NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

MAGEC system for spinal lengthening in children with early onset scoliosis

1 Technology

1.1 Description of the technology

MAGEC system (NuVasive, Inc.) is used to treat early onset scoliosis (a side-to-side curve diagnosed before the age of 10 years) in children aged between 2 and 11 years. The technology is intended to be used in place of current growth rod systems that require repeated invasive surgical procedures. MAGEC system comprises a sterile implant (this can be one or two rods, the size of which depends on body weight - 4.5mm for children weighing ≤27kg, 5.5mm for children weighting ≤36kg and 6.35mm for larger children) and an external remote controller together with a manual distractor (to check the implant is functional prior to implantation) and wand locator (to locate the internal magnet). MAGEC system is inserted surgically in the same way as conventional growth rod systems. A portion of the MAGEC implant contains a distraction element – the 'actuator', which includes an internal cylindrical rare earth magnet, 9–10.5 mm in diameter and 90mm long. The magnet is rotated non-invasively by an external remote controller which, in turn, causes the rod to lengthen and increase distraction of the spine (on average every 3 months, depending on surgeon preference). This external remote control is portable and uses permanent magnets to modify the length of the implant. An indication of the amount of distraction/retraction is immediately visible on the controller's display module. Repeated lengthening of the rod is intended to be carried out in an outpatient setting without the use of sedation or pain relief.

1.2 Relevant diseases and conditions

The MAGEC system is intended for use in early onset scoliosis, specifically where a distraction procedure is indicated.

In the UK, scoliosis affects 3 to 4 children out of every 1,000 and can develop at any time during childhood and adolescence (NHS Choices 2011). At the younger end of the spectrum, boys are affected slightly more than girls (Scoliosis Association, UK). Early onset scoliosis may be associated with congenital vertebral anomalies, bone dysplasia, connective tissue disorders, neuromuscular disorders or idiopathic spinal deformities. Lung development, pulmonary function, spine length and spinal mobility are at risk. In young children, growth and lung function are affected. Scoliosis also impacts on the appearance of a patient's back. Treatment of early onset scoliosis must focus on both the spine and the development of the chest to improve the child's long-term quality of life.

1.3 Current management

Current treatment options for scoliosis include spinal surgical distraction using conventional growth rods.

There are four main types of treatment for early onset scoliosis, namely casting, bracing, insertion of growth rods and spinal fusion. Treatment selection depends on the age and development of the child as well as the type of curvature of the spine. Casting can be used to guide a child's spine into a normal position during growth. This can be done by applying an external brace, made from a combination of plaster-of-Paris and modern casting material, which is worn permanently by the child. Alternatively the patient may be put in a brace. This system allows growth before a more permanent treatment is offered.

Surgery, using distraction-based procedures, can be performed if the curvature continues despite bracing and casting. This involves surgically inserting growth rods (single or dual), which are attached to the spine or ribs above and below the curve. The rods can be placed from the level of the shoulder blade on the spine and extend down to the ribs, spine or pelvis. If a

conventional growth rod is used the child returns about every six months to undergo a surgical procedure for rod lengthening. Once the spine has finishing growing a final spinal fusion operation is undertaken and the rods are removed.

NICE medical technology guidance on the MAGEC system for spinal lengthening in children with scoliosis recommends considering using MAGEC in children aged 2 years and over who need surgery to correct their spinal curvature.

1.4 Regulatory status

The MAGEC system received a CE mark in October 2009 as a class IIb device for spinal bracing and distraction.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduced incidence of surgical complications including anaesthetic risk, infections and delayed recovery
- Reduced psychological trauma to the child and family
- Improved quality of life due to reduced time away from school (patient) and work (parent)

The benefits to the healthcare system claimed by the company are:

- The avoidance of costs associated with repeated surgical interventions including theatre time, consumables, in-hospital stay and treatment of complications
- Reduced costs to society from parents taking time off work and the child taking time away from school

2 Decision problem

Population	Children with early onset scoliosis in whom a surgical distraction procedure is indicated.
Intervention	MAGEC system

Comparator(s)	Spine-based surgical distraction procedure with conventional growth rods	
Outcomes	The outcome measures to consider include: • Total number of surgical procedures and anaesthetics • Total number of outpatient attendances and procedures • Recovery time • Total length of stay • Rate of distraction procedure success • Infection rates and other surgical complication rates • Total number of imaging procedures • Cobb Angle • Thoracic Spine Height • Quality of life • Device failure, including technical information characterising the failure, and rates of failure • Device and radiation exposure-related adverse events • Incidence of psychological problems	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	None identified	
Special considerations, including those related to equality	Although MAGEC system is described for treatment of children with early onset scoliosis, who are between the ages of 2 and 11, the system could be used in children outside this age range providing they weigh more than 11.4kg and have a BMI <25. Patients with contraindications could include patients with pacemakers or who require an MRI scan during the period of implantation.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No

Any other special considerations	Not applicable

3 Related NICE guidance

Published

- The EOS 2D/3D imaging system (2011) NICE diagnostics assessment guidance [DG1]

In development

None identified

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association of Spine Surgeons
- British Orthopaedic Association
- British Scoliosis Society
- British Society for Children's Orthopaedic Surgery

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- The Scoliosis Association (UK) (SAUK)