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Hip and knee arthroplasty implants contraindicated in obesity

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ABSTRACT

INTRODUCTION High patient weight is a risk factor for mechanical implant failure and some manufacturers list obesity as a contraindication for implant use. We reviewed data from the 2012–2013 UK National Joint Registry to determine whether surgical practice reflects these manufacturer recommendations.

METHODS The product literature for the most commonly used hip and knee implants was reviewed for recommendations against use in obese patients (body mass index [BMI] ≥ 30kg/m^2). The total number of obese patients undergoing hip and knee arthroplasty was calculated, as was the proportion receiving implants against manufacturer recommendations.

RESULTS Out of 200,054 patient records, 147,691 (74%) had a recorded BMI. The mean BMI for patients undergoing primary total hip arthroplasty was 29kg/m^2, compared with 31kg/m^2 for total knee arthroplasty. Of the 25 components reviewed, 5 listed obesity as a contraindication or recommended against implant use in obese patients. A total of 10,745 patients (16% of all obese patients) received implants against manufacturer recommendations.

CONCLUSIONS A high proportion of patients are receiving implants against manufacturer recommendations. However, there are limitations to using BMI for stratifying risk of implant fatigue failure and manufacturers should therefore provide more detailed guidelines on size specific implant load limits to facilitate surgical decisions.

KEYWORDS

Hip – Knee – Arthroplasty – Obesity – Prosthesis – Implant

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Obesity is a risk factor for developing osteoarthritis of the hip and knee.[1] Defined as a body mass index (BMI) of ≥30kg/m^2, the prevalence of obesity has doubled in many European countries in the last 20 years.[2] In 2013, 26% of the UK adult population were classified as obese.[2] This trend is reflected in National Joint Registry (NJR) figures where the mean patient BMI continues to rise.[3]

The longevity of total hip replacement (THR) and total knee replacement (TKR) is determined by a combination of patient factors, surgical technique and implant design. In the presence of obesity, the risks of surgery are known to be greater.[4,5] Heavier patients also exert greater loads on implanted prostheses. It is therefore crucial that all orthopaedic implant designs are tested thoroughly under appropriate loading conditions prior to general market availability and that manufacturers inform surgeons of any foreseen limitations in the target population.

Some manufacturers list 'obesity' as a contraindication for implant use. This potentially has significant implications regarding the responsibility of surgeons in cases of mechanical implant failure if these implants are used in this patient population. We are aware of one current case of litigation concerning femoral stem fatigue failure in an obese patient where the manufacturer has denied liability on these grounds. In light of the potential magnitude of this problem, the aim of this study was to determine whether surgical practice reflects manufacturer recommendations in obese patients.

Methods

NJR data for 2012–2013 were analysed to identify the most commonly used primary THR and TKR components. The product literature (instructions for use) for the top five primary cemented and uncemented femoral stems and acetabular cups, together with the top five primary TKR components, was requested from the manufacturers and reviewed to ascertain the recommendations for component use in obese patients (BMI ≥ 30kg/m^2).

Results

The most commonly implanted primary THR and TKR components are shown in Table 1. Out of 200,054 patient

Table 1 The most commonly used hip and knee arthroplasty components and manufacturer recommendations for patients with obesity/excessive weight

	Implant	Manufacturer	Recommendation	Instructions for use reference
Cemented femoral stems	Exeter™ V40™	Stryker	Warning in heavy/obese patients	96E112 Rev. G
	CPT®	Zimmer	Warning in heavy patients	87–6203–912–22
	C-Stem® AMT	DePuy	Caution in obesity or excessive patient weight	IFU-78410023 Rev. E
	C-Stem®	DePuy	Caution in obesity or excessive patient weight	IFU-78410023 Rev. E
	CPCS	Smith & Nephew	**Contraindication – Morbid obesity (relative or absolute)**	81078790 Rev. C
Uncemented femoral stems	Corail®	DePuy	Caution in obesity or excessive patient weight	W90942 Rev. E
	Furlong®	JRI	**Contraindication – Obesity**	115–029 Issue 13
	Taperloc®	Biomet	**Relative contraindication – Morbid obesity**	5401000158 Rev. 10
	Accolade®	Stryker	**Contraindication – Obesity**	0095–3-200V
	M/L Taper	Zimmer	Warning in heavy patients	87–6203–501–22 Rev. E
Cemented acetabular cups	Contemporary	Stryker	Warning in heavy/obese patients	96E112 Rev. G
	Exeter® RimFit™	Stryker	Warning in heavy/obese patients	96E112 Rev. G
	Marathon™	DePuy	Caution in obesity or excessive patient weight	IFU-0902–00–701 Rev. N
	Elite Plus™ Ogee®	DePuy	Caution in obesity or excessive patient weight	IFU-0902–00–701 Rev. N
	Elite Plus™	DePuy	Caution in obesity or excessive patient weight	IFU-0902–00–701 Rev. N
Uncemented acetabular cups	Pinnacle®	DePuy	Caution in obesity or excessive patient weight	IFU-0902–00–701 Rev. N
	Trident®	Stryker	**Warning – Do not implant in obese patients**	QIN 4350 Rev. G
	CSF Plus	JRI	**Contraindication – Obesity**	155–019 Issue 14
	Exceed ABT™	Biomet	**Relative contraindication – Morbid obesity**	5401000427 Rev. 07
	Trilogy®	Zimmer	Counselling for heavy patients	87–6203–367–22
Total knee arthroplasty	PFC® Sigma®	DePuy	Caution in obesity or excessive patient weight	IFU-0902–00–252 Rev. K
	NexGen®	Zimmer	Counselling in heavy patients	87–6203–453–23
	Triathlon®	Stryker	**Contraindication – Obesity**	QIN4376 Rev. G
	Vanguard	Biomet	**Contraindication – Pathological obesity**	0902–00–077D
	Genesis™ II	Smith & Nephew	Contraindicated in conditions that tend to place increased loads on implants such as weight, which are incompatible with a satisfactory long-term result	81074901 Rev. O

records, 147,691 (74%) had a recorded BMI. The mean BMI for patients undergoing primary THR was 29kg/m^2, compared with a BMI of 31kg/m^2 for primary TKR. Of the 25 components reviewed, 5 listed obesity as a contraindication or recommended against implant use in obese patients and 4 reported morbid or pathological obesity as a contraindication. Of the remaining implants, all advised caution or patient counselling with regard to the risks of implant use in heavy, overweight or obese patients. Of all NJR data records reviewed with a recorded BMI of ≥30kg/m^2, 10,745 patients (16%) received implants against manufacturer recommendations (Table 2).

Table 2 National Joint Registry figures for the most commonly used hip and knee arthroplasty components. Dark shaded rows indicate implants that list obesity as a contraindication or recommend against implant use in obese patients.

	Implant	Number of procedures	Number with recorded BMI	Number with BMI =30kg/m^2	Mean BMI
Cemented femoral stems	Exeter™ V40™	30,762	23,120	8,654	28.5kg/m^2
	CPT®	5,574	4,038	1,536	28.6kg/m^2
	C-Stem® AMT	2,835	1,780	671	28.5kg/m^2
	C-Stem®	1,790	839	313	28.5kg/m^2
	CPCS	666	581	202	28.2kg/m^2
Uncemented femoral stems	Corail®	18,507	13,380	5,540	29.0kg/m^2
	Furlong®	3,565	2,621	**1,117**	29.2kg/m^2
	Taperloc®	3,250	2,372	1,001	29.1kg/m^2
	Accolade®	2,672	2,088	**851**	28.9kg/m^2
	M/L Taper	1,373	1,064	440	28.9kg/m^2
Cemented acetabular cups	Contemporary	10,327	8,048	2,971	28.4kg/m^2
	Exeter® RimFit™	4,338	3,343	1,275	28.7kg/m^2
	Marathon™	3,653	2,230	880	28.8kg/m^2
	Elite Plus™ Ogee®	3,309	2,462	902	28.4kg/m^2
	Elite Plus™	1,682	1,274	467	28.3kg/m^2
Uncemented acetabular cups	Pinnacle®	17,701	12,555	5,153	29.0kg/m^2
	Trident®	10,861	7,987	**3,146**	28.7kg/m^2
	CSF Plus	3,759	2,710	**1,132**	29.1kg/m^2
	Exceed ABT™	3,624	2,713	1,146	29.1kg/m^2
	Trilogy®	3,329	2,685	1,010	28.5kg/m^2
Total knee arthroplasty	PFC® Sigma®	26,899	19,921	11,384	31.0kg/m^2
	NexGen®	13,733	10,058	5,773	31.1kg/m^2
	Triathlon®	10,865	8,209	**4,499**	30.8kg/m^2
	Vanguard	8,000	6,171	3,423	31.0kg/m^2
	Genesis™ II	6,980	5,442	3,017	30.7kg/m^2

BMI = body mass index

Discussion

There are conflicting conclusions in the literature regarding the effect of obesity on functional outcomes and complication rates following primary THR and TKR. Some authors have highlighted that obesity does not have a negative impact on functional improvement[6–10] whereas others emphasise that obese patients have poorer postoperative function, quality of life and satisfaction.[5,11–18] Similarly, although some studies have been unable to identify a higher rate of complications in obese patients,[6,8,19–21] others have observed significant increases in operative time and postoperative infection,[5,12,16,22–31] THR dislocation rates,[5,13,25,26,32] TKR patellofemoral symptoms[33,34] and venous thromboembolism.[24,32,35] Obesity may also be associated with poorer long-term implant survival[11,16,24,36] and greater overall cost.[37,38]

Fatigue failure of THR femoral stems is a rare complication, usually as a consequence of excessive stress on the tensile surface of the implant.[39–42] Risk factors include high patient weight, greater level of activity, undersized implants, lack of proximal support, varus or retroverted orientation and the presence of metallurgic defects or other stress risers.[39–41,43–46] Although metallurgic defects appear to be the main cause of reduced fatigue strength, cases of failure in metallurgic normal stems do occur, prompting some authors to warn against use of small implants in patients with a raised BMI.[42,47,48]

Of the 25 THR and TKR components reviewed in this study, 5 listed obesity as a contraindication or recommended against implant use in obese patients. With more than 10,000 patients receiving implants against manufacturer recommendations each year, these results suggest that

surgeons are either unaware of the listed contraindications for some implants or knowingly use these implants against manufacturers' advice. In doing so, the surgeon may be adopting responsibility for the consequences of mechanical implant failure. By using the word 'caution' or 'warning', 15 of the remaining 20 implants still imply that there is a specific risk associated with use in the presence of obesity. Only 5 of the 25 implants reviewed appear not to warn against use in 'obese' patients.

This paper serves to highlight a number of important issues. First, in relation to implant failure, the use of BMI (or any terms of reference based on it such as 'obesity') is inherently flawed. The fatigue strength of any metallic construct is determined by the magnitude of internal stresses and number of load cycles. The internal stresses of a femoral stem are influenced by both the magnitude of the force vector (ie body weight) and its distance from the centre of rotation (moment arm). A patient of 1.67m and weighing 84kg is obese according to BMI. However, a patient of 1.85m and weighing 100kg has a BMI of $<30 kg/m^2$ and is therefore not classified as obese. If the moment arm, implant material and dimensions are the same for each patient, then the stem internal stresses will clearly be greater for the taller patient despite not being obese.

Second, by using obesity as a warning or contraindication for implant use, should we question the standards against which available implants are being tested? It would appear that if a surgeon is going to abide by manufacturer recommendations, then very few commonly used implants are as safe in the overweight population as they are in the remainder[2]. Is this really true? Given the steadily increasing size of this at-risk group, should there be specific implants for patients with certain dimensions and how should this population be defined? Certainly not by BMI or by the use of the term 'obese'.

Finally, should we as surgeons be informing patients of these warnings and the use of implants against manufacturer recommendations or should we simply not perform hip and knee arthroplasty in this population until better implants are available? It remains the case that implant selection is not straightforward, especially for new surgeons, and this choice is affected significantly by both training and the media.

With regard to the litigation risk associated with the use of these implants against manufacturer recommendations, this is different in the National Health Service (NHS) setting and in the private sector. In the NHS, there is no contractual relationship between patient and surgeon, with care being provided free as a public statutory obligation. The duty of care in that setting is based on common law, a breach of which gives rise to a claim of negligence. In the private sector, however, the patient has a contract for the provision of services and can therefore also sue for a breach of this contract. If a prosthesis has been used, there is a statutory implied term that the goods will be fit for purpose.

An area that is less clear is the recent emergence of 'fee assured' consultants, where patients are directed to surgeons via an insurance company. In this situation, the contractual arrangement is unclear and so much of the contractual liability may lie with the insurance company involved.

One important limitation of this study is the possibility of selection bias leading to overestimation of the proportion of patients who are obese, and therefore the mean BMI of patients undergoing hip and knee arthroplasty. The NJR editorial board acknowledges that 'all BMI data has to be viewed with caution as surgeons may be more likely to enter BMI data when the BMI is high'.[3] Nevertheless, given that only 74% of NJR records reviewed had a recorded BMI, the absolute number of obese patients receiving implants against manufacturer recommendations is likely to be greater. Further studies surveying surgeon awareness of these recommendations and investigating failure rates in relation to patient mass rather than BMI would be of interest.

Conclusions

Advances in lower limb arthroplasty for heavier patients should be a combined effort between surgeons and industry to ensure that treatments are robust and safe. Manufacturers update their instructions for use regularly and many acknowledge the reduction in fatigue strength associated with particular implant geometry, such as smaller femoral stem size and increasing offset. Implant failure will remain a potential complication following arthroplasty, influenced by numerous factors including patient habitus. However, BMI is not the optimal method for stratifying risk of implant fatigue failure, and we would welcome more detailed guidelines on size specific implant load limits to facilitate surgical decisions and preoperative patient counselling. Surgeons must consider the risks associated with arthroplasty procedures in larger patients, and we should ensure that patients are fully informed of all risks involved to protect ourselves from potential litigation.

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References

1. Richmond SA, Fukuchi RK, Ezzat A *et al.* Are joint injury, sport activity, physical activity, obesity, or occupational activities predictors for osteoarthritis? A systematic review. *J Orthop Sports Phys Ther* 2013; **43**: 515–B19.
2. Health and Social Care Information Centre. *Statistics on Obesity, Physical Activity and Diet: England, 2013*. London: HSCIC; 2013.
3. National Joint Registry for England and Wales. *10th Annual Report*. Hemel Hempstead: NJR; 2013.
4. Wallace G, Judge A, Prieto-Alhambra D *et al.* The effect of body mass index on the risk of post-operative complications during the 6 months following total hip replacement or total knee replacement surgery. *Osteoarthritis Cartilage* 2014; **22**: 918–927.
5. Liu W, Wahafu T, Cheng M *et al.* The influence of obesity on primary total hip arthroplasty outcomes: a meta-analysis of prospective cohort studies. *Orthop Traumatol Surg Res* 2015; **101**: 289–296.
6. McLaughlin JR, Lee KR. The outcome of total hip replacement in obese and non-obese patients at 10- to 18-years. *J Bone Joint Surg Br* 2006; **88**: 1,286–1,292.

7. Bourne RB, McCalden RW, MacDonald SJ *et al.* Influence of patient factors on TKA outcomes at 5 to 11 years followup. *Clin Orthop Relat Res* 2007; **464**: 27–31.
8. Andrew JG, Palan J, Kurup HV *et al.* Obesity in total hip replacement. *J Bone Joint Surg Br* 2008; **90**: 424–429.
9. Baker P, Petheram T, Jameson S *et al.* The association between body mass index and the outcomes of total knee arthroplasty. *J Bone Joint Surg Am* 2012; **94**: 1,501–1,508.
10. Baker P, Muthumayandi K, Gerrand C *et al.* Influence of body mass index (BMI) on functional improvements at 3 years following total knee replacement: a retrospective cohort study. *PLoS One* 2013; **8**: e59079.
11. Foran JR, Mont MA, Etienne G *et al.* The outcome of total knee arthroplasty in obese patients. *J Bone Joint Surg Am* 2004; **86**: 1,609–1,615.
12. Mulhall KJ, Ghomrawi HM, Mihalko W *et al.* Adverse effects of increased body mass index and weight on survivorship of total knee arthroplasty and subsequent outcomes of revision TKA. *J Knee Surg* 2007; **20**: 199–204.
13. Davis AM, Wood AM, Keenan AC *et al.* Does body mass index affect clinical outcome post-operatively and at five years after primary unilateral total hip replacement performed for osteoarthritis? *J Bone Joint Surg Br* 2011; **93**: 1,178–1,182.
14. Zhang ZJ, Zhao XY, Kang Y *et al.* The influence of body mass index on life quality and clinical improvement after total hip arthroplasty. *J Orthop Sci* 2012; **17**: 219–225.
15. Järvenpää J, Kettunen J, Soininvaara T *et al.* Obesity has a negative impact on clinical outcome after total knee arthroplasty. *Scand J Surg* 2012; **101**: 198–203.
16. Kerkhoffs GM, Servien E, Dunn W *et al.* The influence of obesity on the complication rate and outcome of total knee arthroplasty. *J Bone Joint Surg Am* 2012; **94**: 1,839–1,844.
17. Liljensøe A, Lauersen JO, Søballe K, Mechlenburg I. Overweight preoperatively impairs clinical outcome after knee arthroplasty. *Acta Orthop* 2013; **84**: 392–397.
18. Murgatroyd SE, Frampton CM, Wright MS. The effect of body mass index on outcome in total hip arthroplasty: early analysis from the New Zealand Joint Registry. *J Arthroplasty* 2014; **29**: 1,884–1,888.
19. Haverkamp D, de Man FH, de Jong PT *et al.* Is the long-term outcome of cemented THA jeopardized by patients being overweight? *Clin Orthop Relat Res* 2008; **466**: 1,162–1,168.
20. Patel AD, Albrizio M. Relationship of body mass index to early complications in knee replacement surgery. *Arch Orthop Trauma Surg* 2008; **128**: 5–9.
21. Suleiman LI, Ortega G, Ong'uti SK *et al.* Does BMI affect perioperative complications following total knee and hip arthroplasty? *J Surg Res* 2012; **174**: 7–11.
22. Winiarsky R, Barth P, Lotke P. Total knee arthroplasty in morbidly obese patients. *J Bone Joint Surg Am* 1998; **80**: 1,770–1,774.
23. Namba RS, Paxton L, Fithian DC, Stone ML. Obesity and perioperative morbidity in total hip and total knee arthroplasty patients. *J Arthroplasty* 2005; **20(Suppl 3)**: 46–50.
24. Amin AK, Clayton RA, Patton JT *et al.* Total knee replacement in morbidly obese patients. *J Bone Joint Surg Br* 2006; **88**: 1,321–1,326.
25. Lübbeke A, Stern R, Garavaglia G *et al.* Differences in outcomes of obese women and men undergoing primary total hip arthroplasty. *Arthritis Rheum* 2007; **57**: 327–334.
26. Chee YH, Teoh KH, Sabnis BM *et al.* Total hip replacement in morbidly obese patients with osteoarthritis. *J Bone Joint Surg Br* 2010; **92**: 1,066–1,071.
27. Jämsen E, Nevalainen P, Eskelinen A *et al.* Obesity, diabetes, and preoperative hyperglycemia as predictors of periprosthetic joint infection: a single-center analysis of 7181 primary hip and knee replacements for osteoarthritis. *J Bone Joint Surg Am* 2012; **94**: e101.
28. Wang JL, Gadinsky NE, Yeager AM *et al.* The increased utilization of operating room time in patients with increased BMI during primary total hip arthroplasty. *J Arthroplasty* 2013; **28**: 680–683.
29. Raphael IJ, Parmar M, Mehrganpour N *et al.* Obesity and operative time in primary total joint arthroplasty. *J Knee Surg* 2013; **26**: 95–99.
30. Liabaud B, Patrick DA, Geller JA. Higher body mass index leads to longer operative time in total knee arthroplasty. *J Arthroplasty* 2013; **28**: 563–565.
31. Pruzansky JS, Bronson MJ, Grelsamer RP *et al.* Prevalence of modifiable surgical site infection risk factors in hip and knee joint arthroplasty patients at an urban academic hospital. *J Arthroplasty* 2014; **29**: 272–276.
32. Haverkamp D, Klinkenbijl MN, Somford MP *et al.* Obesity in total hip arthroplasty – does it really matter? *Acta Orthop* 2011; **82**: 417–422.
33. Stern SH, Insall JN. Total knee arthroplasty in obese patients. *J Bone Joint Surg Am* 1990; **72**: 1,400–1,404.
34. Healy WL, Wasilewski SA, Takei R, Oberlander M. Patellofemoral complications following total knee arthroplasty. Correlation with implant design and patient risk factors. *J Arthroplasty* 1995; **10**: 197–201.
35. Mantilla CB, Horlocker TT, Schroeder DR *et al.* Risk factors for clinically relevant pulmonary embolism and deep venous thrombosis in patients undergoing primary hip or knee arthroplasty. *Anesthesiology* 2003; **99**: 552–560.
36. McElroy MJ, Pivec R, Issa K *et al.* The effects of obesity and morbid obesity on outcomes in TKA. *J Knee Surg* 2013; **26**: 83–88.
37. Kim SH. Morbid obesity and excessive hospital resource consumption for unilateral primary hip and knee arthroplasty. *J Arthroplasty* 2010; **25**: 1,258–1,266.
38. Dowsey MM, Liew D, Choong PF. Economic burden of obesity in primary total knee arthroplasty. *Arthritis Care Res* 2011; **63**: 1,375–1,381.
39. Woolson ST, Milbauer JP, Bobyn JD *et al.* Fatigue fracture of a forged cobalt-chromium-molybdenum femoral component inserted with cement. A report of ten cases. *J Bone Joint Surg Am* 1997; **79**: 1,842–1,848.
40. Della Valle AG, Becksaç B, Anderson J *et al.* Late fatigue fracture of a modern cemented forged cobalt chrome stem for total hip arthroplasty: a report of 10 cases. *J Arthroplasty* 2005; **20**: 1,084–1,088.
41. Lam LO, Stoffel K, Kop A, Swarts E. Catastrophic failure of 4 cobalt-alloy Omnifit hip arthroplasty femoral components. *Acta Orthop* 2008; **79**: 18–21.
42. Ishaque BA, Stürz H, Basad E. Fatigue fracture of a short stem hip replacement: a failure analysis with electron microscopy and review of the literature. *J Arthroplasty* 2011; **26**: 665.e17–665.e20.
43. Galante JO. Causes of fractures of the femoral component in total hip replacement. *J Bone Joint Surg Am* 1980; **62**: 670–673.
44. Chao EY, Coventry MB. Fracture of the femoral component after total hip replacement. An analysis of fifty-eight cases. *J Bone Joint Surg Am* 1981; **63**: 1,078–1,094.
45. Wroblewski BM. Fractured stem in total hip replacement. A clinical review of 120 cases. *Acta Orthop Scand* 1982; **53**: 279–284.
46. Kishida Y, Sugano N, Ohzono K *et al.* Stem fracture of the cementless spongy metal Lübeck hip prosthesis. *J Arthroplasty* 2002; **17**: 1,021–1,027.
47. Morgan-Hough CV, Tavakkolizadeh A, Purkayastha S. Fatigue failure of the femoral component of a cementless total hip arthroplasty. *J Arthroplasty* 2004; **19**: 658–660.
48. Harvie P, Haroon M, Henderson N, El-Guindi M. Fracture of the hydroxyapatite-ceramic-coated JRI-Furlong femoral component. *J Bone Joint Surg Br* 2007; **89**: 742–745.