

Kommentarer til:

Hip resurfacing

KOMMENTERET VARSEL – 3. ÅRG. – NR. 1 – FEBRUAR 2006

Teknologien

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) har i marts 2005 udsendt det vedhæftede tidlige varsel ”Minimally invasive hip resurfacing” [1].

Hip resurfacing-systemet præsenteres som et alternativ til en traditionel kunstig hofte (total hoftealloplastik), især for yngre patienter med degenerativ hofteledelse. Ved hip resurfacing erstatter man overfladen i hofteleddets skål og overfladen på ledhovedet med metal i stedet for at fjerne det øverste af lårbenknoglen og sætte en metalprotese ned i knogle-piben. Ved ’kun’ at belægge ledhovedet og ledskålen med metal, bevarer man lårbenet så vidt muligt intakt [2].

Ifølge Dansk Hofteregister anvendes minimal invasiv kirurgi endnu ikke i Danmark ved indsættelse af denne nye type protese [3], men da hip resurfacing er en forholdsvis ny teknologi i det danske sundhedsvæsen, suppleres det canadiske varsel her med status for såvel hip resurfacing som for den traditionelle behandling i Danmark.

Nuværende behandling

Den nuværende behandling, som hip resurfacing skal sammenlignes med, er total hoftealloplastik (THA). THA anvendes til patienter med degenerative lidelser i hoften, som er invaliderende pga. smerter og funktionsnedsættelse, og hvor konservativ behandling¹ har været utilfredsstillende [4].

I 2004 var antallet af førstegangsoperationer med kunstig hofte 6687 [5].

Primær slidgigt i hofteledet er den hyppigste årsag til THA og var indikationen for 80% af alle nye hofteproteser i 2004. Den næsthypigste årsag er senfølger efter hoftenær femurfraktur (7,2% af THA operationer). Det er typisk ældre mennesker, som rammes af disse sygdomme. Gennemsnitsalderen ved THA er 69,6 år [6]. Over perioden 1995-2004 var 73,1% af alle opererede patienter over 60 år, 18,2% var i aldersgruppen 50-59 år og resten var under 50 år (8,3%) [5]. Yngre patienter² har større risiko for nedslidning - og dermed behov for udskiftning - af protesen, end ældre patienter har [7]. De væsentligste årsager til udskiftning er irritativt betinget knogleledsbrydning, resulterende i at protesen går løs (aseptisk løsning), samt nedslidning af plastdelen (polyethylen). Sidstnævnte ofte på grund af et højere aktivitetsniveau, som det ses hos yngre. Hos yngre patienter tilråder man derfor at vente længst muligt med alloplastik [4]. Næsten 20% af patienter under 55 år skal reopereres inden for 10 år. Det totale antal revisionsoperationer i 2004 var 989 [4]. Aldersfordelingen på disse revisionsoperationer er ikke kendt, men yngre personer og mænd har større risiko for aseptisk løsning [4].

Anvendelse af hip resurfacing-systemer i Danmark

I Danmark blev den første hip resurfacing-protese indsat i januar 2004. Siden da er indberettet 85 operationer til Dansk Hofteregister. Aldersfordelingen på patienterne er følgende: 10-19 år: 1 patient, 30-39 år: 5 patienter, 40-49 år: 16 patienter, 50-59 år: 32 patienter, 60-69 år: 30 patienter, 70-79 år: 1 patient [3]. Hip resurfacing udføres på flere sygehuse i Danmark, både i kliniske studier og uden for sådanne. Sygehusene bruger forskellige hip resurfacing-systemer (Biomet's ReCap system, De Puy's Articular Surface Replacement system og Corin Medical's Cormet hip resurfacing system), og der anvendes forskellige alderskriterier. De operationer, som indtil nu er indberettet til Dansk Hofteregister, er foretaget på Odense Universitetshospital, Århus Universitetshospital i samarbejde med Silkeborg Centralsygehus, Amager Hospital, Hvidovre Hospital, Erichsens Privatklinik, Frederiksberg Hospital, Frederikshavn Sygehus og Amtssygehuset i Glostrup.

Operationerne i Århus/Silkeborg er en del af et randomiseret forsøg, hvor der i alt skal indgå 50 patienter mellem 50 og 65 år, og hvor BioMet's ReCap hip resurfacing system sammenlignes med konventionel hoftealloplastik. De første resultater forventes i 2008, og forsøget forventes afsluttet i 2014 [8].

Noter:

1. Konservativ behandling omfatter medicinsk smertebehandling og justering af fysisk aktivitetsniveau.
2. ”Yngre” er ikke veldefineret i referencerne. I et 16-års follow up-studie fra Duijsens et al. er patienterne under 50 år. NICE anbefaler, at man ser på, hvor aktiv patienten er.

Kommentarer til: Hip resurfacing

Implementeringsaspekter

Det engelske National Institute for Health and Clinical Excellence (NICE) publicerede allerede i 2002 retningslinjer vedrørende hip resurfacing, og disse er fortsat gældende [2]. NICEs retningslinjer konkluderer blandt andet, at det er vigtigt at informere patienterne om, at der endnu ikke findes så meget viden om sikkerhed og pålidelighed af hip resurfacing-systemer, som der gør for THA. NICE anbefaler kirurger at vælge systemer, hvor der findes evidens for mindst tre år, og denne skal pege på, at der kun er brug for revision hos højst 10% inden for 10 år. NICE havde planlagt at revidere retningslinjerne i 2005, men denne revision er udskudt til 2008 på grund af mangel på ny evidens [9].

Det er vigtigt at vide, om hip resurfacing er omkostningseffektiv sammenlignet med konventionel THA, da det har betydning for, om man kan vurdere, om det er et fornuftigt alternativ for yngre patienter og muligvis også for ældre patienter. I NICEs retningslinjer indgår divergerende økonomiske evalueringer, hvad angår omkostningseffektivitet af hip resurfacing-systemer. Der er behov for et omkostningseffektivitetsstudie, hvor patientnyten også indgår i form af forbedret livskvalitet.

Det anbefales, at man kun anvender hip resurfacing-protesen i forbindelse med kliniske studier, indtil der foreligger resultater vedrørende klinisk effektivitet og holdbarhed fra randomiserede studier, som er tilfredsstillende set i forhold til total hoftealloplastik.

Hip resurfacing-systemer afgiver metal-ioner til kroppen. Om niveauet er anderledes end ved traditionelle hofteproteser, og om immunforsvarets celler reagerer med et irritativt respons er uvist [3, 10]. Det kliniske studie i Århus vil blandt andet belyse sikkerhed af ReCap resurfacing systemet med hensyn til metalafgivelse i kroppen [3].

Udover resultater fra kliniske forsøg kan udviklingen med hensyn til komplikationer og revisionsbehov følges gennem det danske og andre landes nationale implantationsregistre.

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Minimally Invasive Hip Resurfacing

Summary

- ✓ **Metal-on-metal hip resurfacing is an emerging surgical alternative for younger patients who are expected to outlive a conventional total hip replacement implant.**
- ✓ **Minimally invasive hip resurfacing uses a smaller surgical incision and new techniques to expose the hip joint.**
- ✓ **Possible advantages include less damage to soft tissue, muscle and bone; smaller scars; less blood loss; and shorter hospital stays and rehabilitation.**
- ✓ **Possible disadvantages include damage to soft tissue, femur fracture, neurovascular damage, implant malposition and a longer operating time.**
- ✓ **The lack of published or unpublished trials or case reports makes it impossible to draw conclusions about the relative effectiveness of minimally invasive procedures for hip resurfacing.**
- ✓ **Developments in computer navigation systems and fluoroscopic imaging may permit more widespread use of minimally invasive hip resurfacing in the future.**

The Technology

Metal-on-metal hip resurfacing (surface arthroplasty) is a new surgical procedure in Canada. It involves replacing damaged surfaces in the hip joint with a cobalt-chromium metal cap on the top of the thigh bone (femur) and a similar metal alloy cup inside the socket (acetabulum) of the hip bone.¹

Hip resurfacing emerged as a bone-conserving alternative to total hip replacement (THR) in younger, more active patients with degenerative hip disease who would likely outlive a conventional THR. The femoral head and neck are preserved, leaving more options if future revisions, including a THR, are needed.²

In minimally invasive hip resurfacing, a surgeon uses a “mini” incision (7.5 cm to 11.0 cm) and new techniques to expose the hip joint. Possible advantages include less damage to soft tissue, muscle and bone; smaller scars; less blood loss; and shorter hospital stays and rehabilitation.³

Regulatory Status

Surgical procedures, including minimally invasive techniques, do not require Health Canada licensing.

Table 1 describes three metal-on-metal resurfacing implants licensed for use in Canada. Three additional implants, cited in Table 2, are available under Health Canada’s Special Access Programme, if a physician requests importation for individual patients. Metal-on-metal resurfacing implants are not yet approved in the US, although pre-market approval is being pursued for the Birmingham, CONSERVE PLUS and Cormet hip resurfacing systems.^{2,4,5}

Patient Group

Rheumatoid arthritis and osteoarthritis are the main causes of degenerative hip disease. Advanced stages of these diseases can lead to severe disability.^{1,2} The predominant surgery for severe degenerative hip disease is THR. Among younger, more active adults, 25% to 30% require an implant revision within 15 years

Table 1: Metal-on-metal hip resurfacing implants licensed by Health Canada

Device	Manufacturer	Effective Date
Birmingham Hip Resurfacing device	Midland Medical Technologies Ltd. (acquired by Smith & Nephew, March 2004)	October 2002 (Janine Lepage, Smith & Nephew, Montreal: personal communication, 2004 Dec 2)
CONSERVE PLUS [®] implant	Wright Medical Technology	July 2004 ⁶
ReCap [®] Femoral Resurfacing System – Cemented Femoral Head; and Press-Fit Porous Femoral Head	Biomet	February 2004 ⁶ (approval for acetabular component is pending)

Table 2: Metal-on-metal hip resurfacing implants available through Special Access Programme

Cormet hip resurfacing system	Corin Medical Ltd.	October 2004 (Iain Dunbar, Corin Group, Cirencester, UK: personal communication, 2004 Nov 25)
Durom [™] Hip Resurfacing	Zimmer	February 2003 (Joe Alviano, Zimmer of Canada, Mississauga, ON: personal communication, 2004 Nov 25)
DePuy ASR [™]	Johnson & Johnson	February 2004 (Namal Nawana, DePuy Canada, Johnson & Johnson, Markham, ON: personal communication, 2004 Nov 24)

after THR, compared with <5% at 10 years for older patients.⁷ Revision surgery is more difficult to perform and generally leads to poorer outcomes than the primary replacement.⁷ Metal-on-metal hip resurfacing was developed to extend the replacement joint lifespan in patients 40 to 65 years old.⁸

Demand for THR is growing, with about 20,000 performed in Canada between 2001 to 2002. This is an increase of 19% from the number in 1994 to 1995.⁹ An aging population and rising rates of obesity will increase demand.

It is unclear how many metal-on-metal hip resurfacings are performed annually in Canada. The number of potential candidates, based on age, can be extrapolated from registry data. In 2001 to 2002, it was estimated that 15% of all patients who received a THR were younger than 54 years, while 19% were between 55 and 64 years.⁹

Patient selection criteria for minimally invasive hip resurfacing are evolving. Obese patients with a body mass index >30 may be poor candidates for mini-incision hip surgery.^{10,11} Some surgeons restrict the use of metal-on-metal hip resurfacing to male patients with good bone stock who are <55 years of age (Dr. Robert Bourne, London Health Sciences Centre, London, ON: personal communication, 2004 Dec 22). An Australian study of 3,703 resurfacing procedures found that hip resurfacing in postmenopausal women was associated with a 1.9-fold higher femoral neck fracture rate.¹²

Current Practice

A conventional incision for metal-on-metal hip resurfacing is 25 cm to 30 cm, which is comparable to the incision length for a standard THR.^{3,13} Increased proficiency with the resurfacing procedure has allowed gradual reduction of incision length to 15 cm (Dr. Jason Werle, University of Calgary, Calgary: personal communication, 2004 Dec 6). A longer incision is required for muscular or obese patients.¹³ A small number of “pioneering” surgeons are performing minimally invasive hip resurfacing at a few high-volume centres outside Canada.

The Evidence

PubMed, relevant DIALOG[®] databases and The Cochrane Library were searched in November 2004 to locate published literature. The web sites and associated databases of other health technology assessment and related agencies were searched for grey literature. Searches using the Google[™] search engine were also done. Implant manufacturers were contacted for further information. No trials, case reports or abstracts were found that assessed the harm or benefit of minimally invasive procedures for hip resurfacing.

Adverse Effects

Theoretical disadvantages for minimally invasive hip resurfacing relate to the challenge of performing surgery in a restricted visual field and are similar to those seen with THR. These include damage to soft tissue, femur fracture,

neurovascular damage, implant malposition and a longer operating time.³ Preliminary THR reports, with minimally invasive techniques, have shown a trend toward higher, rather than lower, complication rates.^{10,14}

It is unknown if other factors will be affected by the use of mini-incisions, including long-term durability of the resurfaced hip, its stability and dislocation rate, long-term pain relief, motion and function, infection rate, incidence of blood clots or nerve damage.³

Administration and Cost

Costs may increase with the use of navigation systems to facilitate a minimally invasive approach. Longer operating times may also increase costs. One of three Montreal surgeons performing a high volume of hip resurfacing (n=55) and total hip replacements (n=55), in an ongoing randomized comparative trial, reported that hip resurfacing procedures take approximately 21 more minutes (Dr. Pascal Venditoli, Montreal Maisonneuve-Rosemount Hospital, Montreal: personal communication, 2004 Nov 10). A study of a fluoroscopic navigation system used in 31 hip resurfacing cases reported that the use of the system added 10 to 15 minutes to the total operating time in the last 10 cases.¹⁵

The cost of special surgical instruments to perform minimally invasive hip resurfacing is not yet established. Corin Medical Ltd. added Small Incision (SI) instruments to its Cormet implant kit in October 2004 at no additional cost (Iain Dunbar: personal communication, 2004 Nov 15).

Concurrent Developments

Computer-assisted navigation systems are being developed to facilitate minimally invasive surgical approaches. These systems allow pre-operative planning [from computerized tomography (CT) scans] and intra-operative guidance to position the femoral cap and the acetabular cup. A surgical navigation system developed by CAS Innovations was first used in Germany in 2004 to implant a Cormet hip resurfacing device.¹⁶

Rate of Technology Diffusion

Nearly all implant makers are marketing or developing modified instruments and techniques to perform hip resurfacing with minimally invasive incisions. This is based on a perception of the same or better long-term results compared to conventional incision length; and a theoretically shorter and less painful recovery.

Direct-to-consumer advertising in the US, and media coverage targeted to “aging baby boomers” may magnify patients’ expectations of the benefits of mini-incision surgery.

Implementation Issues

The hip resurfacing procedure is more technically demanding than conventional THR and may require longer operating times.² In addition, hip surgery is more difficult through a minimal incision and the technique is difficult to learn.^{17,18} Enhanced training and specialized instruments are necessary for accurate, reproducible results.

Gaining proficiency with the procedure may be challenging, as potential candidates for hip resurfacing make up 10% to 20% of a typical surgeon’s patient population. A limited number of Canadian surgeons have the necessary skills.

Computer navigation systems and fluoroscopic imaging may allow improved visualization and hip implant positioning with mini-incisions,¹⁷ which may encourage more surgeons to attempt minimally invasive hip resurfacing. There are disadvantages to navigational systems, including increased cost and operating time; and the possibility of error from computer malfunction or inappropriate commands.¹⁹ It is unknown if increased costs would be offset by savings from a shorter hospital stay.

Outcome-based research and long-term follow-up are necessary to assess the clinical and economic impact of a minimally invasive approach to hip resurfacing.¹⁰ There is also a need for defined criteria to determine which patients might benefit from this surgical

approach. The Canadian Joint Replacement Registry, formed in 2001, has collected data on hip resurfacing outcomes since 2003.

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