Neutral Citation Number: [2012] IEHC 416

THE HIGH COURT

[2006 No. 716 P]

BETWEEN

NANCY SCOTT

PLAINTIFF

AND

ANDREW MACEY AND THE HEALTH SERVICE EXECUTIVE

DEFENDANTS

JUDGMENT of O'Neill J. delivered on the 19th day of October 2012

1. In this action, the plaintiff sues the defendants for damages for negligence arising out of the manner in which a total hip replacement was carried out on the plaintiff in Sligo General Hospital on 19th February 2003, by the first named defendant.

2. The plaintiff is married with two grown up children, a retired bank official, having taken early retirement at the age of 52 in 2002, and resides in Ballyshannon, County Donegal. The first named defendant is a consultant orthopaedic surgeon in Sligo General Hospital, County Sligo. The background to this matter is as follows.

3. On 7th October 2002, the plaintiff fell on a manhole cover in her back garden. She suffered a serious injury and was unable to walk. She was taken to Sligo General Hospital where she was diagnosed as having suffered a subcapital fracture of her left femur. That day, she underwent a surgical procedure in which a Dynamic Hip Screw (DHS) was inserted through the wall of the femur into the head of the femur so as to re-establish union between these two parts of the plaintiff's femur. This operation was carried out by the first named defendant, and was the standard appropriate procedure to deal with the plaintiff's injury. The operation proceeded uneventfully as did the plaintiff's recovery until the early part of 2003. By early 2003, it was apparent that the plaintiff had developed avascular necrosis of the head of the femur so that the fracture failed to unite. This eventuality is a well-known complication of the injury she suffered and was entirely unrelated to the manner in which the operative procedure was carried out, which the plaintiff accepts was done in an appropriate and professional manner.

4. The standard, indeed the only treatment, to deal with the plaintiff's un-united fracture was a total hip replacement, and the first named defendant arranged for the plaintiff to come into hospital on 17th March 2003, to have that operation carried out. In due course, the first named defendant carried out this operation on the plaintiff under epidural anaesthetic on 19th March 2003. For the purposes of this operation, the first named defendant planned to use a Birmingham Hip Resurfacing Cup and modular head, and an Aesculap stem. As the first named defendant had not used a Birmingham Cup before, nor indeed had he used an Aesculap stem before, he asked a colleague orthopaedic surgeon, Mr. Fintan Shannon to assist as he had considerable experience in the Birmingham hip. By that stage in his career, the first named defendant had done approximately 1,500 hip replacements and Mr. Shannon had done approximately 2000 hip replacements. They were also assisted by a Dr. Hussain, a Senior House Officer who also had considerable experience of hip replacements, having participated in approximately 200 of these.

5. The first part of the operation involved the removal of the un-united femoral head and the dynamic hip screw which secured it to the shaft of the femur. This was accomplished uneventfully. The next stage in the operation was the preparation of the hip socket to receive the Birmingham Cup into which would be fitted the modular head which in turn would be connected to the stem which would be secured in the femur. The hip socket was reamed, meaning that soft bone was hallowed out. The bone was noted to be markedly soft. The trial Acetabulum achieved a good fit and a 52mm Birmingham Cup was solidly impacted.

6. The next stage in the operation was the preparation of the femur to receive the Aesculap stem. Although the Aesculap system did not require the femoral shaft to be reamed, merely broached with two separate types of profilers, namely, the 'A' profiler and the 'B' profiler, the first named defendant decided to ream the shaft with a narrow taper pin reamer in order to clearly establish a canal for the profilers, and in due course - the prosthetic stem itself. He was concerned in this regard because of the presence of the large (2cms) hole in the wall of the femur which had been there to accommodate the dynamic hip screw and created a very real risk of either the profilers or the prosthetic stem exiting through this hole. His second reason for reaming a femoral canal was to *"vent"* fat cells so as to avoid or reduce the risk of embolism.

7. After doing this reaming exercise, the first named defendant then proceeded to broach the canal in the femur so as to get it to the correct size and shape to receive the Aesculap prosthetic stem. The Aesculap system offers a choice of two types of stem, namely, a cemented stem or an uncemented stem and the choice as between the two can be left over by the surgeon until the broaching process has been completed. Broaching involves introducing into the femoral canal a series of profilers, as mentioned above, starting with the smallest size and working through a series of them to get to the correct size. This exercise is done in two stages. The first stage is the broaching of the distal end of the canal. That is done in the Aesculap system with profiler 'A'. When that is complete, profiler 'B' is used to broach or shape the proximal or upper end of the canal. The process of broaching involves a gradual compaction of the soft or cancellous bone rather than any removing of it.

8. The first named defendant went through four sizes of each profiler, culminating with size 14. This is quite a large size, in particular for a small patient, and whilst it seemed appropriately sized for the proximal end, may have been on the large size for the distal end. When the broaching process is completed, the canal is then fully prepared to receive an uncemented stem, having been shaped to the exact size of the prosthetic stem. At this stage, the surgeon can finally make the decision whether to use a cemented stem or an uncemented stem. The first named defendant, in consultation with Mr. Shannon, elected to use a cemented stem. For that purpose, the canal was prepared by way of washing and drying to remove blood and other material which would compromise a strong, stable fixing by the cement. Having done that, and with the cement gun ready, the first named defendant decided to double-check the canal, for the unlikely event that the broaching may have gone out through the DHS hole. The prepared cement mix was abandoned and this check was carried out and it was established that the canal was correctly placed. At this stage, it was decided to use a Hardinge Plug as a cement restrictor. The purpose of the cement restrictor is to stop the cement when put in under pressure, going

down the shaft of the femur, perhaps as far as the knee, and also to ensure that when the cement goes in, a high level of pressure is generated to force the cement into the wall of the femur around the prosthetic stem to establish a firm, stable grip. The Hardinge Plug is a standard piece of equipment for this purpose and is like a small plastic shuttlecock with a circle of separate leaves attached to a base so that when it is inserted into the femoral canal, which has a much smaller diameter than the opened out plug, the leaves fold in and grip into the sides of the femoral canal, thus establishing a base or bottom which restricts the downward passage of the cement.

9. The Hardinge Plug is put into the femoral canal by means of an instrument known as an 'Introducer'. This is a cylindrical shaped metal bar, narrow enough to be able to go down the femoral shaft and has measurements along the side so that the surgeon can judge that it has brought the plug to the intended depth in the canal. At the tip of the Introducer, there is a screw which screws into the centre of the plug, and when the plug has reached the required depth, the Introducer is unscrewed from the plug. At the top of the Introducer is a T-handle and in order to make plug go down the shaft of the femur, the top of the Introducer is tapped or hammered with the appropriate amount of force as necessary.

10. The first named defendant wanted to put the plug so that it ended up just distal to the tip of the prosthesis so that there would be very little or no cement between the plug and the tip of the prosthesis. He tapped the Introducer until it showed that the plug had descended to a depth of 15cms. At that stage, he unscrewed the Introducer from the plug and his plan was to use profiler 'A' to tap the plug down to its full depth which would have been 16cms. Whilst he was hammering or tapping this broach down against the plug, he felt it *"give way"*. In the normal course of events, his expectation was that the plug would respond to the tapping by moving incrementally downwards. The sensation of giving way was unusual in his experience and alarmed him.

11. Later that day, when a postoperative routine X-ray was taken, it became clear that the plaintiff's femur had, during the operation, been fractured on the lateral side. In the course of the trial, expert evidence was given by four orthopaedic surgeons, two for the plaintiff and two for the defendants, and a great deal of consideration was given in their evidence as to precisely what happened that led to this fracture. The first named defendant also dealt with this topic in considerable detail in his evidence, and as he was the person who was directly involved in the event, his understanding of what happened is of crucial importance. The following passage from the evidence of the first named defendant on Day 10 of the trial, commencing with Question 24, sets out the first named defendant's evidence of his considered view of what happened:

> *"24 Q. Well, can we deal then with that secondary issue and perhaps you would outline to the Court what you did by way of review, examination and analysis to try and establish at the time what the cause of the fracture was.*
>
> *A. Well, you firstly look at the fracture itself because the pattern of a fracture can give you a good idea of its causation. Although it was a difficult fracture to assess because there was a lot of cement around it, it looked as though it was an oblique, a vertical split fracture which had allowed the lateral cortex to deviate and allowed the stem then to deviate in line with the lateral cortex. So that's the first thing. Then with updated information from the CT, that confirmed essentially what we thought had happened on the plain films. We were thinking, well, how and why did this happen. I have thought a lot about that and I think that, probably, it was to do with the narrowness of the femoral canal towards the isthmus, which was disproportionately narrow compared with the proximal femur.*
>
> *25 Q. And what did that lead you to conclude as to cause?*
>
> *A. With this type of system you're using a hip replacement system that allows you to make a decision whether you go cemented or uncemented after you've done the reaming. So that means, as we heard yesterday, that you ream up the distal canal first and you then ream up the proximal canal.*
>
> *Now, if you have someone with osteoporosis, you're going to have softer bone in the proximal femur than you do distally where the bone is a tube. Having thought a lot about this I think we ended up with a size 14 broach, which would be the precise fit of a size 14 uncemented stem. That is relatively large for a patient of this size with a relatively small femur. It was suggested, I think two days ago, that the diameter of the femoral canal was 15mm. When you measure it on the X-rays it's 11mm and that's not allowing for magnification, so there may have been a relative mismatch between the size of the femoral canal at the tip of the prosthesis vis-à-vis the proximal femur. The end result of that is . . . (INTERJECTION)*
>
> ***MR. JUSTICE O'NEILL**: A mismatch between?*
>
> *A. Can I show you, my Lord?*
>
> ***MR. JUSTICE O'NEILL:** Yes, certainly.*
>
> *A. We are looking at the proximal femur here, which is big enough to accommodate a size 14 uncemented stem. As you go down the femur you come towards the isthmus, which is the narrowing, and I think this was relatively narrower because this is of solid tube and this is softer bone which gets the osteoporosis more readily. So because you've reamed to 14, which is a relatively large size for this small patient, and you've then got, I would estimate, a 10mm canal, perhaps 10 or 11 -- It measures 11 on x-ray. So when you then say, okay, we're not going to use an uncemented stem (and that would have fitted exactly because it's quite narrow in that plane), we're going to put in a plug, it means that we are then putting in a plug which is cylindrical and it's going to create quite significant hoop stress the tighter it gets. If you had a 15mm canal, it doesn't close up very much in terms of the shuttle cock, but if you have a tight 11mm, possibly 10mm canal, it's very tight.*
>
> *So I think what happened was that, when we were putting in the plug, and although it sits at 17.5cm on the X-ray, it didn't jam at 15, there was probably too much friction between the plug and the tube, with the end result that the tip of the broach . . . (INTERJECTION)*
>
> ***MR. JUSTICE O'NEILL:** Too much pressure?*
>
> *A. Yes, too much grip, and the end of the broach then caused a split in the osteoporotic bone.*
>
> ***MR. JUSTICE O'NEILL**: I don't quite follow that. Do you mean the pressure, the additional pressure of tapping the broach onto the plug because the plug was perhaps excessively pressurised already?*

A. Well, yes, if you imagine that's the plug in a cylinder. The tighter it gets, the more friction between it and the wall of the femur and then the more reactive hoop stresses. There is an equal and opposite reaction to this and if it's getting really quite tight down in an 11/10mm canal, it's not going to take much additional force to create enough hoop stress to add to the bending, sheer and torsional stress and then you have the fracture.

I think what happened with the fracture was that because of the periosteal covering, which is like thick cling film -- There is a springy nature to fractures that are incomplete, a split fracture. When we had the broach down it caused the lateral cortex to diverge and when we took it out the periosteum would tend to close it up again, which would help keep it stable because of the friction between the fracture edges. When you then put the cement in and the prosthesis, that creates an additional stress which gaps the fracture and the cement leaks out.

MR. JUSTICE O'NEILL: *You mean it opens it up again?*

A. Yes. I think that's why it was difficult . . . (INTERJECTION)

MR. JUSTICE O'NEILL: *Do I gather from what you're saying that the actual fracture was not caused by a perforation of the cortical bone in the femur by the tip of the broach but rather was secondary to too much pressure created by the exercise of tapping down the . . (INTERJECTION)*

A. I think, my Lord, it's a combination of both because the pressure of the plug alone wouldn't have caused it. But if you're putting down a shaped implant into a fairly narrow canal and it then hits the buffer, it's got to go somewhere and if it can't push that plug any further down . . . (INTERJECTION)

MR. JUSTICE O'NEILL: *It finds least resistance?*

A. Yes. And I think because of the shape of the fracture, the split fish mouth, it was a combination of both.

MR. JUSTICE O'NEILL: *So you have a situation of, as it were, an immovable object?*

A. Yes.

MR. JUSTICE O'NEILL: *Or something like an immovable object. And then because it was immovable, the tip of the broach deflected to wherever there was least resistance?*

A. Correct, yes. I think that's what happened. I have thought about it a lot. I have looked at the x-rays and the scans and that's the best explanation I can come up with.

MR. JUSTICE O'NEILL: *And do you think that what happened was a piercing of a perforation by the tip of the outside of the femur or was it just simply a split due to excess pressures?*

A. If it was a perforation you would see a small punched out piece of bone lying separate, and it wasn't, it was a split fracture like a fish mouth.

Q. MR. O'NEILL: The analysis that you were carrying out immediately after the operation as to cause reached a conclusion, isn't that right, at the time? You drew a conclusion at the end of your review of the circumstances, including review of the x-rays.

A. Well, I concluded that the difference between my normal hip replacement and this one was that we were using a different system with sharp pointed taper tipped reamers, and I felt that that was a major issue in causing this fracture . . ."

12. When the first named defendant experienced this unusual sensation of giving way, he concluded at the time that either one or other of two things had happened, namely, either that the plug had been driven below the isthmus or that a fracture had occurred. In this latter context, fractures during hip replacement surgery, and in particular during revision hip replacement surgery are a very rare but well-known complication due to a significant extent to the variety of stresses to which the femur is necessarily subjected during the procedure. With all of this in mind, the first named defendant halted the procedure and carried out a number of clinical tests to out rule a fracture. Firstly, he reinserted the 'A' profiler into the canal and satisfied himself that the integrity of the canal was unaffected. Secondly, he visually examined, insofar as he could, and felt as much of the affected area as he could and detected no abnormality, and finally, he asked Dr. Hussein to manoeuvre the plaintiff's leg, which he did, in such a way as to demonstrate that the femur moved as one piece. As result of these tests, the first named defendant was satisfied that a fracture had not occurred and proceeded onwards with the operation. The next stage in the operation was putting the cement into the femoral canal with the prosthetic stem, and when that had hardened in its correct position, it was connected to the modular heard which had previously been selected as a result of a trial reduction done earlier in the procedure. The artificial joint was then reduced i.e. the head connected to the cup which completed the reassembly of the artificial joint. At that stage, the operation site was closed up and the plaintiff removed to a post-operative room for recovery. While there, a routine post-operative X-ray was taken, and although the quality of the film was not good, it did reveal a fracture on the lateral side of the femur adjacent to the tip of the prosthesis. The plaintiff had reacted badly to the epidural anaesthetic and was very ill with severe vomiting, and indeed continued to be quite ill in this way for a number of days after the operation. This outruled, in the first named defendant's view, any return to theatre that night for revision surgery to treat this fracture.

13. As to the cause of the plaintiff's fracture, in the evidence, three schools of thought emerged in relation to this. Firstly, it was Professor Galesko's evidence that in his opinion, the fracture was started initially by the deflection of the of the "A" profiler laterally of the Hardinge Plug, perforating the lateral cortex, with the full fracture then opened up by the pressure created by the cement and the insertion of the prosthesis. The first named defendant thought that the fishmouth fracture occurred when the "A" profiler diverged or deflected laterally to the side of the plug causing the lateral cortex to split because of excessive pressure due to lack of space for the plug and the profiler.

14. Professor McCormack was of the opinion that the cause or causes of the fracture were multi-factorial and that it was not possible to say what had caused the fracture, but he thought it very unlikely the "A" profiler could have done it. His evidence was to the effect that fractures during revision hip replacement operations are a rare but well-known occurrence resulting from a variety of stresses to which the femur is subjected during the course of the procedure, related to the underlying condition of the bone in the

femur.

15. Mr. Quinlan, initially, in his examination in chief, emphatically discounted the "A" profiler as the cause of the fracture, being of the view it would be nearly impossible for this instrument to pierce cortical bone when tapped down lightly from above. It was his view that having regard to the tapering of the end of the "A" profiler, and the fact that its tip was relatively blunt, it would merely slide off the lateral cortex. For it to pierce the cortex, it would have to come at the cortex at an angle of 60 to 70 degrees. In direct evidence, Mr. Quinlan appeared only to consider a perforation fracture, which he discounted. In the course of his cross-examination, Mr. Quinlan, having regard to the length of the prosthesis at 15 cm and to the depth to which the Hardinge Plug had descended, as calculated from the piece of metal in the base of the plug, agreed that it was likely or probable that the "A" profiler had descended to a depth that was greater than the depth at which the Hardinge Plug was located and therefore that it must have bypassed the Hardinge Plug. He agreed that having regard to the constraint of space in that area, the passage of the "A" profiler to the lateral side of the plug had the effect of creating sufficient pressure to burst or split outwards the lateral cortex causing the fishmouth fracture which, in fact, did occur, hinging proximally from close to the DHS screw hole above. In short, Mr. Quinlan's position, in the end, approximated to that of the first named defendant insofar as the cause of this fracture is concerned.

16. A number of features in the evidence tend to persuade me that the fracture was caused by the excess pressure which occurred when the first named defendant was tapping down the Hardinge Plug with the "A" profiler. The first significant feature is the actual experience which the first named defendant had while doing this. He himself described a sensation of *"giving way"*, which was sufficiently unusual to alert him to the necessity to halt the procedure to carry out clinical checks to outrule a fracture. It is highly probable that this sensation of giving way coincided with the opening up of the fracture, thus, obviously easing the pressure which had built up in the area.

17. The second significant feature is the ultimate position of the Hardinge Plug. The first named defendant, by using the introducer, had brought the Hardinge Plug to a depth of 15cms in the femoral canal. I am satisfied that at that time, the depth of 15cms was from the base of the Hardinge Plug *i.e.* within its cup, where the introducer screwed into the base of the cup. That would have meant that the portion of the Hardinge Plug below that, was at a lower depth in the femoral canal, down to about 15.5cms but no lower than 15.8cms. The X-ray of 31st March 2003, which undoubtedly represents the position of the relevant objects *i.e.* the prosthesis and the Hardinge Plug, immediately after the surgery, demonstrated that the metal object in the Hardinge Plug is very slightly distal to the tip of the prosthesis, and, of course, that the prosthesis has diverted laterally. The difference in depth between the tip of the prosthesis and the metal object was measured on the X-ray at 4mms. All the experts agreed that this was an unreliable measurement because of the distorting magnification that occurs with X-rays, but all also agreed that while the absolute measurement was unreliable, the relative proportions between the two was reliably demonstrated. This suggests that, as the tip of the prosthesis which was undoubtedly at a depth of 15cm, was only slightly proximal to the position of the metal object in the Hardinge Plug, which in turn was a few millimetres below the internal floor of the Hardinge Plug into which the introducer screws, that point or place into which the introducer screwed, which was at a depth of 15cm; meaning that there had been no significant downward movement of it after the introducer had been unscrewed and taken away, which in turn meant that the downward tapping of the plug by the "A" profiler did not move the plug distally, and hence, as the profiler descended to a depth of 16cm, this meant that the profiler had somehow moved to the side of the plug, coinciding with the opening up of the fracture.

18. It may very well be that the full extent of the ultimate fracture was not opened up in this action, and indeed it may have been expanded or propagated by the later introduction of the cement and prosthesis, which would undoubtedly have brought to bear far greater pressures than would have been the case in the tapping down of the plug with the "A" profiler, but that cannot gainsay the fact that the initial opening of the fracture occurred when the "A" profiler was being tapped down.

19. In substance, therefore, I am in agreement with the opinions expressed by the first named defendant himself and ultimately supported by Mr. Quinlan, and to a significant extent supported by Professor Galesko as to the cause of this fracture.

20. In these proceedings, the plaintiff claims that the first named defendant was negligent in the manner in which he carried out this aspect of the procedure. Whilst some other aspects of negligence were canvassed, for example, the failure to have carried out an X-ray during the operation when the first named defendant initially suspected a fracture, the case focused almost exclusively around the allegation that the first named defendant was negligent in using the "A" profiler to tap down the Hardinge Plug because it had a sharp, pointed or tapered end rendering it likely to deflect off the plug or through the plug, thereby causing the fracture that occurred. Insofar as the allegation that the first named defendant was negligent in not having an X-ray done during the operation, I am quite satisfied from the weight of the evidence that having regard to the clinical checks that were carried out, it could not be said that there was a deviation from acceptable practice in not having carried out an X-ray, having regard to the risks associated with taking that course, namely, the lengthening of the procedure and the increased risk of infection. I am quite satisfied there was no negligence on the part of the first named defendant in that regard.

21. The real issue in the case is whether or not the first named defendant was negligent in using the "A" profiler to tap down the Hardinge Plug.

22. In order to consider that question, it is essential to stress that it must be looked from a prospective point of view rather than with the benefit of hindsight. In other words, this court must, as best it can, stand in the shoes of the first named defendant and appraise the variety of relevant considerations that arose in this surgical procedure and to assess the decision of the first named defendant to use the "A" profiler for that purpose, in that context.

23. The plaintiff came into the surgery with a complicated medical history. She had had a fall the previous October resulting in the fracture of the head of her femur. Given her relative youth at the time, it is probable that the occurrence of a fracture in these circumstances was indicative of bone in relatively poor condition, namely, either ostheoporitic or osteopenic. Following the surgery for this, she was non-weight bearing on the injured limb for some considerable time, and then when it appeared she was doing well, that process was reversed and it becomes apparent that avascular necrocis has set in which led, in due course, to the decision to do a total hip replacement. Thus, from October 2006 through to March 2003, the plaintiff was relatively immobile and this would have contributed to the deterioration in the condition of the bone in her femur. This, too, would have been accentuated by the presence from the operation in October 2006 of the Dynamic Hip Screw, which, while in place, had the effect of causing further deterioration because of the process of stress shielding.

24. It is very probable, therefore, that the condition of the bone in the plaintiff's femur was, when the total hip replacement was done on 19th March 2003, relatively poor. This would have been well known to first named defendant when planning the surgery.

25. The first named defendant selected the Aesculap system because having regard to the equipment available in the hospital and because he wished to use the Birmingham hip, this was a suitable system, and indeed, there was no criticism of him for selecting this

system.

26. All of the various hip replacement systems come with their own set of tools as did this Aesculap system. This set included the A and the B profilers as the broaches. It did not include a separate trial prosthesis. It would appear the reason for that was because the A and B profilers corresponded exactly in size to the uncemented prosthesis, these could be used as the trial prostheses, as was done by the first named defendant in this case.

27. The first named defendant, having reached the point at which he decided to put in a cemented prosthesis, which is an option which is available in the Aesculap system after the broaching process has been completed, selected the Hardinge Plug as a cement restrictor. No criticism was made of the first named defendant in that regard. The Hardinge Plug is a standard piece of equipment available for a considerable period of time. One size fits all femoral canals because the petals attached to the base of the plug are designed to fold inwards or expand outwards to adapt to the size of any particular canal. The evidence of all the experts establishes that in the process of being inserted, it is very common for some of these petals to become detached and they are usually washed out in the lavage which precedes the cementing process.

28. The Hardinge Plug comes with its own 'Introducer' as described earlier. The first named defendant used this to get the Hardinge Plug to a depth of 15cms at which point he appeared to encounter resistance and he detached or unscrewed the Introducer from the plug. He was heavily criticised for not having left the introducer screwed in place and tapped it to get the plug to the required depth.

29. In response to this, the first named defendant described in some detail the difficulty of using the Introducer deep in the femoral canal. His evidence was to the effect that the Introducer is a straight, cylindrical object which has a diameter of approximately 1 cm over most of its length, though it does narrow towards its end, and because the femur is not a straight bone, but rather, is curved, the introducer tends to become fixed in what he described as a *"three-point fixing".* This would appear to have two consequences, the first being the problem of jamming or getting stuck against the walls of the femur, and the second being that because it is straight and the bone is curved, the end of the Introducer would tend to be off-centre in the canal, namely, to move away from the centre of the canal.

30. Because of this, the first named defendant decided that it was better to discard the Introducer and use the "A" profiler to tap the plug to its final desired position. In selecting a broach to do this, the first named defendant was not doing anything unusual. It is quite clear from the evidence of all the experts that it is common practice to use either a trial prosthesis or broaches to tap a Hardinge Plug into its final position.

31. The criticism of the first named defendant in selecting the "A" profiler for this purpose was based upon the fact that it had a pointed, tapered or sharp end which both Professor Galesko and Mr. Kearns criticised on the basis that there was an unacceptable risk in tapping or hammering an instrument with a pointed or sharp end into a space that one could not see. Professor Galesko was particularly critical of the suitability of the "A" profiler for this purpose because of its pointed end.

32. I accept the first named defendant's explanation of why he did not continue to use the introducer to get the Hardinge Plug to its final position. I can readily envisage that a straight metal cylinder with a diameter of approximately 1cm would become extremely difficult to manoeuvre in a femoral canal whose diameter would have made for a tight fit around the Introducer. When one adds to this the difficulty caused by the fact that the femur is curved, it can readily be envisaged that trying to position this plug down at a depth of approximately 16cm would be very difficult, and indeed it would be very difficult to ensure that the Introducer itself did not, because of its straight shape, force the plug off-centre, thereby compromising its effectiveness as a cement restrictor.

33. If the Introducer is, reasonably, considered unsuitable for the manoeuvre of getting the Hardinge Plug into its final position, one wonders what other instrument could have been chosen by the first named defendant for this task. Mr. Kearns did suggest using another cemented prosthesis. There is no doubt that one was available because the first named defendant himself said that there were always two kept for each procedure. Whilst Mr. Kearns did suggest this, the matter clearly was not pressed.

34. That would leave, then, only either of the two broaches, the A or the B. The first named defendant selected the "A" profiler in order not to interfere with the profiling already achieved by the B profiler in the proximal femur.

35. In determining whether or not the use by the first named defendant of the "A" profiler to tap down the Hardinge Plug was negligent, one must, in the first instance, consider the advantages associated with the use of this instrument and also the risks involved.

36. There were, in my opinion, obvious advantages in using the "A" profiler for this purpose. The femoral canal had been broached so that the "A" profiler, or indeed the B profiler, would fit snugly into the broached canal and thereby the tip of the "A" profiler would have been very likely to have met the centre of the Hardinge Plug. The use of some other instrument that was not profiled to the canal as broached would not have been nearly as likely to encounter the Hardinge Plug towards its centre.

37. The "A" profiler undoubtedly had a pointed or tapered end to it, but in my opinion, this could not be described as sharp. I have had the opportunity of examining these instruments over several days, and it is quite clear that although pointed, the end of the "A" profiler is blunt and unless extraordinary force was applied to it, it could not pierce anything other than the softest and most pliable material. Undoubtedly, it could find its way through the petals of a Hardinge Plug if deflected sideways. I would agree with Mr. Quinlan that unless it approached cortical bone at an angle of 60 or 70 degrees, it would not penetrate or perforate it, but rather, would slide off it.

38. Much evidence was concentrated around the position of the Hardinge Plug after it had been inserted to a depth of 15cm by the first named defendant. In this respect, I am satisfied from the evidence that at that depth in the canal, the cancellous bone surrounding the Hardinge Plug was of a soft or honeycomb variety as distinct from the harder, more crunchy-bar type in the proximal end of the femur. Distal to the Hardinge Plug was the femoral canal itself which Mr. Quinlan described as being approximately 8mm or more in diameter, and we know that the first named defendant had reamed down as far as he could go with the taper pin reamer, which I infer would have taken him down to the isthmus or close to it. Thus, the probable ambiance in which the Hardinge Plug rested after inserted with the Introducer was one in which the petals of the Hardinge Plug were confined by very soft honeycomb cancellous-type bone and distal to it was the empty femoral canal.

39. Because of the nature of the cancellous bone surrounding the Hardinge Plug, it would seem to me to be highly probable that the petals of the Hardinge Plug were not closed in tightly, as was demonstrated by using a jubilee clip during the course of this trial, but must have expanded out to some extent, which would have been permitted by the soft material confining them. If, as seems likely, some of the petals, as ordinarily happens, were shed as the plug was introduced, that would have contributed to leaving some

additional space towards the centre of the cup formed by the petals.

40. A surgeon, therefore, faced with the selection of an instrument to tap down the Hardinge Plug in these circumstances, would, in my opinion, if he closely examined the "A" profiler, be very likely to think that it was likely, in the first place, to move inexorably towards the centre of the plug, and secondly, to be received there by a cup formed by the petals which was sufficiently open to permit the tapered end of the "A" profiler to slot in between the petals towards the floor or bottom of the cup formed by the petals.

41. That, in my opinion, would be the result of a careful and considered examination by a surgeon of the instrument in question used in the circumstances involved.

42. Furthermore, because the canal distal to the plug was open to a diameter of at least 7mm, a surgeon faced with this situation would, in all probability, consider that the application of downward pressure by tapping the "A" profiler into the Hardinge Plug would be very likely to simply move it downwards.

43. These outcomes just described would, in my opinion, be the highly probable results of using the "A" profiler in the circumstances in which the first named defendant used it.

44. One has to bear in mind in all of this that the force being applied by the first named defendant to tap down was of a gentle nature. His evidence in that regard was not challenged.

45. In that circumstance, it would seem to me that the risks of an adverse event occurring, such as did occur, would, when viewed prospectively, have seemed very unlikely to the point of being almost remote or negligible.

46. In the course of his evidence, the first named defendant emphasised the various stresses on the femur at this time, namely, the shearing, bending and tortional stresses resulting from the position in which the plaintiff's leg was held, and then added to that, the hoop stresses arising from the outward pressure generated by the petals of the Hardinge Plug. It would seem to me to be probable that having regard to the poor condition of the bone in the plaintiff's femur, that the accumulation of these stresses was the primary contributory factor in the occurrence of the fracture and that the relatively minor additional force created by the tapping down of the plug with the "A" profiler was the tipping point or the last straw which precipitated the fracture and once the fracture occurred, this created an opening out of the bone at that point which permitted the "A" profiler to exit through the petals of the petals of the plug and down the lateral side of it.

47. In this highly stressed environment, it is hard to see how an instrument with a blunt tip would be preferable to one with a tapered tip. A blunt tip would be less likely to find its way into the space within the petals of the plug and more likely to impact on top of the petals rather than finding its way to the base of the plug within the gap created by the petals. In that circumstance, one would have thought a blunt-tipped instrument, such as a cemented stem, would increase the hoop stresses which the petals of the plug generated, whereas the tapered tip of the "A" profiler, finding its way to the base of the plug was unlikely to increase the hoop stress of the plug and more likely, when tapped gently, to generate a force which would drive the plug distally.

48. I emphasise the necessity of assessing what the first named defendant did prospectively, rather than from hindsight. After the surgery on 19th March, 2003, the first named defendant did correspond with the Irish Medicines Board and others and expressed a concern about the sharp or tapered tip of the "A" profiler, although in his evidence, after closely examining the "A" profiler and the Hardinge Plug in its closed up state, he seemed to satisfy himself that the risks he apprehended in his correspondence were not there.

49. I have come to the conclusion that when assessed prospectively, the risks of the "A" profiler causing damage of the kind that occurred or similar to it would have seemed remote, whereas the obvious advantage of using the "A" profiler to get at the plug, and the prospect of entering the plug centrally or close to it, so as to move it distally, would have seemed in the realm of high probability.

50. The mere existence of a remote risk could not require the abandonment of a procedure which had obvious advantages and carried with it a very high probability of achieving the desired outcome.

51. In these circumstances, I do not think it can be said that the first named defendant, when using the "A" profiler in these circumstances, fell below a standard to be expected of a consultant orthopaedic surgeon carrying out a procedure of this kind. Neither can it be said, in my view, that in considering the use of the "A" profiler in these circumstances, that it should have been obvious that its use in this way was dangerous and likely to cause injury. On the contrary, the reverse was the case.

52. I have therefore come to the conclusion that there was no negligence on the part of the first named defendant in carrying out this procedure and, accordingly, I must dismiss the plaintiff's action.