NEDERLANDSE ORTHOPAEDISCHE VERENIGING | NOV

Advice by the Board of the NOV on the use of primary hip prostheses

a classification based on long-term results

Introduction

Implanting a total hip prosthesis has become a very successful surgical intervention[1]. Next to cataract (stare) surgery total hip replacement surgery is regarded as *the* surgical procedure of the 20th century[2] by the World Health Organisation (WHO).

Around the world, over one million total hip prostheses are implanted annually[3] with a large variety of manufacturers launching an even more wider range of different types of hip prostheses. From numerous scientific publications, but mainly from national prostheses registers, considerable differences in the results (i.e. prosthesis survival) of these various types of prostheses exist. In its Strategic Plan 2012-2016[4], the Dutch Orthopaedic Association (NOV) has made a statement in its mission to work with high-grade quality systems. The NOV underscores that patients are entitled to have the best possible orthopaedic advice. Even more, the NOV aims at maximum transparency of choices made for patients, also in the field of joint implants (e.g. hip prosthesis). In this context, it follows that the interpretation of scientific information about total hip prostheses performance (i.e. absence of revision surgery) should be carried out, and even more this evidence should regulate its use. The NOV, as a scientific association of orthopaedic surgeons in The Netherlands, wishes to assume its responsibility in this respect.

NOV deems that it should offer a classification of hip prostheses in The Netherlands, which will provide information on long-term results for both orthopaedic surgeons as well as patients. The latter was realised by the Hip Task Force, consisting of dr Cees C. P.M. Verheyen (chair), dr L. Paul A. Bom, Henk W.J. Koot, dr Rudolf W. Poolman, prof. dr Rob G.H.H. Nelissen, and dr B. Wim Schreurs, which submitted an advice on quality of hip prostheses to the NOV's Board. At the General Assembly Meeting of the NOV on 4 October 2012, this advice was accepted as a guideline by its members.

In its advice on the quality for the classification of hip prostheses, the NOV applies principles of both the internationally acclaimed NICE criteria [5] (National Institute for health and Clinical Excellence) and criteria[5] by the NHS (National Health Service) of the United Kingdom. Ultimately, it was decided to classify hip prostheses in three categories (1A, 1B and 2) as displayed further down this document.

Decision and consequences

This document reflects the start of a continuous evaluation on the quality of hip prostheses (both stems and cups), which will be refined in the next few years. An update will be executed once a year (reference date: 1 October). The NOV welcomes suggestions and remarks on this initial classification. It is obvious that a cup or

[1] Learmonth ID et al. The operation of the century: total hip replacement. Lancet 370:1508 (2007)
[2] Baltussen R et al. Cost-effectiveness analysis of cataract surgery. A global and regional analysis. Bull World Health Organ 82:338 (2004)
[3] OECD. Health at a glance 2012. Report, OECD Publishing 2012.
[4] http://www.orthopeden.org/vereniging/nieuws/nieuws/presentatie-van-het-strategisch-plan-nov-2012-2016-orthopedie-houdt-nederland-in-beweging
[5] http://publications.nice.org.uk/guidance-on-the-selection-of-prostheses-for-primary-total-hip-replacement-ta2/guidance

stem, which now meets the requirements of NOV 1B, may, in future, move on to 1A category. There are no arguments to advise against the use of those implants.
Furthermore, innovation as a continuous process, which is mandatory for improving patient care, will be stimulated more with this quality classification. Since, all prostheses classified, as NOV 2 will have prospective follow-up, to warrant patient safety.
It also goes without saying that innovations (NOV 2) must remain possible within well-defined criteria. The classification system that was decided upon offers excellent possibilities for orthopaedic surgeons to inform patients about the type of prosthesis to be used and the present classification of that prosthesis.
Annually, current requirements and classification may change as part of a continuous process of quality assessment to improve orthopaedic patient care; even more so, once the Dutch Arthroplasty Register (LROI)[6] can also provide Dutch survival analyses data, the current quality classification will be more specific for the Dutch patient and surgeon.

NOV 1A: Full acceptance and acknowledgement by NOV (Benchmark)
A hip implant (stem or cup) with a mean revision percentage of 10% or less at 10 years with revision for any reason as end point. For this purpose, revision is defined as revision-surgery of any prosthesis components.
Substantiation: supporting data originate from any of the public national registers that use a comparable methodology for data validation and data presentation, and are full members of ISAR (International Society of Arthroplasty Registers)[7] with at least 10 years of follow-up on at least 500 implants *or* those which have an ODEP rating (Orthopaedic Data Evaluation Panel)[8] of 10A.
Consulted registers (reference date: 1 October 2012): Swedish Hip Arthroplasty Register, Danish Hip Registry, Australian National Joint Replacement Registry and New Zealand Joint Registry. ODEP NHS Supply Chain (update 30 August 2012)

NOV 1B: Conditional acceptance (Entry benchmark)
A hip implant (stem or cup) with a mean revision percentage of 5% or less at 5 years with revision for any reason as end point.
Substantiation: supporting data originate from one of the above defined registers with at least 5 years of follow-up on at least 500 implants or an ODEP-rating of 5A or 7A.
Consulted registers: as 1A, with additionally National joint Registry for England and Wales and Slovak Arthroplasty Register

NOV 2: New implants
Prostheses that do not meet or do not yet meet the above mentioned criteria may only be implanted in a research programme which has been approved by the institutions medical ethics review board.

Categories 1A and 1B differ with regard to the period during which the prostheses were monitored (at least 10 or 5 years, respectively) and the maximum revision percentage at this point in time (10 and 5, respectively). Hip implants of categories 1A and 1B are described by NOV on its website[9]. An annual update will be published in January with a reference date of 1 October of the previous year. Implants that meet the requirements set for 1A or 1B but are contrary to applicable NOV advices, will not be included. It concerns components for a regular indication total hip prosthesis, without unusual anatomic abnormality like substantial post traumatic or congenital deformity of the acetabulum and/or femur.
The manufacturers were allowed to remove some of their components from the lists (e.g. production stopped, not for Dutch market).

[6] http://www.orthopeden.org/kwaliteit/lroi
[7] http://www.isarhome.org/directory
[8] http://www.supplychain.nhs.uk/odep/
[9] http://www.mijnbesteheup.nl/

NOV 1A list: full acceptance and acknowledgement by NOV (*Benchmark*)
reference date: 01/10/2012

Acetabular component /cup	**(manufacturer)**	**Femoral component /stem**	
Cemented		**Cemented**	
SHP	(Biomet)	Stanmore	(Biomet)
Stanmore	(Biomet)	Bi-Metric	(Biomet)
Charnley Standard	(DePuy J&J)	Charnley Monobloc	(DePuy J&J)
Charnley Ogee	(DePuy J&J)	Charnley Modular	(DePuy J&J)
Elite Plus	(DePuy J&J)	Charnley Elite Plus	(DePuy J&J)
IP - Interplanta	(Link)	C-stem	(DePuy J&J)
FAL	(Link)	Lubinus SP2	(Link)
CCB Müller low profile	(Mathys)	Müller Straight Stem	(Mathys)
Reflection all poly	(Smith & Nephew)	Spectron	(Smith & Nephew)
Contemporary	(Stryker)	Exeter	(Stryker)
Exeter / Duration	(Stryker)	Exeter V40	(Stryker)
ZCA	(Zimmer)	Omnifit	(Stryker)
Müller low profile	(Zimmer)	CPT	(Zimmer)
		ME Müller s-Stem	(Zimmer)
		MS 30	(Zimmer)
Uncemented		**Uncemented**	
Plasma SC	(BBraun)	Bicontact	(BBraun)
Universal	(Biomet)	Mallory Head	(Biomet)
Mallory Head	(Biomet)	Bi-Metric	(Biomet)
Duraloc	(DePuy J&J)	Taperloc	(Biomet)
Pinnacle	(DePuy J&J)	Corail	(DePuy J&J)
Furlong CSF	(JRI)	S-Rom	(DePuy J&J)
Furlong Threaded	(JRI)	AML	(DePuy J&J)
RM pressfit	(Mathys)	Furlong HAC	(JRI)
Saturne Dual Mobility	(Amplitude)	Twin-Sys	(Mathys)
Bicon Plus	(Smith & Nephew)	SL-Plus	(Smith & Nephew)
Reflection	(Smith & Nephew)	Synergy	(Smith & Nephew)
ABG II	(Stryker)	ABG II	(Stryker)
Trident	(Stryker)	Accolade	(Stryker)
Allofit	(Zimmer)	Omnifit	(Stryker)
CSF Alloclassic	(Zimmer)	Secur-Fit Plus	(Stryker)
CLS Spotorno	(Zimmer)	SL Alloclassic	(Zimmer)
Fitmore	(Zimmer)	CLS Spotorno	(Zimmer)
Morscher	(Zimmer)	Versys	(Zimmer)
Trilogy	(Zimmer)		

NOV 1B list: conditional acceptance and acknowledgement by NOV (*Entry Benchmark*)
reference date: 01/10/2012

Acetabular component /cup	**(manufacturer)**	**Femoral component /stem**	
Cemented		**Cemented**	
Apollo	(Biomet)	Centrament	(BBraun)
Cenator	(Corin)	MainStream Müller	(Biomet)
Opera flanged	(Smith & Nephew)	Olympia	(Biomet)
Weber	(Zimmer)	C-stem AMT	(DuPuy J&J)
		TwinSys	(Mathys)
		CPCS	(Smith & Nephew)
		Synergy	(Smith & Nephew)
		Versys	(Zimmer)
Uncemented		**Uncemented**	
ExceedABT	(Biomet)	Excia	(BBraun)
Delta	(Lima)	Aura	(Biomet)
EP-Fit Plus	(Smith & Nephew)	Summit	(DuPuy J&J)
Polar Dual Mobility	(Smith & Nephew)	CS	(Smith & Nephew)
Lineage ceramic	(Wright Medical)	Antology	(Smith & Nephew)
Trabecular metal	(Zimmer)	Polar	(Smith & Nephew)
		Symax	(Stryker)
		Anca Fit	(Wright Medical)
		Profemur L	(Wright Medical)
		Zimmer M/L Taper	(Zimmer)