Learning Curve for the Two Incision, Minimally Invasive Total Hip Replacement

Richard White, M.D.
Albuquerque, NM

Presented at the Hip Society Meeting, March 13, 2004

(transcription of original presentation)

Presenting very early information from a large group of surgeons, Zimmer two-incision MIS total replacement. Total replacement by use of the smaller incision has been used by several practitioners for many years. But more recently, it has been widely introduced, and the reasons for this are multiple and they include patient benefit, faster rehabilitation, certainly the possibility of increasing market share and they've been done by a number of different varieties. Many people are using a so-called mini-incision, which is just a shorter incision of the traditional approach either with modified anterolateral or the posterior lateral. It's been advocated to use one anterior incision using Smith Peterson modification or as you'll see today, the Watson Jones. The two-incision technique has also been proposed and that usually combines the use of again the anterior limited Smith Peterson incision and a posterior incision. The Smith Peterson for preparation and insertion of the acetabulum and the posterior incision for preparation of the acetabular component. That's what we're going to talk to you about today and talk about the very early results from the large group of surgeons who are trying this technique. This particular two-incision technique initiated initially was started by some cadaver work by Dana Mears in approximately 1997. Zimmer assumed the development role; and Zimmer, soon thereafter, helped to refine the technique, develop more sophisticated instrumentation and develop a training program for surgeons who

were interested in this particular technique; and then, Richard Berger did the first case in clinical practice in February of 2001 as the first case as part of an IRB study. Since that time and through the Fall of 2003, over 300 surgeons have now been trained in this training program to do this procedure. The initial study, of which Richard Berger performed the first, was an IRB study including 19 surgeons reporting data on 244 cases. Based on this pilot study and surgeon feedback, training programs were developed for surgeons who were interested in trying to master this technique. Subsequent to the start of this training program, the index case study was started and this includes reports of 423 cases performed by the first 89 trained surgeons. This information would be the basis of our presentation today, and these surgeons performed these cases over a one-year interval from October 2002 to September 2003.

The purpose of the presentation is just to present the limited data available regarding the process of developing fluency with this two-incision minimally invasive total replacement approach by this so-called learning group. The 89 surgeons, who underwent this Zimmer-sponsored corporate training, were then required to report back to Zimmer using a scanable form on the first 10 cases using this technique. All cases that were reported, all 423, reported on demographics, surgical time, fluoroscopy time, blood loss and all complications, both general and hip-related. The results of the entire 423 cases showed a nearly equal number of females (48%) and males (52%); age was an average of 60; the weight was a median admiral weight of 170 lbs.; the diagnosis was osteo-arthritis in approximately ¾ of the patients. The acetabular components used were all cementless Zimmer Trilogy components of a variety of configuration groups. The femoral components were all cementless. There were no cemented cases and

approximately 2/3 of these were beaded full-coat stems, which was the suggested component to be used in the training sessions. The median length of the anterior incision was 3.6 cm; the operative time had a mean of 146 minutes for these 423 cases and a range of 53 to over 6 hours. Fluoroscopy time carried about 2 minutes. The blood loss had to be about 448 cc's. Inter-operative complications, and again remember that the denominator is 423: 1.4% nerve injury, there were 4.7 % proximal femoral fractures and cracks, and 1.4% greater trochanteric fractures and 1.7% cortical perforation and distal femoral shaft fractures. If you combine all these fractures including cracks, there's an incidence of 7.5% in fracture or perforations. Post-operative complications include 1.2% incidence of dislocation, a .5% post-operative fracture rate, there is 1.2% incidence of combining both deep and superficial infections. There are four early revisions in this series of 0.9%. One was liner exchange only for instability, one was for resection arthroplasty for infection, one was an ORIF of a periprosthetic shaft fracture and subsidence when the patient first got up, and one was for fracture and accompanied stems of size and ability.

In terms of the actual learning curve, we're trying to pick out the parameters that we thought would be valuable. We certainly wanted to look at surgical time, fluoroscopy time and blood loss; and we also pulled out specifically the large complications, which we thought were key complications: fractures, nerve injuries and instability. We also looked specifically at the 19 surgeons who completed all 10 cases. This was training and revision of patients over a one-year period. The majority of the surgeons completed from one or up to four or five cases. Only those trained early completed all 10 cases. The operative time by case number decreased significantly from a mean of

160 minutes at case one to an average of 126 minutes at case 10. The fluoroscopy time from case one of 146 seconds decreased significantly to a mean of 71 seconds in case two. The estimated blood loss by case number perhaps showed a trend that did not show a statistically significant change in cases one through 10.

We also looked at key complications by case number, four of those 19 surgeons completed all 10 cases and for at least for the first 10 cases, there is not a statistically significant decrease in the key complication rate as a function of cases one through 10. The denominator was 19, and the number was the patient.

We also looked specifically at the surgeon experience or the surgeon volume. We looked at those surgeons who completed less than 50 cases per year, 50 -100, 100 – 150 per year and then the more experienced surgeon of 150 cases per year. At least in this group of surgeons, there was no statistical difference in the complication rate by reported surgeon volume.

So the summary of the learning curve for just the first 10 cases: the operative time decreased significantly, there is not a significant difference in blood loss through this period of time and the key complications that we isolated did not also decrease in the first 10 cases. The annual surgeon volume of total replacement did not seem to affect the incidence of key complications also.

There are several weaknesses to this study that are very obvious. The one that is difficult to get a handle on is the fact that it is self-reported by surgeons themselves, and we really don't have any information. Only Zimmer has that information as to whether all of the cases were reported, and there may be a lack of accuracy reporting

on all of the complications. In addition to that, there are a relatively small number of cases called “The Surgeon-Only 10”, which contains information only about the first 10 cases. At the time of this compilation of information, only 19 of the surgeons had completed all 10 cases.

So finally, this data does not allow us to say anything about the additional learning curve beyond 10 cases or the completion of the learning curve and when that might occur. So I guess all of us need to ask ourselves do we want to perform this procedure or any new and innovative procedure, and I think we have to weigh the theoretical benefits against the potential risks. If you’re going to do this particular procedure, this is very different from what most of us are accustom to, with exception of a few people. Most people will have to adapt to a different position, fluoroscopy is required or strongly suggested, there clearly is decreased visualization and tactile feedback in how you do this procedure. At least for this procedure, there may be a favored implant choice, perhaps the beaded full-coat stem and that may or may not be the surgeon’s choice as the primary femoral stem. It appears that even after the procedure is mastered, there will probably be a longer surgical time than the surgeon is accustom to. Although we do not know the end of the learning curve, there may be an increased fracture rate. You and your hospital will need to change your rehabilitation program.

Finally, we clearly need more information to make this important decision. We need controlled studies for evaluating the true benefits of MIS total replacement; we need controlled studies to evaluate complication rates and the learning curve for more than 10 cases. These studies fortunately make progress, and with additional

experience, though, excellent results and lower complication rates have been reported. But I think for every surgeon, it's clear that this is not a short or easy learning curve and a learning curve that clearly exists for much more than 10 cases.

So the evolution of surgical technique, training, altering the learning curve and also the future of computer-assisted surgery or other techniques most likely are the future.

I