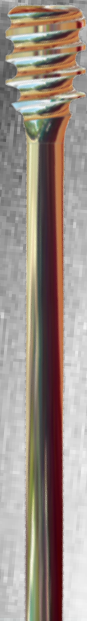




Pega Medical

Fassier-Duval

TELESCOPIC IM SYSTEM



FAQ

FOR SURGEONS

The treatment of Osteogenic Imperfecta (OI) and other genetic bone deformities is the result of teamwork between geneticists, paediatricians, orthopedic surgeons as well as physio-OT. The Fassier-Duval Telescopic Intramedullary System (Fassier-Duval rod) is one of the key surgical solutions in the treatment of these illnesses.

1

Why is the Fassier-Duval rod more effective?

It can be seen as a long term implant. Due to a lower failure rate, a longer in-situ time can be expected, therefore replacement of the rod is less frequent. The Fassier-Duval rod can be replaced in case of a re-fracture, bending of the rod, in case of complications, or when the patient has reached skeletal maturity.

2

What are the particularities of the biomaterial used (Ti alloy, Stainless Steel)?

Stainless Steel remains the standard material. Because Ti alloy is more flexible, it might not be appropriate to avoid recurrence of bone deformities as the patient grows.

3

Is the Fassier-Duval rod recommended for other indications than prevention of long diaphysial fractures of patients suffering from OI?

- For Limb Lengthening Over Nail (LON);
- For simple fractures not requiring torional stability;
- For angular correction in skeletal displasias;
- For pseudoarthrosis.

4

What are the contra-indications of the Fassier-Duval rod?

- Active or latent infection;
- Material sensitivity;
- Patients with neurological or mental conditions.

What kind of complications can be observed with the insertion of the Fassier-Duval rod?

5

- Improper insertion of the device during implantation can increase the possibility of loosening or migration of the components;
- Telescoping may not occur. The rod will behave like the solid rod if the rod is bowed or if the extremity of the male solid component hasn't been cut properly;
- Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing;
- Risk of growth arrest if the threads are left across the bone growth plates;
- Risk of growth problems or bone apposition over the nail at the greater trochanter (risk of coxavalga)

How long is the surgery?

6

Usually the surgery takes 1.5 hours, but it depends on the surgeon's experience. The percutaneous technique is quicker than the open osteotomy technique.

What didactic material exists for the use of the Fassier-Duval rod?

7

- In-hospital technical demonstrations can be arranged on demand as well as assistance during the first-time surgery;
- Operative demonstrations can be organized at the Montreal Shriners Hospital;
- Videos and printed material of the main steps of the surgical technique are available upon request as well as on the website.

How many patients have already undergone surgery with the Fassier-Duval rod?

8

From March 2000 to date over 2000 rods have been implanted in North and South America, Europe, Middle-East and Australia.

What rehabilitation is recommended?

In case of femoral surgery, the following steps are suggested:

- Moulding of a long-leg back slab at the end of surgery;
- Three weeks immobilization;
- Intensive physiotherapy at the hospital: Cast removed and replaced by KAFO / Joints locked in extension with drop lock / X-rays AP and Lat. / Standing activities on supaine stander or tilt-table / Simulation of active movements to regain range of motion and strength;
- Local physiotherapy at home: Program of progressive standing activities using walkers, quad canes or crutches/ Joints unlock once adequate quadriceps strength is achieved / Thigh section of the braces removed/ The patient should be kept in a AFO as long as he/she is growing.

What are the main observations resulting from the clinical studies?

In June 2005 a multicenter study concluded that the Fassier-Duval's monoblock construction eliminated many problems associated with dislodging of the components. Intra-articular migration is also rarely seen with this device. Thus far, the re-operation rate is significantly lower for the Fassier-Duval rod than for first generation telescoping rods and none of the patients needed an arthrotomy of the knee joint. This study showed that the technique for the Fassier-Duval telescopic IM system is fully replicable with similar results at each center involved. In none of the cases, growth arrest was observed.



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