but was not statistically significant. (DAA 240mg versus PA 461.3: P=0.066). Four (31%) and six (38%) of participants from the DAA and PA groups required rehabilitation (P=1). There was no statistical difference between the lengths of rehabilitation between both groups (DAA 106.5hours versus PA 177hours: P=0.16).

WOMAC total scores for participants over 65 years of age favoured the DAA group significantly at baseline (DAA 59.38 versus PA 74.50: P=0.01). Following surgery, the difference between the two groups gradually disappeared. At 2 weeks the DAA group scored 35.38 versus the PA 42.69 (P=0.30). At 6 weeks the PA group reported better

symptoms (PA 20.88 versus DAA 22.23: P=0.83). At 12 weeks results for both groups were similar (DAA 12.54 versus PA 13.19: P=0.89).

WOMAC pain scores differed at baseline significantly in favour of the DAA group (DAA 12.98 versus PA 15.56: P=0.01). At the 2week, 6 week and 12 week post-operative time points, there were minimal variation between both DAA and PA groups.

WOMAC motion scores diverged significantly at baseline in favouring the DAA group. (DAA 4.92 versus PA 6.31: P=0.04). At 2 weeks results were similar. However, at 6 weeks and 12 weeks, the WOMAC motion scores had a non-significant swing in favour of the PA group. (PA 1.63 versus DAA 2.85: P =0.06 at 6 weeks and PA 1.69 versus DAA 1.85: P=0.81 at 12 weeks)

Function scores again favoured the DAA group significantly at baseline (DAA 42.08 versus 52.63: P=0.01). This continued 2 weeks post-operatively with the DAA group scoring 26.23 versus the PA group 32.25 but this was no longer significant(P=0.23). At the 6 week and 12 week time points, results were comparable between both groups.

OHS scores for participants over 65 years of age reflected the statistically significant differences at baseline in favour of the DAA group (DAA 21.77 versus PA 13.75: P<0.001). Further dissimilarities between both groups at later time points were small and

not statistically significant. Tables 3.14a to 3.14h containing the analysis for participants ≥65 years can be found below

Table 3.14a: Demographic characteristics of the participants by treatment group (≥65 years)

Characteristic	DAA Median(IQR)	PA Median(IQR)	P-value[3]
Gender[1] Male Female	 2 (15%) 11 (85%)	 7 (44%) 9 (56%)	0.13[2]
Age at surgery (years)	72.0 (69, 72)	69.5 (67, 72)	0.38
PreOp Height (cm)	164.5 (162, 170)	165 (162, 167.5)	0.98
PreOp Weight(kg)	76.5 (69, 83)	82 (61, 89)	0.83
PreOp BMI	27.3 (25.7, 29.1)	28.2 (24, 32.1)	0.69

[1]Frequency (%)
[2]P-value based on Fisher's Exact test.
[3]P-value based on Wilcoxon rank-sum test

Table 3.14b: Surgical characteristics of the participants by treatment group (≥65 years)

Characteristic	DAA Frequency (%)	PA Frequency (%)	P-value[1]
Side operated on Right Left	 12 (92%) 1 (8%)	 11 (69%) 5 (31%)	0.18
Anaesthetic General Spinal General, Spinal	 6 (46%) 5 (39%) 2 (15%)	 7 (44%) 7 (44%) 2 (12%)	1.00
Anaesthetic rating 1 2 3	 1 (8%) 11 (85%) 1 (8%)	 4 (25%) 8 (50%) 4 (25%)	0.22
Transfusion (No. packs) 0 1 2 3	 12 (92%) 1 (8%) 0 (0%) 0 (0%)	 15 (94%) 0 (0%) 0 (0%) 1 (6%)	0.7

[1]P-value based on Fisher's Exact test.

Table 3.14c: Summary of other safety outcomes by treatment group (≥65 years)

Clinical Parameters	DAA Median(IQR)	PA Median(IQR)	P-value[1]
Operative time(mins)	119 (104, 125)	100 (86.5, 103.5)	<0.001
Wound length (mm)	104 (90, 122)	146.5 (132, 167)	<0.001
Haemoglobin Drop (g/L)	33 (29, 37)	29 (23.5, 36.5)	0.54
Length of stay in hospital (hours)	80(74, 102)	100 (76.5, 122)	0.24
Total hospital stay (hours)	99 (76, 189)	102.5 (76.5, 240)	0.46
PostOp analgesia (morphine/mg) TOTAL	240 (180, 415)	461.3 (259.8, 569.4)	0.066
PostOp analgesia (morphine/mg) NET	227.5 (175, 415)	328.8 (183.8, 491.3)	0.38
Discharge to[3] rehabilitation Home Rehab Centre	 9 (69%) 4 (31%)	 10 (63%) 6 (38%)	 1
Rehab stay duration (hours)	106.5 (71.5, 154.5)	177 (95, 211)	0.16

[1]P-value based on Wilcoxon rank-sum test
[2]P-value based on Fisher's Exact test.
[3]Frequency(%)

Table 3.14d. Primary outcome results: A two-way table of predicted WOMAC means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point ≥65 years. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Total score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	59.38	4.21	74.50	3.80	15.12	4.00	26.23	0.01
2 weeks	35.38	5.19	42.69	4.68	7.30	-6.38	20.99	0.30
6 weeks	22.23	4.54	20.88	4.09	-1.36	-13.34	10.63	0.83
12 weeks	12.54	3.34	13.19	3.01	0.65	-8.17	9.47	0.89
(time x treatment interaction)								0.18

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0002) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.14e: WOMAC Pain score ≥65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Pain score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	12.38	0.92	15.56	0.83	3.18	0.74	5.61	0.01
2 weeks	6.15	1.20	7.31	1.09	1.16	-2.02	4.34	0.48
6 weeks	3.46	1.05	3.69	0.95	0.23	-2.55	3.00	0.87
12 weeks	2.38	0.84	2.44	0.76	0.05	-2.16	2.27	0.96
(time x treatment interaction)								0.20

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.14f: WOMAC Motion score ≥65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Motion score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	4.92	0.49	6.31	0.44	1.39	0.10	2.68	0.04
2 weeks	3.00	0.49	3.13	0.44	0.13	-1.17	1.42	0.85
6 weeks	2.85	0.49	1.63	0.44	-1.22	-2.51	0.07	0.06
12 weeks	1.85	0.49	1.69	0.44	-0.16	-1.45	1.13	0.81
(time x treatment interaction)								0.01

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.14g: WOMAC Function score ≥65 years

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Function score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	42.08	3.10	52.63	2.79	10.55	2.37	18.73	0.01
2 weeks	26.23	3.71	32.25	3.34	6.02	-3.77	15.81	0.23
6 weeks	15.92	3.23	15.56	2.91	-0.36	-8.88	8.16	0.93
12 weeks	8.31	2.20	9.06	1.98	0.75	-5.06	6.56	0.80
(time x treatment interaction)								0.21

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Table 3.14h: A two-way table of predicted OHS means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point ≥65 years. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
Oxford12 Item Score	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	21.77	1.94	13.75	1.75	-8.02	-13.14	-2.90	<0.001
2 weeks	30.62	2.39	28.38	2.16	-2.24	-8.55	4.07	0.49
6 weeks	39.85	1.91	37.63	1.72	-2.22	-7.26	2.82	0.39
12 weeks	43.38	1.42	42.94	1.28	-0.45	-4.19	3.30	0.82
(time x treatment interaction)								0.02

[1]P-value for the F-test of the time by treatment interaction
[2] Means are significantly different from baseline (p≤0.0001) within DAA group
[3] Means are significantly different from baseline (p≤0.0001) within PA group

Hip Precautions

Sub analysis of specific WOMAC and OHS questions in direct relation to hip precautions were evaluated. The five questions identified were

- WOMAC - Bending to floor
- WOMAC - Getting in/out of car
- WOMAC - Putting on socks
- WOMAC - Taking off socks
- OHS - Able to put socks on

For the WOMAC question "Bending to floor", the DAA group had better scores than the PA group at all time points. Significance was only observed at the 6 weeks post-operative mark. (DAA 2.06 versus PA 2.79: P=0.004) For the WOMAC question "Getting in/out of car", the DAA group was significantly better than PA at baseline. However, at post-operative time-points there were no differences between both groups. For the WOMAC question "Putting on socks", the DAA group had better scores than PA group at all time points. This difference was statistically significant at the 2 week and 6 week post-operative time-points. (2 weeks – DAA 3.8 versus PA 4.39: P=0.016) (6 weeks – DAA 2.29 versus PA 3.09: P=0.007) For the WOMAC question "Taking off socks", the DAA group had better scores than the PA group at all time points. Statistical significance was only achieved when comparing 2 week post-operative results. (DAA 3.2 versus PA 4.0: P=0.01) For the OHS question "Able to put socks on", the DAA group had better scores than the PA group at all time points. Like the WOMAC, statistical significance was observed at the 2 and 6 week post-operative time points. (2 weeks - DAA 1.66 versus PA 0.79: P=0.005) (6 weeks - DAA 3.03 versus PA 2.05: P=0.0003).

Table 3.15a: A two-way table of predicted WOMAC "Bending to Floor" means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Bending to Floor	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	4.09	(0.17)	4.39	(0.16)	0.31	-0.15	0.77	0.181
2 weeks	3.60	(0.19)	4.11	(0.19)	0.51	-0.03	1.04	0.065
6 weeks	2.06	(0.18)	2.79	(0.17)	0.73	0.24	1.22	0.004
12 weeks	1.60	(0.13)	1.73	(0.13)	0.13	-0.24	0.50	0.487
(time x treatment interaction)								0.054[1]

[1]P-value for the F-test of the time by treatment interaction

Table 3.15b: A two-way table of predicted WOMAC "Getting in/out of car" means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Getting in/out of car	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	3.94	(0.14)	4.34	(0.14)	0.40	0.01	0.79	0.047
2 weeks	2.86	(0.18)	3.08	(0.18)	0.22	-0.28	0.73	0.384
6 weeks	1.77	(0.13)	1.78	(0.12)	0.01	-0.34	0.36	0.941
12 weeks	1.57	(0.14)	1.52	(0.14)	-0.06	-0.45	0.34	0.780
(time x treatment interaction)								0.403[1]

[1]P-value for the F-test of the time by treatment interaction

Table 3.15c: A two-way table of predicted WOMAC "Putting on socks" means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Putting on socks	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	4.20	(0.15)	4.58	(0.14)	0.38	-0.02	0.78	0.065
2 weeks	3.80	(0.17)	4.39	(0.17)	0.59	0.12	1.07	0.016
6 weeks	2.29	(0.21)	3.09	(0.20)	0.80	0.23	1.37	0.007
12 weeks	1.71	(0.17)	2.05	(0.17)	0.34	-0.14	0.81	0.160
(time x treatment interaction)								0.275[1]

[1]P-value for the F-test of the time by treatment interaction

Table 3.15d: A two-way table of predicted WOMAC "Taking off socks" means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
WOMAC Taking off socks	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	3.97	(0.15)	4.39	(0.14)	0.42	0.01	0.84	0.046
2 weeks	3.20	(0.22)	4.00	(0.21)	0.80	0.19	1.41	0.010
6 weeks	2.17	(0.19)	2.54	(0.19)	0.37	-0.16	0.91	0.167
12 weeks	1.54	(0.14)	1.62	(0.13)	0.08	-0.30	0.45	0.686
(time x treatment interaction)								0.108[1]

[1]P-value for the F-test of the time by treatment interaction

Table 3.15e: A two-way table of predicted OHS "Able to put socks on" means (and SEMs) obtained from the linear mixed model to compare treatment arms at each time point. Results will include mean differences between groups at each time point, 95% confidence intervals and p-values.

Endpoint	DAA		PA		Difference (PA-DAA)			
OHS Able to put socks on	Mean	SEM	Mean	SEM	Difference	95%CI _LL	95%CI _UL	P-value
Baseline	1.54	(0.15)	1.24	(0.14)	-0.31	-0.71	0.10	0.137
2 weeks	1.66	(0.22)	0.79	(0.21)	-0.87	-1.47	-0.26	0.005
6 weeks	3.03	(0.18)	2.05	(0.18)	-0.98	-1.49	-0.46	0.0003
12 weeks	3.31	(0.16)	3.17	(0.16)	-0.14	-0.59	0.30	0.517
(time x treatment interaction)								0.010[1]

[1]P-value for the F-test of the time by treatment interaction

Summary of Statistically Significant Findings

The DAA group had

- Longer operative times (125min versus 100min: P<0.001)
    - Affirmed in subgroup analysis for Surgeon 1 but not Surgeon 2
- Smaller surgical wounds (107mm versus 135mm: P<0.001) for both surgeons
- Higher blood loss (35g/L versus 31g/L: P= 0.04)
    - Associated with Surgeon 1 but not Surgeon 2
    - No difference in requirements of blood transfusions
- Surgeon 1 had a statistically significant shorter acute hospital stay (76.5hours versus 100.5hours: P=0.04)
    - No statistically significant results in combined surgeon hospital length of stay
    - No statistically significant results in Total hospital length of stay
- Lower post-operative total analgesic usage in 2 weeks (263.7mg versus 405.6mg : P=0.04)
    - Not significant in subgroup analysis
- High association of LCNT neuropraxia at 12 weeks post-operatively (83%)
- Weaker straight leg raise function at 2 weeks and 6 weeks post-operatively
    - (2 weeks 2.83 versus 3.29: P = 0.03)
    - (6 weeks 3.86 versus 4.32: P= 0.01)
- Better function in putting on socks at 2 weeks and 6 weeks post-operatively

  WOMAC
    - (2 weeks 3.8 versus 4.39: P=0.016)
    - (6 weeks 2.29 versus 3.09: P=0.007)

  OHS
    - (2 weeks 1.66 versus 0.79: P=0.005)
    - (6 weeks 3.03 versus 2.05: P<0.001)
- Better function in taking off socks at 2 weeks post-operatively
    - (3.2 versus 4.0: P=0.01)
- Better ability to bend to the floor at 6 weeks post-operatively
    - (2.06 versus 2.79: P=0.004)

CHAPTER 4

DISCUSSION & CONCLUSION

DISCUSSION

The contention surrounding DAA THA in the literature pertains to its return to function and complications. The study's primary and secondary research questions attempt to illuminate this topic. As such, the structure of the discussion is based on the primary and secondary research questions described in the introduction section of the thesis.

- Is there a difference in return to function between the DAA and PA?
- Does quality of life reported by patients differ between the DAA and PA?
- Is the length of hospital stay different for patients undergoing DAA compared to the PA?
- Is there a difference in patient's analgesic requirements between the DAA and PA?
- Is there radiological evidence that prosthesis placement in DAA differs when compared to the PA?
- Is there a difference in blood loss between the DAA and PA?
- Is there a difference in complications between the DAA and PA?

Is there a difference in return to function & quality of life between the DAA and PA?

Measuring difference in function is difficult as no single investigation can fully assess all aspects of hip function. To address this, the study adopted a multi-modal approach with validated PROMs and physical assessments. PROMs utilised were the WOMAC, OHS and EQ-5D. Physical assessments' employed were manual muscle testing, hip range of motion and the 10 metre walk test. The results of these investigations are discussed.

Patient Reported Outcomes

Primary analysis of overall WOMAC and OHS results using linear mixed model methods did not identify significant differences in patients return to function three months following primary THA. The DAA group had statistically higher pre-operative scores compared to the PA group. Although overall WOMAC and OHS scores for the DAA group were higher than the PA group, no statistical significance was observed between the two groups at post-operative time points. EQ-5D utility and VAS scores did not differ between both groups at any time points.

Sub analysis by surgeon/site to account for effects not covered by the study protocol did not show a difference in WOMAC, OHS and EQ-5D scores. This suggests that there were either insufficient variations between surgeon/site to produce functional differences or that effects produced by variations were too small for detection with this study's methods of investigation. Similarly sub analysis by age comparing patients younger than 65 years old to those 65 years or older identified no differences.

The results of the study are not surprising as PROM results from the literature comparing DAA to PA are mixed. (81, 82) While some studies report no differences, others report PROM results favouring the DAA. Maffiuletti reported better WOMAC stiffness scores with the DAA.(72) Nakata reported better Merle d'Aubigne and Postel walking scores favouring the DAA at 2 months.(74) Barrett reported improved HHS and HOOS at 6 weeks and 3 months for the DAA.(78). Conversely, Taunton reported better SF-12 scores favouring the MPA group 3 weeks post-operatively. (79) When comparing the DAA to LA, better scores were reported by the DAA group in PROMs up to 1 year post-operatively.(75, 183) This diversity of results prompts the question of whether an appropriate PROM was utilised.

Multiple PROMs have been developed to analyse changes following THA. (184-190) PROMs directly provide clinicians with patient feedback on health conditions and its response to therapy.(191) An advantage of using PROMs are that PROMs provide an individual patient's perspective on treatment. This can be different to a physician's perspective and raw lab values. Some effects of a disease and its subsequent treatment can only be described by patients. (192) As such, PROMs are the preferred outcome measure in a patient centred health care model. Good PROMs have properties of high content validity, high internal consistency, high test-retest reliability, high inter-tester reliability, high sensitivity, high interpretability, good agreement and good ability to detect change.(192)

A Recognised weakness of PROMs is in inter-tester reliability. This can be exemplified by a difference in report regarding the presence of a limp during the gait cycle. A patient may

not perceive a limp whilst walking whilst a physician may be able to Recognise a subtle limp during clinical examination. This is highlighted in differences of the patient completed modified HHS versus physician completed HHS. (193)

To compensate for weakness of a single PROM, this study utilises two validated PROMs to increase sensitivity and reliability. An additional strength of the study lies in the use of the OHS. The OHS has a good track record of completion, is reliable and has good correlation with other PROMs like the HHS.(188, 194) The OHS has not been used in published randomised studies comparing the DAA to PA. However, the OHS has been utilised in several prior published non randomised DAA versus PA studies. (55, 73, 89) The OHS is also utilised by the English Joint Registry and the local Arthroplasty Clinical Outcomes Registry (ACORN) in New South Wales. (6, 195) The OHS study data can be used for further referencing and validation against studies and registries utilising this PROM.

While the two PROMs utilised in the study have strengths in validity, consistency, reliability, agreement and interpretability, they have Recognised weaknesses.

Weakness of WOMAC and OHS

On weakness of the OHS is the possibility of obtaining incomplete or improper answers. An example is ticking between boxes or misinterpreting questions. The investigators identified this during data collection. The OHS question of "During the past 4 weeks, for how long have you been able to walk before pain from your hip becomes severe (with or

without a stick)?" had to be frequently corrected for misinterpretation. This was mitigated during the study with investigators going through PROMs with patients and assisting in scenarios of ambiguous answers. While this eliminates type 2 errors, further research bias can be accidentally introduced by the investigator. Other criticisms of the OHS include issues with question clarity, restrictive type questions and double barrelled questions.(196)

Floor & ceiling effects in questionnaires have been observed with the WOMAC & OHS (197, 198) Floor and ceiling effects can be described if a PROM does not identify poor scores in a patient who has clinically deteriorated or does not identify better scores for a patient who has clinically improved. It is possible that the best score in the WOMAC domains does not necessarily indicate perfect hip function as it does not evaluate more demanding activities such as sport and recreational activities. This is conversely true in the measurement of impairment as the inability to perform higher function activities is not captured. Recognising this in his systematic analysis, Thorborg recommended the HOOS for assessment of post-operative changes in THA and hip arthroscopy.(199) The HOOS supplements questions from the WOMAC in domains of symptoms, pain, sports, recreational activities and quality of life. Question differences between the HOOS, WOMAC and OHS are listed below.

Symptoms

- Do you feel grinding; hear clicking or any other type of noise from your hip?
- Difficulties spreading legs wide apart?
- Difficulties to stride out when walking?

Pain

- Straightening your hip fully

Function, Sports and Recreational Activities

- Squatting
- Running
- Twisting/pivoting on loaded leg
- Walking on uneven surface

Quality of Life

- How often are you aware of your hip problem?
- Have you modified your life style to avoid activities potentially damaging to your hip?
- How much are you troubled with lack of confidence in your hip?
- In general, how much difficulty do you have with your hip?

Due to domains focusing on sports and recreational activities, PROMs like the Lower Extremity Function Scale (LEFS), International Hip Outcome Tool (IHOT-33) and Copenhagen Hip and Groin Outcome Score (HAGOS) are seen to be more applicable for younger cohorts of patients. Use of questionnaires with many items focusing on intensive hip activities may lead to a bias in assessment if significant discrepancies exist in a cohort's age. The median age of patients in the study was 59 for DAA group and 62.5 for PA group. When compared to the mean age of 67.8years reported for patients who have

primary conventional total hip replacements in Australia, one could arguably favour the use of the PROMs assessing higher hip function like the HOOS. (58)

Quality of Life & Patient Satisfaction

Recognising that the WOMAC and OHS lack psychometric measures, the EQ-5D-3L was utilised in the study. This allowed investigators to gauge the impact of DAA and PA THA on patient quality of life. Overall results did not identify any significant difference between DAA and PA groups at all-time points for EQ-5D Utility and EQ-5D VAS scores.

The EQ-5D is a validated PROM utilised in the assessment of THA. The EQ-5D is used in the Swedish and ACORN Joint registries. Lindgren identified differences in EQ-5D scores when comparing patient's satisfaction in between PA and LA THA.(195, 200) Despite this apparent strength, there are Recognised drawbacks in utilising the EQ-5D. Questions asked are not specific to the hip unlike the HOOS. Like the WOMAC a ceiling effect has been reported.(82) Furthermore the study's analysis of EQ-5D Utility scores were performed with EQ-5D Weights from the United Kingdom (UK).(171) Australian weights have been published but have yet to be validated. (201) Although unlikely, the utilisation of UK EQ-5D weights may result in subtle differences when compared to results obtained with Australian EQ-5D weights. Two separate calculations were not performed for this study. To overcome this, results comparing Australian to UK weights could be generated and compared to determine equivalence and analysed for differences.

Recognised drawbacks with the 3L version of the EQ-5D prompted the EuroQol group to develop an alternative 5L version to improve its reliability, sensitivity and reduce ceiling effects. The 5L version maintains all previous domains but expands selection options from three to five. (202) An example of the differences in the mobility domain is in Table 4.1.

Table 4.1: Differences between the mobility domain of the EQ-5D 3L and 5L

EQ-5D-3L – Mobility	EQ-5D-5L – Mobility
• I have no problems in walking about • I have some problems in walking about • I am confined to bed	• I have no problems in walking about • I have slight problems in walking about • I have moderate problems in walking about • I have severe problems in walking about • I am unable to walk about

Conclusion on PROMs

Use of the WOMAC, OHS and EQ-5D-3L in the study is justifiable. However, the ceiling effects and the limited sensitivity of questions could have affected the study's ability to analyse the impact of DAA THA on wider aspects of hip function. This could have been addressed with the use of better questionnaires such as the HOOS. Use of the HOOS may also have affected results for younger patients in the study. This could have resulted in different PROM findings in the age sub analysis. The ceiling effect of the EQ-5D-3L could

have been mitigated with use of other questionnaires such as the EQ-5D-5L, SF-12 or SF-36.

Physical Assessments

Physical assessments following THA compliments subjective reports in patient PROMs. Akin to PROMs, the choice of an appropriate physical assessment is critical to obtain relevant and significant results. Discussed in this section are results and rationale of the physical assessments utilised in the study. The study utilised the 10 metre walk test as the main measure of physical function. Hip abduction power, straight leg raise power and hip range of motion were secondary assessments of physical function.

10Metre Walk Test

Results of the 10 metre walk tests identified no difference in self-selected and fast-paced velocities between the DAA and PA groups at all-time points. Due to test differences, results are not compatible for direct comparison with other randomised DAA studies. Table 4.2 demonstrates that walking speeds obtained were comparable with Reininga's non randomised DAA study. (77)

Table 4.2: A comparison of walking speeds between studies.

Author	Walking Speed	Pre Operative (m/s)		6 weeks Post Operative (m/s)		12 weeks Post Operative (m/s)	
		DAA	PA	DAA	PA	DAA	PA
Reininga	Normal	1.1	1.1	1.1	1.1	1.2	1.2
	Fast	1.3	1.4	1.3	1.3	1.5	1.4
Cheng	Normal	1.12	1.05	1.19	1.16	1.28	1.27
	Fast	1.47	1.41	1.56	1.55	1.74	1.72

The recommended physical assessments for OA of the hip by the OARSI group are the TUG test or the 6 minute walk test.(203-205) Alternatively, the minimum set of tests consisting of either the 30second chair-stand test, 40 metre fast-paced walk test or a stair-climb test can be utilised. (106) A weakness of this study was that none of the recommended OARSI assessments were employed. Although the 10 metre walk test is not part of the OARSI recommended set of assessments, use of velocity as a functional measure and the 10 metre walk test in the assessment of arthroplasty have been described.(78, 80, 206, 207)

The lack of an adequate, unhindered open space for the 6 minute walk test was the principal reason the test was not selected for the study. Another reason the 6 minute walk test was not adopted was due to the inevitable testing of aerobic capacity associated with prolonged fast walking.(208) A test of endurance may result in bias towards patients with lower ASA scores. Unlike the 6 minute walk test, the aerobic component of the 10 metre

walk test is minimised as patients can rest between measurements. The 10 metre walk test was preferred over the TUG as there were concerns in younger patients that compensatory upper body use during the transfer phase of the TUG could confound results. The use of force plates during the sit to stand test have been described to account for this confounder.(84) The investigators were not able to obtain force plates for use in the study. Lastly, arm chairs utilised during the TUG would require adjustments to ensure fair testing for participants of different heights.(209)

Weaknesses in current techniques of physical assessment lie in the inability to account for the impact of different gait aids on test results. The types of gait aids used are merely documented and cannot be factored into calculations. It is unethical to assess patients with impaired mobility without the use of appropriate gait aids. To account for this gait aid utilisation is reported separately.

Another weakness is with the use of velocity as an outcome measure. Velocity has been described to decline 13 months post-operatively in elderly patients.(210) Repeated physical testing measures in the elderly are that it can be affected by disease and senescence. An alternative form of physical assessment is with gait analysis. Gait analysis allows for more detailed scrutiny of gait variations. These variations are usually hard to detect and measure with plain clinical evaluation. The study investigators recognised the benefits of gait analysis but were unable to incorporate gait analysis testing due to complexities in logistics, assessment and evaluation.

Range of Motion & Hip Muscle Strength

Dynamic physical assessment testing requires the integration of multiple body regions and systems to execute specific movements. This has advantages over more static type clinical measures. Components of range of motion, flexibility, muscular strength, endurance, coordination, and balance can be assessed simultaneously by observing the movement patterns. However due to the increased requirements of executing more complex movements, tests results can be affected by other physical impairments to the body such as heart disease, lung disease, neurological disorders, metabolic disorders and drugs. An example would be the difficulty of walking 6 minutes continuously for a patient with advanced chronic obstructive pulmonary disease. Despite having good joints and cognition, the patient's performance during a 6 minute walk test is impaired by poor respiratory function. Static measures are more focused in its area of assessment. Hip range of motion, straight leg raise and hip abduction testing were the static measures utilised in the study to compliment the 10 metre walk test.

Both study groups did not have significant differences between recovery of hip range of motion and hip abduction post operatively. The study identified that straight leg raise function was impaired significantly in the DAA group at 2 weeks and 6 weeks when compared to the PA group. Previous randomised studies did not assess anterior thigh muscle function following DAA THA. This finding is interesting as cadaveric and haematologic studies reported findings suggesting less muscle damage with the DAA THA compared to the PA.(65, 90)

In contrast to the study's results, Winther identified no significant differences in quadriceps strength using a leg press machine when comparing the DAA and PA up to 3 months post-operatively. The muscle groups activated to perform a leg press are inherently different to that of a straight leg raise. During a straight leg test the axis of force transmitted and muscle groups utilised are anterior to posterior force whilst the single leg press is a force caudal to cranial. Anterior abdominal musculature assists in straight leg raise testing when compared to a leg press. This makes it difficult to ascertain if there was a true measurable impairment in quadriceps function following DAA surgery. Winther's study also found better abductor strength in favour of the PA group at 6 weeks in which this study was unable to replicate.(112)

The MRC grading scale employed is a validated, clinically convenient and relevant test.(211, 212) The MRC grading scale is specific in detecting muscle weakness but not specific to the degree of impairment.(213) Other reported weaknesses of the MRC grading scale are disordered thresholds in low to mid response categories and variable inter-observer agreement.(214-217) The examination by a single investigator reduced inter-examiner errors of testing. Strength testing in the study could have been improved with the use of a dynamometer or weight machines to provide a more objective measure of hip strength.

Another limitation of the study was that other muscle groups such as the short external rotators, hip adductors and extensors were not examined. Furthermore, surgical notes did not identify specific DAA patients in which short external release was performed. Hence, it

was not possible to determine if release and repair of the short external rotator muscles resulted in impaired hip external rotation.

Hip Precautions

A theoretical advantage is thought to exist for DAA patients given the study's institution of hip precautions for PA patients. Better outcomes have been reported by patients with no hip precautions in randomised studies following anterolateral THA without increased risk of dislocations. Patients were able cease gait aids, drive and return to work sooner compared to patients in the restricted group. (27, 41) In seeing this, Restrepo concluded in his retrospective study of 2,386 patients that post-operative recovery following anterolateral and DAA THA did not require routine hip precautions (218)

DAA WOMAC and OHS scores although higher at all study time points were not significantly better. Sub analysis of questions affected by hip precautions was performed to determine if differences between groups originated from the differences in hip precautions. Significant differences were identified favouring the DAA group. The DAA group had better function in putting on socks at 2 weeks and 6 weeks post-operatively, better function in taking off socks at 2 weeks post-operatively and better ability to bend to the floor at 6 weeks post-operatively.

Use of hip precautions by surgeons to reduce early post-operative dislocation is preferential. Surgeon decision is dependent on the intra-operative stability, surgical approach and patient factors. Conventional hip precautions are used to reduce the

incidence of posterior dislocations. Hip precautions given to patients generically restrict hip flexion to 90˚ and discourage internal rotation during flexion. Hip precautions also discourage sleeping in a lateral position and low seats. The duration of hip precautions vary but is generally 6 weeks. (219)

While there is evidence for not using hip precautions after DAA and anterolateral THA, sporadic evidence is only available for the discontinuation of hip precautions following PA THA. Research reporting the discontinuation of hip precautions after PA THA concurrently describe surgical techniques in partial preservation of the short external rotators. This is thought to be the reason for low dislocation rates in PA THA without hip precautions. (220, 221) A reduced duration of 4 weeks for hip precautions has also been described to achieve low dislocation rates following MPA. (219)

In contrast to previous randomised DAA THA studies, the impact of hip precautions on functional recovery has not been investigated. Although functional return was favourable in DAA THA, this was not attributed to the use of hip precautions in the PA group. (78-80) Future research investigating hip precautions in PA THA is needed to consolidate this finding.

Gait Aids

Results identified no differences at all-time points for gait aids used & gait aid cessation. While gait aid use has not been historically compared as an outcome, recent publications have associated DAA THA with earlier cessation of gait aids when compared to the PA.

The date of cessation of gait aid use varies from as early as three weeks (22 days) to five weeks (33 days). (79, 80, 83)

This study did not record the precise post-operative day in which patients ceased using gait aids. It can be deduced from results that cessation of gait aids occurs between two and six weeks post-operatively As such this study's results on utilisation of gait aid cannot be meaningful compared with other studies.

While perceived to be functionally better, earlier gait aid discontinuation has yet to be correlated with better patient satisfaction. Without an accurate daily report or log by patients, an alternative way of investigating this would further assess patients at the 4 week post-operative mark.

Is there a difference in length of hospital stay?

Results of the study showed no difference in acute and total length of hospital stay between both groups. (Acute: DAA 77hours versus PA 95 hours: P= 0.15) (Total: DAA 96 hours versus PA 100 hours: P=0.15). Discharge destinations did not differ between both groups. (Home: DAA 83% versus PA 74%) The length of rehabilitation was similar for both groups. (DAA 154.5hours versus PA 166 hours). Subgroup analysis identified that Surgeon 1 had a significantly shorter hospital stay for DAA patients. (DAA 76.5hours versus PA 100.5hours: P=0.04) Fewer patients were discharged to rehabilitation for Surgeon 2. (Surgeon1 - 27% versus Surgeon2 - 5%) As such, the study is unable to exclude the effect of surgeon and site dependant factors on results.

The reported range of hospital stay for DAA THA varies from 1.4 days to 30 days post-operatively. In contrast with other approaches, DAA THA patients reportedly have shorter hospital stays.(74, 78-80, 92). Surgical approach constitutes one of the many Recognised factors affecting hospital length of stay after THA. Husted reported that by having appropriate specialised units, patient education, good home support and patient selection, a shorter hospital stays could be attained.(222) The implementation of fast track arthroplasty protocols in Denmark, North America and Canada has reduced hospital length of stays at various institutions. (223-227) Although minimally invasive surgical techniques were described, the use of different approaches to achieve improved hospital length of stay was not elaborated by authors.

Additionally, intra-operative and post-operative analgesic protocols have been Recognised to play a role in reducing hospital stay. Kerr reported a local infiltration analgesic protocol combined with post-operative oral and transdermal analgesic regimens that resulted in a discharge rate between 61-80% for arthroplasty patients by the second post-operative day. (96)

As such it is possible to conclude that fast track and local infiltration analgesic protocols are likely to be a major contributory factor for the diverse range of hospital stay reported for uncomplicated primary THA in the literature. It is also important to note that differences in definitions of hospital stay were identified when comparing results. Raphael reported his definition of hospital length of stay as time after surgery to time of discharge. For this study hospital stay follows the standard definition which is from time of admission to time of discharge. (225)

With limitations in the study's protocol and a dual surgeon/site performance, the study can only conclude that hospital length of stay is dependant not solely on surgical approach but on the surgeon and institution. A further study by a single surgeon at a single site with modified protocols can determine the impact of DAA THA on the length of hospital stay. With multiple attributes affecting length of hospital stay, it is not surprising that results of minimally invasive surgery in conjunction with and fast track protocols are controversial.(228-230) Nonetheless, it can be hypothesised that shorter hospital stays can potentially be achieved with a combination of minimally invasive technique, analgesic and fast track protocols. This would need to be justified with further research utilising strict protocols. For further research, the utilisation of pre-operative screening with TUG tests and WOMAC scores could assist in the recruitment of a homogenous study group which may not require rehabilitation. (231)

Is there a difference in analgesic requirements between the DAA and PA?

Results identified a significant difference in total two week total opiate analgesic usage favouring the DAA group. (263.7mg versus 405.6mg: P=0.04). As the study did not exclude patients with prior opiate use, some recruited patients utilised regular opiate analgesics for control of pre-operative arthritic symptoms. Investigators attempted to address this confounder by including pre-operative calculations of fortnightly opiate analgesic utilisation. This enabled calculations of a pre-operative to post-operative net usage. Differences in net opiate use between the 2 groups were not significant. As such even though statistical significance was obtained, the investigators Recognise that the results were potentially affected by a selection bias.

Reports of post-operative pain following DAA THA in the literature are mixed. (76, 78, 80, 83, 85) The use of local infiltration analgesics protocols and its impact on post-operative pain is controversial. Den Hartog and Solovyova have reported in randomised trials that perioperative infusion of local infiltration analgesia does not make a difference in THA.(95, 97) The investigators Recognise that differences in local infiltration analgesia protocols between the studies make it difficult to draw firm conclusions for the efficacy of local infiltration analgesia during DAA THA. (96)

Other Recognised methods of managing post-operative pain following THA include regional blocks and intra-thecal morphine. (232, 233) Use of additional pain management strategies can confound post-operative reports of pain. Patients in the study did not receive any regional blocks or intra-thecal morphine by anaesthetists.

The study has strengths in following up pain to the 2 week time point by means of quantifying opiate analgesics consumed. A limitation of this study was that the VAS pain scale was not utilised. This was due to inconsistent documentation by nursing staff when administering pain medication.

Other differences in clinical parameters

Operative time & wound length

The study identifies that wound lengths for the DAA group were significantly shorter than that of the PA group by a mean of 28mm ($P<0.01$). When wound length is discussed, the topic is often intertwined with minimally invasive surgery. The literature has conflicting

views on minimally invasive surgery. Clinical randomised studies, non-randomised studies and meta-analysis studies argue strongly both for and against minimally invasive surgery. (22, 90, 101, 234-241) The study's results for DAA surgical wounds lengths are more consistent with described minimally invasive techniques in comparison to the PA group. Current studies comparing DAA to MPA are also unclear on its effect on pain and function. (73, 74, 79, 85, 242) It is therefore difficult to draw a conclusion on the impact of surgical wounds on post-operative recovery and function.

The study also identifies a significant increase in operative times for the DAA group. (DAA 125 minutes versus PA 100 minutes: $P<0.01$). This was significant for Surgeon 1 and trended towards significance for surgeon 2. This is consistent with reports of increased operative times associated with DAA THA in comparison to other approaches. (74, 78, 85, 89, 92, 101) An increase in operative time is thought to arise from traction table and fluoroscopy use that is not required during the PA.

Is there radiological evidence that prosthesis placement in DAA differs when compared to the PA?

The mean femoral stem position in the study was varus relative to the outer cortex of the femur. The degree of varus did not differ statistically between both groups. (1.09° DAA versus 1.62° PA: $P=0.29$) groups. The mean acetabular inclination for the DAA group was 46.07° and for the PA group 45.86°. Mean acetabular anteversion was greater at 24.57° for the DAA group when compared to 20.34° for the PA group. ($P=0.06$). Outliers from Lewinnek's safe zone were higher for the DAA group with 20(57%) cases compared to the

PA group 13(34%) cases. (P=0.06) (139) The study utilised validated protocols and computer software for assessment of component position.(243) Analysis by two independent blinded senior radiologist reduced biased reporting of radiological results. Despite this more accurate results could have been obtained if radiographic data was collected using computer tomography. Component placement in this study is comparable with other published results. (144, 153) The varus stem position in the study falls within normal published limits. Although a varus femoral stem position has been associated with early wear using older type implants, midterm results with modern uncemented femoral implants seem to tolerate a larger degrees of malposition (Varus/valgus <5˚). (244-247)

Early stem subsidence of more than 3mm was identified in 6/72(8%) of patients. Four of the affected patients were male. Early femoral stem subsidence can be a major complication. If a subsiding implant does not stabilize, revision surgery is often required to correct the problem. Fortunately, in this study all implants stabilized. Although potentially serious, not all forms subsidence is concerning. Subsidence is commonly reported with use of both cemented and uncemented implants.

Subsidence is common in the first years for cemented polished tapered designed femoral stems. Subsidence in cemented stems is due to bone creep as well as the implant engaging the cement mantle over cycles of stress and relaxation. (248) As such a high percentage of cemented implants have reported mean subsidence distances of between 1.52 mm and 2.1 mm at approximately 10 to 15 years of follow-up. (249, 250)

For uncemented femoral stems, subsidence occurs in the early post-operative period when a patient first weight bears. A range of 0 to 5.5 mm has been reported up to 1 year following elective THA. (251) Cinotti reported in a study of 9 years' follow-up that 17% (12/72) of uncemented metaphyseal fit stems subsided less than 4mm in the early post-operative period. However, the stems that subsided achieved good stability at subsequent reviews. (252) This is because the initial mechanical press fit stability is superseded by osseointergration of the implant that is protective against subsidence.

Factors affecting subsidence are not solely related to the method of implant fixation. Implant design, surgical technique and patient factors also contribute. Collared type implants naturally resist subsidence by loading the medial calcar. Although stem subsidence have been reported with other surgical approaches, 5 of 6 subsidences in the study occurred in the DAA group. Difficulties in visualization of the femur during DAA THA have been reported; potentially affecting component placement and sizing. (56) Matching this study's results, the male gender is identified to carry a higher risk of early subsidence. (253)

While stem subsidence has been reported with DAA THA, no prior studies reported similar incidences nor quantified the degree of subsidence.(142, 254, 255) Potential factors contributing to subsidence in this study are the uncemented press fit wedge tapered design and surgical technique. Good long term results have been published with similarly designed femoral implants. However, the flexible properties of the femoral stem utilised in the study may have contributed to the in increased risk of subsidence (256-259) Also 4 of 6 stems (2 DAA and 2 PA) that subsided over 3mm occurred for Surgeon 2.

Specific differences in component alignment when comparing DAA and PA THA vary in the literature. The differences reported are generally small and did not result in significant short term complications. (74, 78, 85) As such, this difference thought to be more likely associated with surgical technique rather than approach. Long term DAA THA data regarding complications associated with component position such as instability and early revision is limited. A single study by Sariali reported 10 year data findings of low dislocation rates associated with DAA THA. (69) To investigate this, long term registry follow-up is required.

Is there a difference in blood loss between the DAA and PA?

All patients who required blood transfusions post-operatively had normal pre-operative haemoglobin values. Results of the study identified a small but significant increase in blood loss in the DAA group. (DAA 35g/L versus PA 31g/L: P=0.04) Surgeon subgroup analysis confirmed that blood loss was increased in the DAA group for Surgeon 1 but not Surgeon 2. This highlights that blood loss may be related to surgical technique as much as surgical approach. The difference of 4g/L did not result in increased blood transfusions for the DAA group.

Measurements of blood loss following surgery are challenging. Techniques utilised in this study merely estimate blood loss. Estimation methods described in the literature include intraoperative measurements from suction canisters or gauze packs. However, these can be inaccurate due to addition or depletion of fluids and human error.(260-262) Fluid can be added to the surgical field by means of skin prep, non-haematogenous bodily or tissue fluids, irrigation and local anaesthetic. Fluid can be lost when absorbed by drapes, gauze

packs or if spilled onto the floor. Photometric and gravimetric techniques exist to more accurately calculate intra-operative blood loss. Compared to conventional estimation techniques, photometric and gravimetric techniques are more complex.(263-266) Pre- and post-operative haemoglobin values estimating total blood loss within the 24 hour post-operative period was preferred instead as it was convenient and part of routine post-operative patient care. (267)

A confounder for using haemoglobin difference is the use of intra-operative blood transfusions or large amounts of colloid/crystalloids. Fortunately, during the study, neither blood transfusions nor large volumes of intravenous fluids were required intra-operatively. Post-operative blood transfusions were recorded to substantiate changes between preoperative and post-operative haemoglobin values.

Another confounder identified in the study that could have skewed measurements of blood loss during THA surgery was the use of TXa. TXa functions as an antifibrinolytic to prevent clot breakdown in wounds. TXa use is Recognised to reduce intra-operative blood loss and the need of blood transfusion.(268-270) TXa use was dependant on anaesthetist during surgery and its use was not included in the study's protocol. TXa use was reported for two patients. One was for a Jehovah's Witness patient in the DAA group. A participant from the PA group received TXa for an unspecified reason. Both patients did not require transfusions. Given the minimal use in the trial in both groups, it was unlikely to affect results.

Results obtained affirm other reports of increased blood loss during DAA THA.(74, 78, 89) Estimation techniques utilised by this study for assessment of blood loss have been utilised in other studies.(75, 76)

Is there a difference in complications between the DAA and PA?

Lateral Cutaneous Nerve of Thigh Neuropraxia

The study's observed 83% LCNT neuropraxia rate falls within the upper limit of the literature (2.8% and 88.3%). (81, 124, 271, 272) This complication rate is large in contrast with the study's PA group that reported no neuropraxias or wound hypoesthesia. Investigators observed that patients did not routinely volunteer information about altered sensation to the thigh following DAA THA. It is possible that the study's higher rate of LCNT neuropraxia is due to underreporting in the literature. Another reason that could explain the high incidence was the utilisation of a strict definition of absence of normal sensation to define neuropraxia.

No patient at 3 months of follow-up complained of meralgia paresthetica, inconvenience or discomfort of the lateral thigh. Unlike Houma's findings, the presence of LCNT neuropraxia did not affect patients' quality of life scores. This could be due to a lack of sensitivity in questions by the EQ-5D when compared to the Japanese Orthopaedic Association Hip Disease Evaluation Questionnaire (JHEQ). (81)

Likely causes of deficiencies in LCNT sensation following DAA THA are indirect traction neuropraxia or direct trauma to terminal cutaneous branches of the nerve. Despite adopting lateralisation techniques described to minimise LCNT neuropraxia, it appears that damage to minute cutaneous branches of the LCNT is unavoidable.(57, 273) The modified bikini DAA approach while theoretically having increased potential of LCNT trauma given its oblique incision has reported rates of 60% that fall within parameters of quoted literatures reports.(55) It is interesting to note that in Kennon's 2003 publication on DAA THA, there was no report or comment on LCNT neuropraxia. One can potentially hypothesise if use of accessory percutaneous incisions can potentially reduce intraoperative skin tension and lower neuropraxia rates.(61)

Given the lack of functional impairment of LCNT neuropraxia in DAA THA this can be viewed as analogous to damage to the infrapatellar branch of the saphenous nerve during total knee arthroplasty and anterior cruciate ligament reconstructions.(274, 275)

Dislocations

The dislocation rate in the study is 2/73 (2.74%) with one case in each group. (DAA 1/35(2.86%) versus PA 1/38(2.63%)) This falls within the upper limits of reported dislocation rates in the literature.(39, 69, 276) Common causes for dislocations in conventional primary THA can be divided into patient, surgical and implant factors. Patient factors include compliance with hip precautions, increased pre-operative range of motion, neuromuscular disease, musculoskeletal disease and alcohol abuse. Surgical factors include previous hip surgery, surgical approach, component position, component

sizing, offset, soft tissue repair and balancing. Implant factors include femoral head size, liner construct and articular interface. (20, 40, 70, 141, 277-286)

On review of the study's two dislocation cases, both cases were single events and did not recur. The DAA patient sustained an anterior dislocation. This was due to femoral stem subsidence. The dislocation occurred during the patients sleep. Despite this, the patient was successfully managed non-operatively with a heel raise and temporary reverse hip precautions.

The second case of dislocation occurred on the first post-operative day in a patient from the PA group. The cause of dislocation was identified to be an unRecognised dislocation during patient transfer off the operating table. The patient was managed conservatively with routine hip precautions. Neither patient had further dislocations up to 1 year of follow-up.

Both patients with dislocations had 36mm sized femoral heads. Lateral radiographs identified sufficiently anteverted femoral components for both cases. For the DAA patient, acetabular component placement was outside Lewinnek's safe zone (inclination 43.7˚, anteversion 27˚). The PA patient had acetabular component placement within Lewinnek's safe zone. (inclination 45.4˚, anteversion 8˚).

Lewinnek's safe zone though classically utilised as a guide for acetabular component placement and stability has had increasing evidence to dispute it.(287) Other factors such as kinematic and functional acetabular anatomy during dynamic motion have been described to play a role in hip joint stability.(288-290)

A potential confounder in interpreting dislocation results is the hip precautions for the PA group. A true unbiased assessment between surgical approaches would have no hip precautions to reflect stability. However as described in the hip precautions section, use of hip precautions is surgeon dependant and considered conventional practice with PA THA. Given the lack of hip precautions in the DAA group and only a single dislocation due to stem subsidence, it is possible to hypothesise that DAA THA has an inherently stable nature. The study concludes that DAA THA and has comparable results in stability to the PA THA used with hip precautions.

Wounds, Fractures & Other Complications

Three minor wound problems occurred in both DAA and PA groups. There were no post-operative wound complications that required surgical intervention. The literature identifies that DAA THA has an increased risk for return to surgery and an association of obesity with wound complications.(135, 291) The mean BMI of DAA and PA patients were 27.73kg/m^2 and 28.3kg/m^2 respectively. Results obtained are unable to confirm an association of DAA and obesity with increased wound complications.

Three fractures were identified in the study. Two fractures occurred in DAA patients. The first was a Recognised intra-operative femoral perforation on broaching that was managed with protected weight bearing for 6 weeks. The second was an asymptomatic partial fracture of the greater trochanter identified 6 weeks post-operatively. A peri prosthetic fracture due to trauma resulted in the exclusion of a PA patient. Although there were more fractures in the DAA group that was related to surgery, this was not statistically significant. The results of the study cannot confirm published findings of increased fracture risks associated with DAA THA. (271, 292)

A single patient required re-operation for a 3cm leg length discrepancy following DAA THA. The original components were retained with an acceptable correction of the leg length discrepancy to a 1cm difference. This highlights reported issues with traction table use and intra-operative leg length assessments. Similar re-operations for leg length discrepancy have been reported.(87) This could potentially be overcome with the adoption of DAA techniques that utilise a conventional operating table on top of fluoroscopy.

Other challenges with DAA THA include the need for specialised equipment. The loss of a patient from the trial due to malfunction of the offset acetabular reamer reflects this. Iliopsoas tendonitis was identified in 2 DAA patients. This was not observed in PA patients. Neither patient had an oversized acetabular component. At the 1 year follow-up, both patients reported improvements with conservative measures. Iliopsoas tendonitis is an uncommon complication following THA. Proposed mechanisms are due to mechanical irritation of the iliopsoas tendon from oversized or retroverted acetabular components and anterior acetabular irregularities (eg: bone cement, residual osteophytes). Surgical

treatments include iliopsoas tendon release and revision of acetabular components. (137, 293, 294) Currently there is no Recognised association of iliopsoas tendonitis with surgical approach.

A single patient from the PA group developed a below knee DVT. This was within published rates of post-operative DVT following primary THA with modern prophylaxis. (295-298)

A single patient developed post-operative trochanteric bursitis after PA THA. This was consistent to published results. Post-operative trochanteric bursitis has been associated with LA THA.(299, 300)

There were no reported cases of deep infection, squeaking, post-operative haematoma or heterotopic ossification.

CONCLUSION

The study concludes that DAA THA has comparable results with PA THA. The null hypothesis in the primary research question on whether there is a difference in return to function between the DAA and PA cannot fully be rejected. Similar recovery rates were observed between both DAA and PA groups for both surgeons. However, sub analysis identified an association of better early hip function with the absence of hip precautions for DAA THA. This has not been described in previous published DAA THA research. Nevertheless, a better choice of PROMs and physical function tests could provide a stronger basis for rejection of the null hypothesis.

Analysis of secondary research questions identified other differences between DAA and PA THA. The study identifies that DAA THA is associated with increased operative time, smaller surgical wounds and increased blood loss in comparison with PA THA. The findings identified were similar to reports in the literature. Although combined results identified significant blood loss, Surgeon 2 had comparable blood loss between the DAA and PA. This suggests that blood loss may be averted with good surgical technique. Blood loss though having a significant difference between the DAA and PA groups was not sufficient to affect clinical outcomes and need for transfusions. Even though Tranexamic Acid use was not included in the protocol and the drug employed in two cases, it did not seem to skew results.

Overall length of hospital stay was similar between both DAA and PA patients. The duration of rehabilitation was not reduced with use of DAA THA. However, subgroup

analysis identified significantly a shorter acute hospital for DAA patients operated by surgeon 1. Surgeries performed at two different sites prevented homogenous analysis and introduced an additional confounder to interpretation of data.

Analgesic requirements were significantly reduced for DAA THA patients in the first 2 weeks post-operatively. However, the statistical significance was lost when a net opiate use was calculated. The inclusion of patients utilising opioid medications pre-operatively could have resulted in dependence and skewed data in favour of opiate naïve patients.

Radiographically no statistically significant differences were observed in component position or complications for both groups. The DAA group had a higher number of outliers for acetabular component position in Lewinnek's safe zone. The DAA group also had a higher association of early femoral stem subsidence for surgeon 2. It is Recognised that causes of implant malposition and subsidence are multifactorial. However, it is likely to be more related to surgical technique, templating and sizing errors.

A high rate of LCNT neuropraxia of 83% for DAA THA is reported but this is without functional impairment. Fractures of the greater trochanter and perforations can occur despite surgeon experience. The remaining complications observed in the study are similar to those of the reported literature and with other approaches in THA.

This study adds to the body of knowledge regarding THA, in particular the findings of impaired straight leg raise function in DAA THA during the early post-operative period when compared to PA THA. This was identified using manual muscle testing with the MRC grading scale. Manual muscle testing by a single investigator ensured minimal bias and consistent results. However, results could have been substantiated and better quantified with use of a dynamometer or weights. The remaining physical parameters assessed had results comparable to the literature for both early outcomes and complications.

The most robust aspect of the study is in its statistical analysis. A.Priori testing ensured adequate participant numbers. Linear mixed model analysis has advantages over conventional statistical methods of being able to longitudinally assess data and account for random effects. Linear mixed models are also based on a maximum likelihood (ML) and restricted maximum likelihood (REML) methods. ML and REML have advantages over analysis of variance methods in modelling real world data that is often unbalanced.

Other strengths of the study are in its use of validated PROMs and simple practical tests and examinations. There was no loss of patients to follow-up. Randomisation was robust and resulted in equal distribution between groups. Both surgeons were experienced in performing DAA and PA THA. Participant gender demographics were similar to the Australian National Joint Registry Report with 55% female and 45% male patients. Radiographic analysis by two blinded independent senior radiologists was advantageous to reduce bias.

The main limitation of the study was in its limited blinding. The lack of blinding of patients, staff and investigators post-operatively could have introduced bias in assessment. However, subsequent data analyses were performed in a blinded manner.

A further limitation of the study was that the two surgeons in the study did not have equal representation thus leading to a performance bias. Surgeon 1 performed 74% of operations. Two exclusions from the DAA group for surgeon 2 aggravated this bias. This was primarily due to logistical difficulties in obtaining theatre access in a public hospital for Surgeon 2 to perform more surgeries.

Although the DAA and PA groups did not have statistically significant differences in modality of anaesthesia, the lack of standardisation of the mode of anaesthesia potentially introduced another confounder to the study's results. The absence of consistent surgeon specific anaesthetists in a public hospital roster was the main factor in the variations of anaesthetic modalities.

Another limitation of the study is that only early short term results are available. The study was not able to analyse inflammatory markers and did not perform gait analysis testing. The study also did not assess with magnetic resonance imaging the soft tissue damage of surrounding structures following THA and is unable to consolidate or refute findings in the literature. A lack of patient diaries prohibited accurate data collection on cessation of gait aids.

Further areas of research that could be explored include the role of DAA THA in younger healthier patients with minimal co-morbidities. Pre-operative screening with WOMAC and TUG scores can be utilised to recruit a homogenous group of patients. A change of functional outcome measures to reflect a younger cohort of patients such as the LEFS, HOOS, IHOT-33 and Forgotten Joint Score can be utilised to prevent a ceiling effect on results and improve sensitivity. Quality of life measures utilised can be upgraded to the EQ-5D-5L or SF-36. A comparison of hip function and recovery without hip precautions for a PA/MPA group could better demonstrate differences with DAA THA. Tranexamic acid use can be utilised to validate or refute blood loss in DAA THA in comparison with other approaches. Testing of the short external rotator muscle group could also determine if their sparing or release during DAA THA has a clinical effect on hip strength. The effect of surgical approach in conjunction with fast track protocols and local infiltration analgesics can also be explored in an ideal setting of a high volume arthroplasty centre.

In closing, the author identifies that outcomes following DAA THA as gleaned from the literature vary from surgeon to surgeon. Both DAA and PA THA can provide good results. The study recognises that outcomes following THA are multifactorial and this study only explores a single aspect of this field in detail. Further research is needed in order to determine if there are more differences between DAA THA and other approaches. The study advises surgeons and trainees deciding to pursue DAA THA to be wary of its potential complications and results particularly during the learning curve. In a setting of established techniques and good clinical results with low complications, one should first audit initial outcomes with DAA THA to justify its use.

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