SCOLIOSIS ASSOCIATION UK

MAGEC rods

Masood Shafafy, Consultant Spinal Surgeon, Nottingham University Hospitals

After the Panorama documentary, 'The Great Implant Scandal', which aired in November, 2018, we asked Masood Shafafy to answer some of your concerns and questions.

1. How have rods been tested for their safety?

2. What is the approval process?

3. How rigorous is the approval process?

Any orthopaedic device that is going to be implanted into someone needs to go through a number of tests and procedures before it can be used in clinical practice. There are established standards, set by regulatory bodies, to which devices must conform. In the European Union (EU) devices are assessed by the Conformité Européenne (CE), which gives marks indicating whether the implant conforms to health, safety, and environmental protection standards. There is a similar process in America undertaken by the Food and Drug Administration (FDA). The initial tests are to make sure the materials used are safe (non-toxic and do not cause an allergic reaction to live tissues). These tests are usually done on live animals which are similar to people in terms of their tissue and immune system, such as, rodents, rabbits, sheep, pigs, and occasionally primates. According to the manufacturer, MAGEC rods have undergone these tests.

The other aspect of these devices which need to be tested is their mechanical safety. In simple terms these tests are to make sure the devices are going to function under physical and physiological load. These are bench tests or in vitro (outside the body) tests, which again the manufacturer states have been done.

In fact, these tests are generally prerequisite for any implant to start their application for CE marking or FDA approval.

In addition to providing the regulatory authorities with the verified results of the above tests, there must also be an initial premarketing clinical trial on patients with scoliosis. The trial is conducted under strict protocol, over a set period that allows for a satisfactory follow-up assessment before the product is given approval. The focus of the initial trail is often on the short-term safety of the product rather than its long-term efficacy and endurance. Looking at a range of implants, often CE marking is granted before FDA approval, which has led to the conclusion that FDA approval is more rigorous. This was the case for MAGEC rods which, at the moment, has both certifications.

Once approval is granted it is the duty of manufacturers and clinicians to conduct post-marketing trials with the same rigour to keep the product under check. Historically, this has always been an area that has not received the same attention, and it is here that most problems surface.

4. What was the percentage of complications when tested?

We do not have data for such complication rates, but we can assume that the results were satisfactory to be granted CE marking and FDA approval.

5. At what age and degree of curve can a child be a candidate for MAGEC rods?

MAGEC rods are designed to be used in children between age 2 and 10, although in exceptional cases they can also be used in older children. The curve

This article was published in *Backbone*, Spring 2019.

SCOLIOSIS ASSOCIATION UK

Helpline: 020 8964 1166
Registered Charity No. 1181463

4 Ivebury Court, 325 Latimer Road
London W10 6RA

www.sauk.org.uk
/ScoliosisAssociationUK
info@sauk.org.uk
@ScoliosisUK
020 8964 5343
scoliosis_association_uk

Edition: 1
Planned date of review: Spring 2022.
Last updated: Spring 2019

needs to be proved to be progressive despite non-surgical treatment (a brace or a plaster cast) and the curve has to be at least 40°, although there is disagreement between surgeons in the absolute size of the curve.

6. Are there any data about safety concerns in relation to rods used in surgery?

The most reliable and unbiased database is British Spine Registry, albeit up to now it has not been compulsory to add data to it and relies on the willingness of the clinicians to enter their data. There are several follow-up studies about MAGEC published in spinal journals and presented at various meetings. Although the messages from these are mixed there are more studies in support of MAGEC than against. Furthermore, most independent spinal professional organisations such as the British Scoliosis Society (BSS), the British Association of Spine Surgeons (BASS) and Scoliosis Research Society (SRS) have not expressed any major safety concerns with respect to the use of MAGEC rods. Further research may tell us more.

7. Why are MAGEC rods being used if there are complexities?

MAGEC rods have been developed as a treatment option for a difficult and complex condition called early onset scoliosis in childhood. The challenge in this condition is the progressive spinal curve that cannot be controlled or corrected and fused because the child is still growing, and at that age further growth is crucial for breathing and lung development. It is therefore mandatory for the clinician to use a method that controls the curve whilst allowing the spine to grow. This in itself creates mechanical challenges since the metal work and implant is facing two forces: the curve and the growth. For this reason, most methods for this condition are associated with a higher rate of complications than for surgery in adolescents in whom final correction and fusion is done. MAGEC was developed for use in children with a lot of growth ahead of them, in the hope the above objectives would be achieved whilst reducing the unacceptable complications already seen with other methods.

8. Why were patients not informed of these complexities such as leakages?

9. Why is there no transparency?

10. Is there a danger of titanium leaking from other types of rods?

11. What happens to my child if there is debris leaking from the MAGEC rods?

For MAGEC, as for any other new technique, clinicians in the initial phase learned about it as time went on. During the first few years these concerns were not raised. Because these concerns have now been raised it is the duty of the clinician to discuss them openly with parents. As for the idea of leakage itself, it relates to blackening of tissues near the MAGEC actuator (rotating cog) and also seepage of free metal ions including titanium. Both of these have not been shown to be much different from other established treatment methods. To reassure parents some clinicians have started measuring these ions regularly in patients with MAGEC rods but overall there is no guideline or protocol. As for the effect of the ions, there is no long-term result for MAGEC rods as they have been used for about 10 years and so far there has been no documented adverse effect.

Openness and transparency to patients is the pillar of clinical practice, particularly where children are concerned. However, when information is not complete and the full picture is not clear, it can create anxiety. Entering data in the British Spine Registry is the most important factor in ensuring transparency about performance of spinal implants, including MAGEC.

12. What type of metal is used in MAGEC rods?

They are made mainly from titanium alloy (Ti6Al4V), but there are some steel components.

13. Is there an infection control report?

So far MAGEC rod surgery has not been associated with increased rates of infection compared with other methods. In fact, most indications are that MAGEC may have a lower rate of infection.

This article was published in *Backbone*, Spring 2019.

SCOLIOSIS ASSOCIATION UK

4 Ivebury Court, 325 Latimer Road
London W10 6RA

www.sauk.org.uk
/ScoliosisAssociationUK
info@sauk.org.uk
@ScoliosisUK
020 8964 5343
scoliosis_association_uk

Helpline: 020 8964 1166

Registered Charity No. 1181463

Edition: 1
Planned date of review: Spring 2022.
Last updated: Spring 2019

14. What options do we have now if we are affected by the MAGEC rod complexities?

This depends on the age of your child and the type of complication. If the child is still growing and is aged less than 10 the surgeon can choose to change the MAGEC rod or use an alternative growth friendly technique. However, in children and adolescents older than 10 a definitive correction and fusion is a better option.

15. How are they measuring the benefits of MAGEC rods?

16. Is there a report of benefits from the MAGEC rods for each year?

Benefit is measured in terms of control and correction of the scoliosis and growth of the child over time, and is done by measuring the curve and the length of elongation of MAGEC over a set time. There are also other measurements between the vertebrae. Most clinicians measure distance between the first thoracic vertebra and the 12th, which is an indirect measurement of lung volumes.

17. Why are rods extended every 12 weeks without any consultation appointments or annual review?

There is no hard and fast rule about the time over which rods are extended. In a fast-growing child this is generally 12 weeks but it could be reduced to 6 weeks or increased to 6 months. Consultation, X-ray, and clinical review by measuring height, weight and sitting height as well as assessing the general alignment of the spine should happen annually and more frequently if there are issues.

18. Why are MAGEC rods being used if there are issues and not vertebral body tethering (VBT)?

These are totally different implants for totally different problems. MAGEC is used for growing children younger than 10 with childhood scoliosis where as VBT has been developed for scoliosis in adolescents. VBT could prove in the long term to be effective but current alternatives, such as final fusion, have an established track record with minimal complications and side-effects. MAGEC was developed in response to the less than satisfactory track record of these alternatives for younger children in the hope of reducing the associated complications.

19. Will the public be able to access Panorama research information and test results?

This I cannot answer. I suspect the BBC needs to be approached for that. I assume individuals featured in the programme can also be approached.

20. How do we know what level of information our consultants had when advising on MAGEC rods?

Over all, consultants offering any form of treatment should be equipped with the most up-to-date information about that treatment. This is particularly important with a new treatment. However, there are times that the available information is limited and under these circumstances openness and honesty must prevail.

21. How many children have been reported so far to have been affected negatively by MAGEC rods?

The exact figure is not available. Current research and publications show an approximate overall complication rate of up to 30% (1 in 3). This figure similar to that of other methods. Most of these complications are addressed with revision surgery with no obvious long-term impact. There are no clear data for long-term effects of revisions surgery.

Spinal fusion and scoliosis questions

1. Why is it after spinal fusion for scoliosis a curve can reoccur?

The rate of recurrence of scoliosis with modern implants within the limits of fusion is low and if it occurs is slow. When it happens, it is due to a combination of factors, which include, severe curve in a child with a lot of growth potential, inadequate correction, fixation or fusion mass, and/or metal work failure, including rod breakage or screw pull outs. Sometimes a new curve develops at the junction of fused and unfused spine. Such curves can be due to

This article was published in *Backbone*, Spring 2019.

SCOLIOSIS ASSOCIATION UK

4 Ivebury Court, 325 Latimer Road
London W10 6RA

www.sauk.org.uk
/ScoliosisAssociationUK
info@sauk.org.uk
@ScoliosisUK
020 8964 5343
scoliosis_association_uk

Helpline: 020 8964 1166

Registered Charity No. 1181463

Health & care information you can trust
The Information Standard Certified Member

Edition: 1
Planned date of review: Spring 2022.
Last updated: Spring 2019

the inherent abnormal tendency of the spine to twist above or below the fusion and sometimes as a result of the clinician trying to limit the extent of fusion for long-term benefit.

2. Is a scoliosis reoccurring after spinal fusion relevant to age?

Sometimes, but it can also be due to the factors stated above.

3. If a person who has reached skeletal maturity has a fusion, are they more likely to curve again, as opposed to a child who is still growing?

No, the opposite. After skeletal maturity, risk of curve progression is reduced.

4. Is there any research and data available to the public on spinal fusion?

Yes. There are many publications available on the internet. Some give access to the full article but for most you can read only the abstract. The full text is usually available for a fee and can be obtained from local libraries, the Cochrane library and British Library.

5. What is the complexity rate with having spinal fusion?

I assume the question is about the complication rate for fusion for scoliosis. This varies according to age, condition of the patient and the type of scoliosis. Scoliosis correction and fusion in adults and children with neuromuscular conditions have the highest rate of complications of up to 40%. Whilst this drops to around 2-5% in fusion for idiopathic scoliosis in adolescents.

6. Is it normal to be in pain after spinal fusion?

It depends how long after the surgery is. Fusion surgery for scoliosis initially is uncomfortable and immediately post operation is, naturally, painful. However, as one progresses things become more comfortable. After 3 months some discomfort needing occasional simple pain killers is not unusual. However, pain is unusual for patients at 1-year after surgery and beyond.

7. How do I go about getting a check up on my rods post surgery?

It depends how long ago your surgery was. Within a few years of surgery you should be able to contact your consultant's team at the hospital you had surgery and request to be assessed. However, beyond that you should ask your GP to make a new referral to your local spinal service.

8. Should there be any concern over Harrington rods?

Overall, if there are no symptoms then there are no concern. However, Harrington rods over the years can become prominent, or impinge on soft tissues. If they are causing pain and click at the same time then they need to be looked at.

9. Why is VBT not offered on the NHS?

This is a question that needs to be addressed by NHS England. They look at the cost, evidency of effectiveness, and alternatives to any given treatment and according to the evidence they approve or reject funding for specific treatment. At the moment VBT is not approved by NHS England.

10. Why is VBT being offered in countries such as Turkey and Spain and not the UK?

I have partly answered this question above. Turkey, Spain, and Germany offer this treatment in the private sector, and their public sectors, as far as I am aware have similar policies to NHS England. In other words this treatment is offered only for fee paying patients.

This article was published in *Backbone*, Spring 2019.

SCOLIOSIS ASSOCIATION UK

4 Ivebury Court, 325 Latimer Road
London W10 6RA

www.sauk.org.uk
/ScoliosisAssociationUK
info@sauk.org.uk
@ScoliosisUK
020 8964 5343
scoliosis_association_uk

Helpline: 020 8964 1166

Registered Charity No. 1181463

Health & care information you can trust
The Information Standard Certified Member

Edition: 1
Planned date of review: Spring 2022.
Last updated: Spring 2019