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Litigation after hip and knee replacement in the National Health Service

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Abstract

The results of hip and knee replacement surgery are generally regarded as positive for patients. Nonetheless, they are both major operations and have recognised complications. We present a review of relevant claims made to the National Health Service Litigation Authority. Between 1995 and 2010 there were 1001 claims to a value of £41.5 million following hip replacement surgery and 523 claims to a value of £21 million for knee replacement. The most common complaint after hip surgery was related to residual neurological deficit, whereas after knee replacement it was related to infection. Vascular complications resulted in the highest costs per case in each group.

Although there has been a large increase in the number of operations performed, there has not been a corresponding relative increase in litigation. The reasons for litigation have remained largely unchanged over time after hip replacement. In the case of knee replacement, although there has been a reduction in claims for infection, there has been an increase in claims for technical errors. There has also been a rise in claims for non-specified dissatisfaction. This information is of value to surgeons and can be used to minimise the potential mismatch between patient expectation, informed consent and outcome.

Introduction

The National Health Service Litigation Authority (NHSLA) was created in 1995 to indemnify National Health Service Trusts in England. Initially it was only responsible for larger claims, but since 2002 has kept data on all claims made against the NHS. Up to March 2010 the NHSLA has handled more than 57 000 claims for negligence of all types, of which more than 22 400 were related to surgery (excluding obstetrics and gynaecology), at a total cost of £1.82 billion.[[1,2]] In the year 2010/2011 it made payments of more than £729 million for clinical negligence.[[3]] The NHSLA estimates that its potential liabilities for all clinical negligence are in the region of £16.6 billion.[[3]] This aim of this study was to review claims made through the NHSLA relating to hip and knee replacement surgery, to explore the reasons for litigation and to explore trends over time.

Hip and knee replacement surgery produce some of the highest health gains, both in terms of improvement in quality of life and in cost-effectiveness.[[4-6]] Both are major procedures, however, and are associated with well-recognised morbidity and, rarely, mortality.[[7,8]]

The National Joint Registry for England and Wales reported that > 163 000 hip and knee replacement operations were performed in the year 2009/2010, nearly double the 90 000 operations noted in the first annual report of September 2004. It takes the total number of hip and knee replacements to > 900 000 since the registry began collecting data in 2003.[[9,10]]

When total claims for negligence are considered year on year, based on the year of incident as opposed to the year in which the claim was made, the number of claims recorded by the NHSLA has remained relatively stable. Between 1995 and 2006 the mean number of claims per year was 5701 (5190 to 6282), although owing to the varying time interval between incident and claim it cannot be determined with any certainty how this trend has evolved in recent years.[[1]] There is, however, a general perception that

litigation for alleged medical negligence is increasing.[[11]] This perception has led to concern that surgeons are practising defensively at the expense of best practice.[[11-13]]

Although previous studies have reviewed the general state of litigation for orthopaedics[[14]] within the NHS and others within the private sector,[[15]] it is not clear whether in the United Kingdom there is evidence of any trend towards increasing litigation associated with hip or knee replacement.

Materials and Methods

In 2011, a freedom of information request was made to the NHSLA asking for data about all claims involving orthopaedics and trauma, to include year of incident, the year the claim was made, the nature of the claim and, where applicable, the costs incurred (defence costs, claimant costs and damages paid). Data were provided by NHSLA from the period 1995/96 to 2009/10. These data were then filtered to include only those cases involving hip and knee replacement. Definitions such as 'hip operation' or 'knee operation' were considered ambiguous and therefore excluded from this analysis. The details of each claim were then categorised and are summarised in Tables I and II.

Table I. Causes attributed to claims made for hip replacement surgery

Cause	Description
Neurological deficit	Any nerve damage cited in claim
Technical errors	Claims relating to the technical aspects of the operation such as incorrect components/incorrectly inserted, and retained cement
Local infection	Infection of the surgical site only. (Pneumonia etc. included in miscellaneous)
Miscellaneous	Claims either not Specific or inclusive of a low number of rarer causes of claims
Leg-length inequality	Claims for leg-length inequality
Peri-operative injury	Injuries sustained during the operation, such as fractures, burns, lacerations and injuries during transfer
Pain	Any reference made to pain were included in this category in addition to the cause if detailed
Wrong-side surgery	Any surgery mistakenly performed on the contralateral side
DVT/PE	Where reference to deep vein thrombosis (DVT) or pulmonary embolus (PE) was made in the claim
Post-operative care	This group includes all aspects of post-operative care, such as falls and issues surrounding nursing and physiotherapy care as well as post-operative renal failure
Fatality	Where there was death from any cause
Dislocation	All claims citing dislocation
Vascular complications	Any vascular insult including vessel injury and compartment syndrome
Delay	Where there was delay from any cause cited
3M	Claims relating to the 3M total hip replacement
Prosthetic failure	Including ceramic fracture or where a specific allegation of prosthesis failure was made

Table II. Causes attributed to claims made for knee replacement surgery

Cause	Description
Local infection	Infection of the surgical site only. (Pneumonia etc. included in miscellaneous)
Technical error – component	All allegations relating to the technical aspects of the implant and the operation; incorrect implant, wrong size or poor alignment.
Alleged negligence	This term was commonly and specifically used without reference to another cause
Miscellaneous	Claims either noon specific or inclusive of a low numbeof rarer causes of claims
Post-operative care	This group includes all aspects of post-operative care, such as falls and issues surrounding nursing and physiotherapy care as well as post-operative renal failure
Pain	Any reference made to pain were included in this category in addition to the cause if detailed
Technical error – other	Technical issues during the operation that did not relate to the components, such as cementophytes, retained drains and patella not being resurfaced
Neurological deficit	Any nerve damage cited in claim
Vascular complications	Any vascular insult including vessel injury and compartment syndrome
Peri-operative injury	Injuries sustained during the operation, such as fractures, burns, lacerations and injuries during transfer.
DVT/PE	Where reference to deep vein thrombosis (DVT) or pulmonary embolus (PE) was made in the claim
Poor range of movement	
Fatality	Where there was death from any cause
Delay	Where there was delay due to any cause cited
Prosthetic failure	Where there was failure of a component, e.g. the modular rotating platform, or the whole prosthesis
Dislocation	All claims citing dislocation

Owing to the nature of the descriptions attached to a given claim, no distinction was made between the various types of hip and knee replacements. As a claim for negligence may arise from cumulative dissatisfaction, many claims attribute more than one cause for complaint, meaning that there are more ‘causes’ discussed than individual claims. Consequently, an individual claim may appear more than once in the data as each cause is included separately. Where either ‘no costs’ or only ‘defence costs’ were incurred, this was taken to mean that the case was successfully defended (provided the case was closed). Where either claimant’s costs or damages were paid, this was interpreted as the NHS having lost the case. The data were then sorted to compare, for each cause of claim, the total number of claims closed and the total number of these claims that were paid out.

The data were divided into two periods, 1995/96 to 2002/03 and 2003/04 to 2009/10 (the approximate halfway point) to allow analysis of any change in the nature and number of claims between the two periods. The second period included both open and closed claims.

Results

Over the study period a total of 22 500 claims were made to the NHSLA relating to surgery (excluding obstetrics and gynaecology), with costs > £1.8 billion. Of these, 8950 (40%) involved orthopaedics at a cost of £402 million (22%).

Of the orthopaedic claims, 1527 (17%) were related to hip or knee replacement surgery. The value of these claims to date exceeds £62 million, or 15.5% of the total awards made in relation to orthopaedic surgery. Of the claims, 224 (14.6%) remain 'open' or unsettled at the time of writing (136 hips and 88 knees).

Hip replacement surgery accounted for 1001 of the claims, at a current cost of over £41.5 million. This corresponds to 11% of orthopaedic claims and 10% of the overall cost. After knee replacement surgery 523 claims had been made, at a cost of £21 million, which represented 6% of all orthopaedic claims and 5% of the total cost.

Causes of claims data

A summary of claims relating to hip replacement surgery is detailed in Table III. A total of 413 of 1001 claims were paid out. The mean total cost of contested cases that were subsequently lost and where damages were paid was £98 000.

Table III. Summary of claims data for hip replacement surgery (DVT, deep-vein thrombosis; PE, pulmonary embolism)

Cause of claim	Total number of cases (%)	Cases closed	Percentage paid (%)*	Highest cost (nearest £100)†	Mean cost (nearest £100)‡
Neurological deficit	159 (*13.9*)	138	46	£384 500	£116 800
Technical error	138 (*12.0*)	123	68	£814 500	£111 700
Infection	133 (*11.6*)	113	46	£639 700	£138 600
Miscellaneous	124 (*10.8*)	101	38	£531 600	£107 000
Leg-length inequality	100 (*8.7*)	100	44	£595 000	£84 000
Peri-operative injury	86 (*7.5*)	68	56	£131 900	£48 200
Dislocation	78 (*6.8*)	71	51	£448 300	£105 200
Post-operative care	71 (*6.2*)	63	62	£466 900	£59 500
Delay	59 (*5.1*)	55	45	£324 300	£39 100
Pain	49 (*4.3*)	43	44	£448 300	£111 700
Fatality	37 (*2.4*)	31	68	£207 800	£49 300
DVT/PE	36 (*3.1*)	32	50	£292 000	£58 300
Prosthetic failure	36 (*3.1*)	32	50	£354 800	£81 000
3M system	34 (*3.0*)	34	3	£46 600	£46 600
Vascular	13 (*1.1*)	10	70	£1 052 500	£375 800
Wrong site	4 (*0.3*)	4	75	£24 400	£17 400

*refers to % of total claims that incurred claimant's cost and/or damages
† includes all costs, defence, claimants and damages
‡ mean cost of contested claims subsequently lost

The highest single cost, at > £1.05 million, arose from a case of vascular injury in which the involvement of the vascular surgeons was delayed, resulting in compartment syndrome. Although cited as a cause in only 13 (1.1%) of claims, vascular injury resulted in the highest mean pay-outs. A further four of the 13 claims resulted in compensation > £100 000, one of which was > £1 million. These four claims addressed major vessel injury, compartment syndrome, amputation and one death.

Other causes of litigation that resulted in compensation above the mean of £98 000 were infection, neurological deficit, technical error, pain and dislocation. A 'miscellaneous' group included 13 paid claims which cost more than £100 000, 12 of which were non-specified 'dissatisfaction' with outcome.

Comparable data on claims for knee replacement surgery are summarised in Table IV. A total of 218 of 523 claims were paid out, with a mean cost for cases contested and loss of £93 000. The highest single cost was for a vascular injury that resulted in compartment syndrome and subsequent amputation. Vascular injuries accounted for 4.2% of claims but generated the highest mean cost (£232 900). There were ten further claims that resulted in payments of more than the mean figure for knee replacements (£93 000). Seven of these involved compartment syndrome, amputation or both, and the remaining three cases were for vascular injury or ischaemia.

Table IV. Summary of claims data for knee replacement surgery (DVT, deep-vein thrombosis; PE, pulmonary embolism)

Cause of claim	Total number of cases (%)	Cases closed	Percentage paid (%)*	Highest cost (nearest £100)†	Mean cost (nearest £100)‡
Infection	95 (*16.7*)	81	41	£447 700	£138 700
Tech. error component	63 (*11.1*)	50	76	£391 600	£70 600
Alleged negligence	64 (*11.2*)	47	28	£158 300	£65 100
Miscellaneous	55 (*9.6*)	49	46	£246 900	£63 200
Post-operative care	51 (*8.9*)	48	65	£395 500	£65 800
Pain	50 (*8.8*)	44	39	£286 000	£87 000
Tech. error other	42 (*7.4*)	31	61	£111 300	£29 100
Neurological deficit	36 (*6.3*)	31	52	£393 500	£123 800
Vascular	24 (*4.2*)	22	68	£779 000	£232 900
Peri-operative injury	21 (*3.7*)	19	53	£230 200	£56 500
DVT/PE	20 (*3.5*)	16	38	£192 200	£115 100
Poor range of movement	19 (*3.3*)	18	44	£230 200	£75 400
Fatality	10 (*1.8*)	9	79	£106 300	£44 200
Delay	9 (*1.6*)	8	63	£61 800	£26 700
Prosthetic failure	7 (*1.2*)	5	60	£253 700	£176 800
Dislocation	4 (*0.7*)	3	67	£202 800	£123 200

* refers to % of total claims that incurred claimant's cost and/or damages
† includes all costs, defence, claimants and damages
‡ mean cost of contested claims subsequently lost

Other causes that resulted in mean costs greater than average were prosthesis failure, infection, neurological deficit, dislocation, and DVT/PE.

Trends

For hip replacements, the total number of claims per annum has changed little between the two time periods. There were 575 claims in the period 1995/96 to 2002/03 and 581 between 2003/04 and 2009/10 (Table V). Although the absolute number of claims after hip replacement was relatively stable, there was an increase over the two time periods in the proportion of claims for injury resulting in neurological deficit, which is now the commonest cause of litigation for hip replacement surgery.

Table V. Comparison of data before and after 2002/3 for hip replacements (DVT, deep-vein thrombosis; PE, pulmonary embolism)

Cause of complaint	1995 to 2002/03	2003 to 2009/10
All causes	575	581
Technical error	13	11
Neurological deficit	12	15
Infection	11	12
Miscellaneous	10	12
Leg-length inequality	9	9
Post-operative care	6	6
Delay	6	4
3M hip system	6	0
Dislocation	6	8
Peri-operative injury	5	10
Pain	5	4
DVT/PE	4	2
Prosthetic failure	4	2
Fatality	3	3
Vascular injury	1	1
Wrong site	0	1

The time trend data for knee replacement show a 46% increase in the total number of claims, from 232 to the end of 2002/03 to 337 in 2009/10 (Table VI).

Table VI. Comparison of data before and after2002/3 for knee replacements (DVT, deep-vein thrombosis; PE, pulmonary embolism)

Cause of complaint	1995 to 2002/03	2003 to 2009/10
All causes	232	338
Infection	20	14
Miscellaneous	13	8
Post-operative care	11	8
Neurological deficit	9	5
Pain	9	9
Technical error –component	8	13
Vascular injury	6	3
Poor ROM	6	2
Technical error – other	5	13
Alleged negligence	5	16
Peri-operative injury	3	4
DVT/PE	3	4
Fatality	2	1
Dislocation	1	1
Delay	1	2
Prosthetic failure	0	2

Within the individual categories there is evidence of considerable change in the cited reason for bringing a case. ‘Alleged negligence’ increased from 5% to 16%, ‘technical error – component’ and ‘technical error – other’ increased by 5% and 4%, respectively. Conversely, the proportion of claims associated with infection dropped from 20% to 14%, ‘miscellaneous’ fell from 13% to 8%, ‘post-operative care’ from11% to 8%, neurological deficit from 9% to 5%, and vascular causes from 6% to 3%.

Discussion

Despite an increase in the number of hip replacements being carried out during the study period, there has not been a dramatic increase in the overall number of claims, 495 claims citing 575 complaints up to the end of 2002/003 and 506 claims citing 581 complaints in 2009/10. Although there is a lag between event and the initiation of claims, there does not appear to have been a disproportional increase in litigation for hip replacement surgery. Indeed, considering the increased volume of surgery, in relative terms the number of cases of litigation has fallen.

Claims after knee replacement increased by 45% over the two time periods. Although this is a bigger increase than seen with hip replacement surgery, the number of total knee replacements carried out since 2004 has nearly doubled. Consequently, this also constitutes a relative decrease in litigation. In total knee replacement the causes 'technical error – component', 'technical error – other' and 'post-operative care' are among the most cited causes in overall claims, and are also among the more significant in claims paid out (76% to 61%), a trend similar to that seen after hip replacement surgery. It is striking from the time-trend data that the proportion of litigation due to infection has fallen from 20% to 14% by 2010. This must been seen as encouraging.

It is difficult to draw clear conclusions from the group of claimants citing 'alleged negligence' owing to a lack of detail. This may be due to the way in which the data were recorded, or may simply reflect claims that relate to more general dissatisfaction with the outcome of knee replacement surgery. What cannot be ignored, however, is that between 2002/03 and 2009/10 this group underwent the largest increase in claims. The non-specific nature of this type of claim, in which it is difficult to isolate the nature of the complaint and therefore the resulting loss, may be the cause of the low rate of pay-out, only some 28% of all cases being closed.

Within this dataset there are limitations in the description that accompanies each claim. The NHSLA information is intended primarily for claims management. The data are not

structured for clinical purposes, and the clinical detail within the claim is limited to the major points of the claim. Furthermore, before April 2002 the NHSLA did not specifically collect data on cases below a certain level (varying between £10 000 and £50 000), so it is not possible to draw specific conclusions about trends before this date.

One assumption we were required to make in this analysis was the absence of co-liability. It is possible that there were other unknown and confounding factors whereby a patient had a reasonable claim for an NHS operation but the NHSLA was not found to be liable. An example of this would be the claims associated with the 3M hip, in which the liability for costs was passed to the third party.

The current analysis also only addresses legal challenges that followed alleged negligence, and there are likely to be occasions where clinical negligence has occurred but litigation has not been pursued, and conversely, cases where clinical negligence has not been proven or admitted but a settlement has been agreed.

Although the current data provide an overview of the causes of litigation, it has not been possible to distinguish between the different types of joint replacement operation performed, such as hip resurfacing, unicondylar knee replacement, patellofemoral joint and more established total replacements. Further work on the patterns of poor outcome and legal intervention associated with specific techniques would be instructive.

This study shows that over the last decade or so the absolute number of claims made against the NHSLA for hip replacement surgery has remained fairly stable, but has decreased as a proportion of the total procedures performed. Furthermore, the reasons for the claims are consistent and generally well recognised by surgeons.

There have, however, been changes in the pattern of litigation for knee replacement surgery, and although cases of infection have reduced in number, a previously small and non-specific category where there is simply ‘alleged negligence’ has notably increased. This is of concern for surgeons, as it is difficult to plan against such a non-specific allegation and it does not help refine techniques or improve outcomes.

Of equal concern is that there are three categories ('technical error – component', 'technical error – other' and 'post-operative care'), which appear on nearly a third of the claims but are not specifically discussed on the BOA consent form. We suggest that the pre-operative consenting process might be refined to draw explicit links between non-specific features such as pain and the possibility of technical shortcomings in the procedure.

It is encouraging that litigation for infection has diminished after both THR and TKR: this may reflect improvement in practice. There remains a large group of patients who sue the NHS for poorly specified reasons, but the NHSLA data provide no evidence to suggest that orthopaedic surgeons are, within the bounds of the NHS, subject to a more litigious culture.

References

1. **No authors listed.** NHSLA. The NHS Litigation Authority Factsheet 3: Information on Claims, 2010. www.nhsla.com/NR/rdonlyres/C1B3F310-E13D-4C71-B248-C5384438E603/0/NHSLAFactsheetclaimsinformation200708.doc (date last accessed 8 October 2012).

2. **No authors listed.** NHSLA. The NHS Litigation Authority Factsheet 1: Background Information, 2011. http://www.nhsla.com/NR/rdonlyres/C9A80E89-2BFA-44F5-A01C-90B86D765B2D/0/NHSLAFactsheet1August2011.pdf (date last accessed 8 October 2012).

3. **No authors listed.** NHSLA. The NHS Litigation Authority Factsheet 2: Financial Information, 2011. www.nhsla.com/NR/rdonlyres/465D7ABD-239F-4273-A01E-C0CED557453D/0/NHSLAFactsheet2financialinformation200708.doc (date last accessed 8 October 2012).

4. **Mason J, Drummond M, Torrance G.** Some guidelines on the use of cost effectiveness league tables. *BMJ* 1993;306:570-2.

5. **Räsänen P, Paavolainen P, Sintonen H, et al.** Effectiveness of hip or knee replacement surgery in terms of quality-adjusted life years and costs. *Acta Orthop* 2007;78:108-15.

6. **Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster JY.** Health-related quality of life in total hip and total knee arthroplasty: a qualitative and systematic review of the literature. *J Bone Joint Surg [Am]* 2004;86-A:963-74.

7. **No authors listed.** Ortho Consent. British Orthopaedic Association: Hip. http://www.orthoconsent.com/body2.asp?BodyPartID=4 (date last accessed 8 October 2012).

8. 7. **No authors listed.** Ortho Consent. British Orthopaedic Association: Knee. http://www.orthoconsent.com/body2.asp?BodyPartID=7 (date last accessed 8 October 2012).

9. **No authors listed.** National Joint Registry for England and Wales: 1st Annual Report, 2004. http://www.njrcentre.org.uk/ (date last accessed 8 October 2012).

10. **No authors listed.** National Joint Registry for England and Wales: 7th Annual Report, 2010. http://www.njrcentre.org.uk/ (date last accessed 8 October 2012).

11. **Gidwani S, Zaidi SM, Bircher MD.** Medical negligence in orthopaedic surgery: a review of 130 consecutive medical negligence reports. *J Bone Joint Surg [Br]* 2009;91-B:151-6.

12. **Upadhyay A, York S, Macaulay W, et al.** Medical malpractice in hip and knee arthroplasty. *J Arthroplasty* 2007;22(Suppl):2-7.

13. **Hettrich CM, Mather RC, Sethi MK, et al.** The cost of defensive medicine. *AAOS Now* 2010;4.

14. **Atrey A, Gupte CM, Corbett SA.** Review of successful litigation against english health trusts in the treatment of adults with orthopaedic pathology: clinical governance lessons learned. *J Bone Joint Surg [Am]* 2010;92-A:e36-6.

15. **Roberts K.** MDU Services Ltd. Orthopaedic Claims in Private Practice, 2007. http://www.the-mdu.com/section_hospital_doctors_and_specialists/topnav_advice_centre_1/hidden_Article_title_index.asp?doctype=advice&userType=hospital (date last accessed 8 October 2012).