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Availability of Total Knee Arthroplasty Implants for Metal Hypersensitivity Patients

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Purpose: To provide information on the type of "hypersensitivity-friendly" components available for primary total knee arthroplasty (TKA) in the current market.
Materials and Methods: Implant manufactures were identified using the 2013 National Joint Registries of the United Kingdom and Sweden and contacted to obtain information about the products they offer for patients with metal hypersensitivity.
Results: Information on 23 TKA systems was provided by 13 implant manufacturers. Of these, 15 systems had options suitable for metal hypersensitivity patients. Two types of "hypersensitivity-friendly" components were identified: 10 implants were cobalt chrome prostheses with a "hypersensitivity-friendly" outer coating and 5 implants were made entirely from non-cobalt chrome alloys.
Conclusions: The results of this study suggest that several hypersensitivity TKA options exist, some of which provide the same designs and surgical techniques as the conventional implants. The information in this study can guide TKA surgeons in making informed choices about implants and identifying implants that could be examined in future controlled studies comparing outcomes between "hypersensitivity-friendly" and conventional implants.

Keywords: **Knee, Arthroplasty, Metal hypersensitivity, Implants**

Introduction

Total knee arthroplasty (TKA) is a common procedure performed in increasing numbers. However, up to 20% of patients undergoing TKA may have less than satisfactory outcomes[1]. Although several reasons have been proposed for dissatisfaction and poor outcomes post TKA, it has been suggested that a certain proportion of such patients may be suffering from implant-related metal hypersensitivity[2-4].

Cutaneous metal hypersensitivity, as demonstrated by skin patch testing, is common with an estimated prevalence of 10%–17% in the general population[5-9]. Often, this hypersensitivity is caused by metals such as nickel, palladium, cobalt, and chrome[2]. Currently, there is uncertainty as to the role of metal hypersensitivity- related symptoms in patients with deep seated implants[4,10,11]. Previous works have suggested that the use of standard implants in patients with metal hypersensitivity may be linked to aseptic loosening, deep localised inflammatory reactions, as well as ongoing pain[12-14].

Previous research has highlighted various clinical strategies that can be adopted by arthroplasty surgeons when faced with patients who complain of cutaneous metal hypersensitivity[2,10]. It has been recommended that for patients reporting only mild cutaneous reactions, the use of conventional cobalt-chromium implants may be justified without additional investigation[2,10]. However, for patients reporting substantial localised reactions or systemic reaction to the metals, patch testing should be performed, which can then guide the choice of metal implants to utilise[15-17].

Currently, there are a large number of knee arthroplasty im-

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plants marketed worldwide and finding information on the availability of "hypersensitivity-friendly" TKA implants can be challenging and time consuming. This study aims to determine the availability of such implants for use by orthopaedic surgeons. Identifying such implants could help design future controlled studies comparing outcomes between "hypersensitivity-friendly" implants and conventional implants.

Materials and Methods

TKA implants utilised in the United Kingdom and Sweden were identified from their respective 2013 National Joint Registries. Companies manufacturing/marketing these TKA implants were contacted via different modalities (emails, phone calls, and company representatives) and were questioned using a predesigned questionnaire with regard to the availability and characteristics (designs and materials) of their TKA implants.

Results

Twenty-two companies were identified from the United Kingdom National Joint Registry. Of these, 13 replied to the questionnaire. Six implant companies failed to respond and we were unable to contact two others. Thirteen implant companies were identified from the Swedish joint registry, 10 of which also sold the same implants in the United Kingdom. The remaining 3 implant companies were contacted but failed to respond.

Hence, replies were obtained from 13 implant manufacturers, providing information in relation to 23 TKA implants. The characteristics of these implants are shown in Table 1. Fifteen out of the 23 TKA systems had a "hypersensitivity-friendly" option for both tibial and femoral components, which was identical in terms of design and instrumentation to the conventional system. Twelve of the 15 knee systems are available off the shelf, and the other 3 systems need to be custom-made. One hypersensitivity knee system produced a partially coated implant. Nine implant systems offered completely coated "hypersensitivity-friendly" components. Five systems had implants made entirely from either titanium or oxidised zirconium materials.

Discussion

Our results suggest that there is a substantial variation in the type of "hypersensitivity-friendly" implants available to knee surgeons. The majority of standard TKA systems are traditionally made with cobalt chromium alloy and occasionally titanium or zirconium. The cobalt chrome alloy does contain a mixture of metals including nickel that are linked to metal hypersensitivity. Hence, companies have developed metal "hypersensitivity-friendly" implants for use in such patients. Furthermore, in regards to the tibia, all polyethylene tibial components can also be deemed to be "hypersensitivity-friendly". An all polyethylene option has been shown in recent studies to have similar outcomes to modular tibial components[18]. These components have the effect of reducing cost and exposure to metal allergens when used in this subset of patients. All polyethylene components have some inherent disadvantages such as a lack of modularity (limiting intraoperative options), no option for liner removal in the setting of acute irrigation and debridement for infection, and no option for late liner exchange[19].

Our results suggest that designs of "hypersensitivity-friendly" implants fall into two categories: coated implants and the others that are made fully of materials alternative to cobalt chrome[20].

Most of the manufactures that responded had standard cobalt chrome implants coated with a superficial "hypersensitivity-friendly" metal layer (usually titanium nitride or zirconia nitride) which encapsulates the prosthesis. These implants can be made custom-made or be available off the shelf depending on the implant and manufacturer. The advantage of this method is that it allows the manufacturer to keep some of the tribological properties of cobalt chrome such as strength and durability[20]. Worryingly, this method of coating the implant could be affected by asperities and scratching that can occur to the prosthesis during implantation or during the lifetime of the implant from various modes of wear. If such asperities were to occur, then it could potentially expose the patient to the underlying metal and lead to a hypersensitivity reaction. Most manufacturers informed us the implants they produced were completely encapsulated with the "hypersensitivity-friendly" coating, including both the articulating and non-articulating surfaces (the part in contact with bone). One company coated only the articulating surface, due to concerns that coating the surface facing the bone could impair cementation.

Another method of manufacturing "hypersensitivity-friendly" implants is developing implants made entirely of non-cobalt chrome alloys. Such alternatives identified from this work were implants made entirely from titanium or zirconium alloys[21,22]. These implants would reduce the risk of the patient being exposed to nickel, cobalt, and chrome due to asperities in the long-term[14,15,23]. A potential disadvantage of titanium implants is reduced strength compared to cobalt chrome alloys.

Understanding which TKA system gives the options of con-

Table 1. Conventional and Metal Hypersensitivity-friendly Components

Manufacturer	Total knee arthroplasty system	Traditional system		"Hypersensitivity-friendly" system					
		Femoral component	Tibial component	Availability of all polyethylene tibia	Availability of alternatives	Femoral composition	Tibial composition	Same design as the traditional system	Same instrumentation as the traditional system
B.Braun & Aesculap	Columbus AS implant system	Cobalt chrome	Cobalt chrome	No	Yes	Complete zirconia nitride coating of the standard implant available off the shelf	Complete zirconia nitride coating of the standard implant available off the shelf	Yes	Yes
Biomet	Vanguard	Cobalt chrome	Cobalt chrome	No	Yes	Complete titanium niobium nitride coating of vanguard knee available off the shelf	Complete titanium niobium nitride coating of vanguard knee available off the shelf	Yes	Yes
	AGC concise systems	Cobalt chrome	Cobalt chrome	No	No	N/A	N/A	N/A	N/A
Conformis	Itotal G2	Cobalt chrome	Cobalt chrome	N/A	No	N/A	N/A	N/A	N/A
Corin	AMC	Cobalt chrome	Cobalt chrome	No	Yes	Partial titanium nitride coating of femur custom-made	Partial titanium nitride coating of tibia custom-made	Yes	Yes
	Unity	Cobalt chrome	Cobalt chrome	No	No	N/A	N/A	N/A	N/A
	Rotaglide	Cobalt chrome	Cobalt chrome	No	No	N/A	N/A	N/A	N/A
Depuy	Attune	Cobalt chrome	Cobalt chrome	No	No	N/A	N/A	N/A	N/A
	PFC Sigma	Cobalt chrome	Fixed bearing-titanium Mobile bearing-cobalt chrome	Yes	Yes	Complete titanium nitride coated femur custom-made	Complete titanium nitride coated tibia custom-made	Yes	Yes
	LCS complete	Cobalt chrome	Cobalt chrome	No	Yes	Complete titanium nitride coated femur off the shelf	Complete titanium nitride coated tibia off the shelf	Yes	Yes
Exactech	Logic knee	Cobalt chrome	Cobalt chrome	Yes	No	N/A	N/A	N/A	N/A

Table 1. Continued

Manufacturer	Total knee arthroplasty system	Traditional system		"Hypersensitivity-friendly" system					
		Femoral component	Tibial component	Availability of all polyethylene tibia	Availability of alternatives	Femoral composition	Tibial composition	Same design as the traditional system	Same instrumentation as the traditional system
Implant cast	ACS (advanced coated system)	Cobalt chrome	Cobalt chrome	No	Yes	Complete titanium nitride coating of the standard implant available off the shelf	Complete titanium nitride coating of the standard implant available off the shelf	Yes	Yes
JRI	Trekking	Cobalt chrome	Cobalt chrome	No	Yes	Complete titanium nitride coating of femur available off the shelf	Complete titanium nitride coating of tibia available off the shelf	Yes	Yes
Mat Ortho	Medial rotation knee	Cobalt chrome	Cobalt chrome	Yes	Yes	Complete titanium nitride coating of femur system available off the shelf	Complete titanium nitride coating of tibia system available off the shelf	Yes	Yes
Smith and Nephew	Genesis II	Cobalt chrome	Titanium	Yes	Yes	Oxinium oxidised zirconium implants available off the shelf	Titanium tibial component	Yes	Yes
	Legion primary	Cobalt chrome	Titanium	Yes	Yes	Oxinium oxidised zirconium implants available off the shelf	Titanium tibial component	Yes	Yes
	Journey BCS/ BCS 2	N/A only comes as oxinium	Titanium	Yes	Yes	Oxinium oxidised zirconium implants available off the shelf	Titanium tibial component	Yes	Yes
	TC plus profix	Cobalt chrome	Titanium	Yes	Yes	Oxinium oxidised zirconium implants available off the shelf	Titanium tibial component	Yes	Yes

Table 1. Continued

Manufacturer	Total knee arthroplasty system	Traditional system		"Hypersensitivity-friendly" system					
		Femoral component	Tibial component	Availability of all polyethylene tibia	Availability of alternatives	Femoral composition	Tibial composition	Same design as the traditional system	Same instrumentation as the traditional system
Stanmore	Smiles-hinged prosthesis only	No standard femur cruciate sacrificing or retaining components available	No standard tibia cruciate sacrificing or retaining components available	No	Yes	Complete titanium nitride coated implant custom-made	Complete titanium nitride coated implant custom-made	Yes, standard hinged prosthetic knee	Yes, standard hinged prosthetic knee
Stryker	Triathlon	Cobalt chrome	Cobalt chrome	Yes	Yes	Complete titanium nitride coated femur available off the shelf	Complete titanium nitride coated tibia available off the shelf	Yes	Yes
	Scorpio NRG	Cobalt chrome	Cobalt chrome	No	No	N/A	N/A	N/A	N/A
Zimmer	Nexgen	Cobalt chrome	Titanium tibial component	Yes	Yes	Titanium femoral component available off the shelf	Titanium tibial component available off the shelf	Yes	Yes
	Persona	Cobalt chrome	Titanium tibial component	N/A	No	N/A	N/A	N/A	N/A

N/A: not available in this design or material.

ventional versus "hypersensitivity-friendly" implants may help surgeons decide which system to use routinely[24]. Surgeons may choose an implant system that gives the option of using a "hypersensitivity-friendly" prosthesis in a small subset of patients where there is a concern of severe metal hypersensitivity but allows for the same technique and instrumentation as the conventional prosthesis in most of the patients in their clinical practice. Unfortunately, joint registries do not report outcomes separately for conventional and "hypersensitivity-friendly" implants in terms of long-term survivorship although this would be of interest to clinicians.

There are several limitations of this work, including the fact that some implant companies failed to respond to our questions. Therefore, other implant variations may exist that are not included in this review. Furthermore, we investigated implants intended mainly for use in primary TKA, and we did not seek information with regards to components used in revision surgery or complex primary arthroplasty.

"Hypersensitivity-friendly" metal implants are designed to help surgeons manage patients with metal hypersensitivity. There is, however, no strong evidence for the type of implants best to use in patients that have mild local skin reactions to nickel, cobalt, or chromium[25-27]. Guidelines and expert consensus studies do recommend that conventional implants be used in most patients with mild local cutaneous metal hypersensitivity reactions reported by patients or determined by patch testing[10,15,28,29]. Conversely, when there is a history of severe local cutaneous metal hypersensitivity reactions or generalised systemic reactions, it has been suggested that patients should be patch tested and appropriate "hypersensitivity-friendly" implants utilised[2,10,28,30]. Future randomised trials comparing "hypersensitivity-friendly" implants with conventional implants with regard to clinical outcomes and survivorship would be of great value in determining the role of metal hypersensitivity in ongoing pain and aseptic loosening following TKA and in developing more robust guidelines for clinical practice. Inclusion in such studies of implants that have the same design and surgical technique for both the conventional and hypersensitivity option would be ideal. Hence, the information gathered in the current study could further help in the design of future trials.

Conclusions

The results of this study can guide TKA surgeons in making informed choices about implants, and identifying implants that could be examined in future controlled studies comparing outcomes between "hypersensitivity-friendly" and conventional implants.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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