

The Fassier-Duval Rod Success Story

[Emmanuelle Rondeau] On April 15, 2010, Dr. François Fassier, Chief of Staff at Shriners Hospitals for Children (SHC) - Canada in Montreal revealed the results of the latest study on the Fassier-Duval Rods. "The Rods have proven to be very reliable. We have been able to reduce the rate of re-operation from 50% with other models down to 17% with the Fassier-Duval Rod" stated Dr. Fassier. The Montreal invention is the fruit of the collective knowledge and expertise of Dr. Fassier, Dr. Pierre Duval, Orthopedist at Brome-Missisquoi-Perkins Hospital and of Ariel Dujovne, President and CEO of Pega Medical. The Fassier-Duval Rod is used to strengthen the long bones of the legs and arms and grows as the child grows. It is currently the standard of care and is used in more than 45 countries worldwide.



Dr. Pierre Duval, Tim Bosch, Dr. François Fassier and Mr. Ariel Dujovne at the 10th anniversary celebration of the creation of the Fassier-Duval Rod.

The results of this study were presented at the European Pediatric Orthopedic Society (EPOS) Annual Meeting in April and to the members of the Pediatric Orthopedic Society of North America (POSNA) in May.

Furthermore, functional studies show that gross motor function is significantly improved after surgery, allowing most children who would otherwise be wheelchair-bound to walk independently.

Developing the Rods

In the early 1990s, Dr. François Fassier and Dr. Francis Glorieux created an osteogenesis imperfecta (OI) outpatient clinic at SHC - Canada in order to respond to the many needs of children and families affected with brittle bone disease. Dr. Glorieux and his research team developed a medical treatment with bisphosphonates and the success of the clinic was immediate. This treatment is not a cure, but it strengthens bones enough for children to walk and be more active and to lead more "normal" lives. However, it does not correct curved or deformed bones and the increased level of activity can also result in a higher risk of fracture.

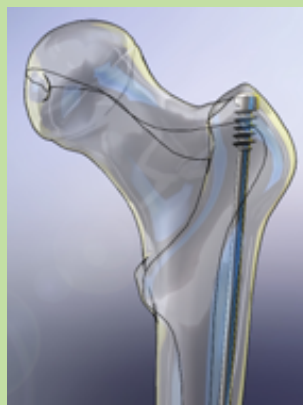
The surgical correction of long bone deformities in children with OI entails osteotomies (breaking the bones at specific points) and rodding (metallic implants inserted inside the bone). Dr. Fassier was facing a growing number of patients needing surgery and the number of complications with existing rods was significant.

Dr. Fassier had an idea to improve on the existing models, but needed help to bring his idea to life. The first step was to conduct a retrospective study of rodding at SHC-Canada between 1972 and 1996. In this study, Dr. Fassier looked at 126 roddings altogether. The complication rate was 55% with both elongating rods and rigid rods and the re-operation rate was 27% with elongating rods and 51% with rigid rods.

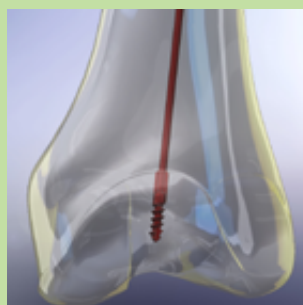
During the same period, the design of the new rod was developed. It had to meet specific criteria:

- Expand smoothly as the child grows;
- Prevent the rod from migrating away from its intended location in the bone;
- Avoid damage to the joints and growth plates;
- Minimize scarring and the impact of surgery.

Once the new Rod was designed, Dr. Duval, who at the time was completing a fellowship with Dr. Fassier, performed the necessary in vitro studies to evaluate how the new rod would



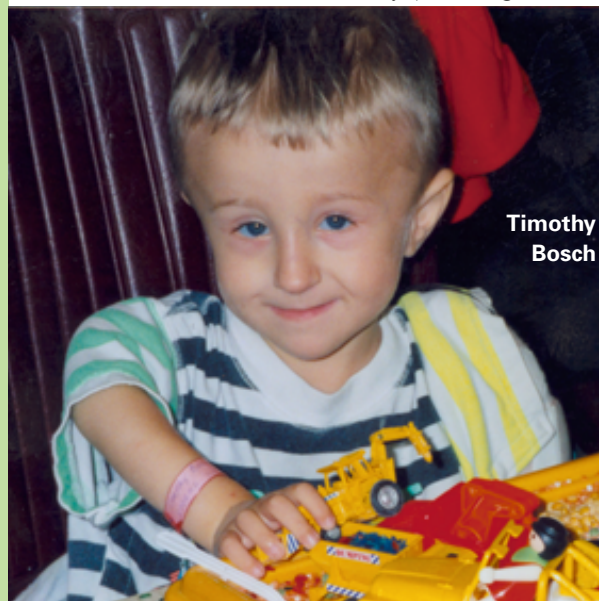
The Fassier-Duval Rods are made of stainless steel. Their threaded ends allow maximum stability while not affecting the growth plates of the bones.



Tim Bosch was the first patient to receive a Fassier-Duval Rod in his humerus.

hold in the bone and evaluated its ability to expand as the bone grew.

The clinical application started in March 2000. In 2006, the first results of a multi-centre study (including Gillette



Timothy Bosch

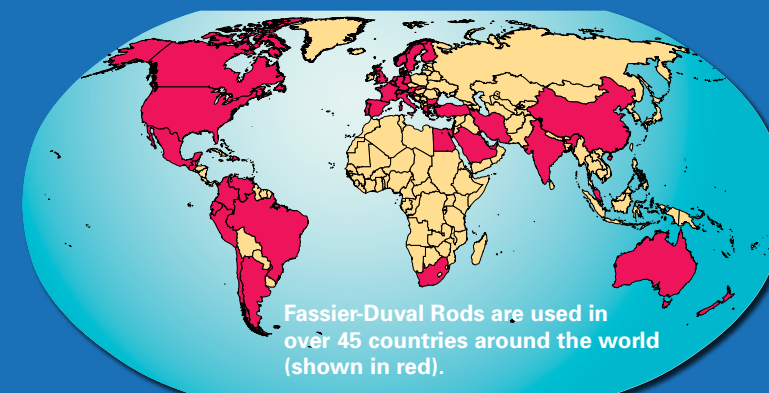
"I have had over 400 fractured bones and have had over 50 major surgeries" stated Timothy. He went on to share: "Over the years, I have grown to befriend my bone doctor, Dr. Fassier. He has performed most of the surgeries that I have had. To me, Dr. Fassier is more than a doctor. He is a friend that I trust with my life. Through the years that I have lived, he has done a lot for me and my family. Dr. Fassier is the most skilled surgeon I have ever known."

Children's Specialty Healthcare, Johns Hopkins, Omaha Children's Hospital, SHC-Chicago, SHC-Portland and SHC-Canada) were presented at the POSNA Annual Meeting. These results showed re-operation rates as low as 14%. Since then, the Fassier-Duval Rod has become the standard of care around the world. The rodding technique is no longer only used to help patients with osteogenesis imperfecta, but also children with congenital malformations of the bone, bone tumors, neuromuscular and metabolic diseases that affect bone strength or density, skeletal dysplasia, and other diseases or syndromes and for patients who require bone lengthening.

The surgical technique associated with this Rod means that there is no need to open up the articulations which decreases recovery time. This also results in less blood loss, less soft tissue destruction and pain, smaller incisions, less scarring, quicker recovery time and fewer complications.

Canadian Innovation Adopted World-Wide

According to Ariel Dujovne, until 2004, there were approximately 200 surgeries performed annually mostly in Canada. "Since then, the number has doubled each year to reach 1800 surgeries in 2009 with a total of 7000 worldwide to date. Half been in the USA and the rest in more than 45 other countries. This export growth resulted in Pega Medical been recognized with the MercadOr 2010 Award as the New Exporter of the Year for the Laurentians and Lanaudiere regions of Quebec", concluded Mr. Dujovne. He also points out that parents of children affected with OI are very educated about the disease and are often the ones that insist that their surgeon use the Fassier-Duval Rod due to its proven superior reliability. |



Fassier-Duval Rods are used in over 45 countries around the world (shown in red).