

The Pega Medical Clinical Report

Bioengineering services and products

Multicenter Radiological Assessment of the Fassier-Duval Femoral Rodding*

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Introduction

The lower incidence of revision surgery achieved with early designs of telescopic rods (27%) when compared to non-expandable rods in Osteogenesis Imperfecta (OI) patients (51%) has been offset by the high incidence of mechanical failure observed in the expandable devices. With reported complication rates of up to 55% for both traditional solutions, the development of a new concept was long overdue. A new telescopic IM rod with no articular effraction was developed with the objective of maintaining the advantages of telescopic rods while avoiding recurring mechanical complications. This new device has proximal and distal threaded fixation, and it can be implanted anterograde with a minimally invasive postero-lateral approach.

The Fassier-Duval Telescopic IM System (F-D nail) was first introduced in 2000, and it has been used to date in over 600 surgeries worldwide. The present multicenter study analyzes for the first time the radiological outcome of the device in the hands of six experienced surgeons. The radiological observations are then correlated with clinical results in the specific patient group. Other indications for the device, such as skeletal pseudoarthrosis and lengthening over nail, were not the subject of the current study.



PRE-OP

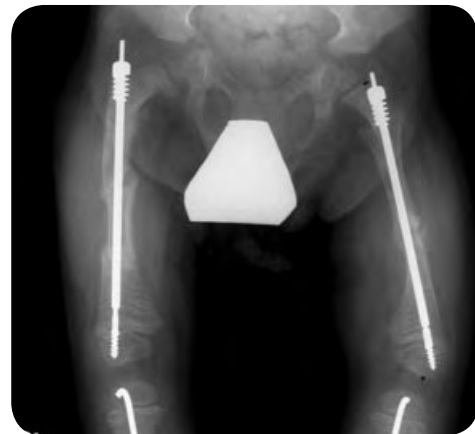
A-P radiograph showing limb deformity typical of an OI patient.

Materials and Methods

The exclusive patient inclusion criteria was that all patients were OI sufferers, that one or both femurs had been rodded for fracture and/or deformity correction, and that the patient has a minimum of 6 month follow-up.

The study was limited to radiological observations of factors that could have an impact in the clinical outcome by means of sequential x-rays. The initial longitudinal (proximo-distal) positioning of the proximal and distal fixations of the F-D nail with respect to bony landmarks was recorded immediately after surgery. Any changes from the initial position was measured and recorded at each time period for which x-rays were available. These changes observed as longitudinal migration are an indication of the true amount of in-vivo telescoping. The longitudinal migration was characterized as either actual migration—relative displacement of the implant within the bone due to a loss of fixation—or apparent migration—overgrowth of the bone over the implant which remains in its initial position or expands more slowly than the rate of bone apposition during growth.

Complications involving lateral migration, nail deformity, nail breakage, not telescoping, infections, knee intrusion, and epiphysiodesis were observed and reported. These radiological observations were also divided into two categories: complications which resulted in re-operations, and complications that pose no significant risk of re-operation.



IMMEDIATE POST-OP

A-P radiograph of patient fitted with Fassier-Duval telescopic IM nails showing initial position.

Results

A total of 158 patients were analyzed with 112 cases having a follow-up of more than 6 months post-op. Within the 112 patients, there were 47 males and 65 females with an average age of 49.2 months (range 13-155 months) and average weight of 13.3 ± 9.2 kg. The average follow up time was 23.9 months (range 6-52 months). Forty-four patients were diagnosed as OI type III, 35 as OI type IV, 21 remained unclassified, 7 were type I and there were 1 type VI and 1 type VII patients (no data were available for 3 patients). Fifty-four patients had 3.2 mm diameter nail implants, 27 were given 4.0 mm nails and the remainder were 4.8, 5.6 or data was unavailable.

The most common type of complication observed was migration of the proximal fixation. A total of 22 patients (19.6%) had upward migration, and another 24 patients (21.4%) had an apparent downward migration. Of the 22 cases of upward proximal fixation migration, 7 required re-operation to push the nail down at follow up times ranging from 2 weeks to over 2 years. The remaining 15 patients had migrations less than 1 cm upwards which did not alter the nail function.

Eight of the cases could not be evaluated due to nail deformity or breakage and in 10 cases, post-op x-rays were unavailable. There was 1 case of lateral migration (progressive cut through the cortex).

Fifteen patients (13.4%) experienced upward migration of the distal fixation while 4 patients (3.6%) experienced downward migration. Post-op x-rays for 10 patients were unavailable. There were 7 cases of nail breakage (6.2%) amongst which 1 occurred due to a bone fracture and the remaining due to fatigue fracture of the nail. Twenty five cases of nail deformity (22.3%) were observed, 1 was due to bowing of the female nail and 18 to bowing of the male nail. The other six cases occurred secondary to a fracture. The rod did not telescope for 3 patients.

There were 16 patients that required re-operations (14.3%) as a result of

complications. Of these, 7 of the surgeries were to correct proximal nail advancements, 1 was for knee intrusion (lateral migration) while 8 were complete rod replacements. Five of the eight required rod replacements were due to damage from fracture, 2 were due to migration and 1 was performed for the removal of a broken female nail.



ONE YEAR POST-OP
A-P radiograph showing normal growth and extension of the nail.

Discussion

The most common reported complication is migration of the proximal fixation. The early upward migration of the proximal fixation is suspected to occur when cortical bone purchase is not achieved and the proximal thread remains in cartilage. This problem can be corrected a priori by making sure at least one thread is screwed into hard bone. Post-op occurrence of upward migration can be surgically corrected by repositioning the nail down. Two of the cases in the current study were reoperated within 3 months post-op and most likely occurred because of inadequate positioning during the initial surgery. For the remaining cases, the complication occurred at various times following initial rod insertion. With the exception of those cases that required nail advancement, all migrations were less than 1 cm and did not affect the function of the nail nor did they cause any reported symptoms.

An apparent downward migration of the proximal fixation was observed for 21.4% of the patients evaluated. X-ray images suggest these were not true migrations but rather the result of bone deposition around and above the proximal nail. Despite the apparent migration, the rod continued to function and telescope for these patients. Both the cause and prevention of this complication in certain patients will require further investigation, including a better understanding of the greater trochanter growth.

Similarly, of the 19 cases of nail bowing, the nail continued to function and telescope for 18 of the patients as bowing occurs most frequently in the male nail. The reason for failure of the nail to telescope in three of the cases observed remains unclear, however none of the cases required revision. Besides a female nail bow, another reason for not telescoping could be intra-op damage to the male nail above the female (the technique of cutting the male nail during surgery should be carefully performed).

One case of distal intrusion through the knee was observed. This complication could be attributed to inadequate fixation during the initial surgery. It occurred within 6 weeks of the initial surgery and was corrected immediately. This complication can easily be avoided by careful positioning of the threads in the middle of the epiphysis particularly in the sagittal plane. One should not hesitate to perform an

additional percutaneous osteotomy for optimal rod placement.

Amongst cases that required nail replacement, the majority (5 out of 8) was due to damage from a fracture and thereby unrelated to either the rod itself or the surgical technique. One of the nail replacements was due to inadequate initial distal fixation resulting in lateral migration; the remaining two were related to complications from spontaneous nail breakage. These spontaneous nail breakages which occurred in 6 implants were from cases during the early clinical trial series done in Canada. Both the design and the surgical technique have been modified prior to the implant entering the world market; no further implant fractures have been reported since then.

Post-op statistical correlations between various parameters were difficult to perform due to the wide range of sample sizes. However, in comparing OI type III and type IV with complications, no statistical link was observed using chi-square and Fisher's exact test except that nail deformity resulting from a fracture is more common for OI type IV patients ($p=0.01$, $n=44$ for type III and $n=35$ for type IV). In comparing age group 1-2 years of age to age group 3-4 years versus complication rate ($n=27$ and $n=20$ respectively), no statistical link was found relating age to complication. In comparing weight group 1-10 kg with 11-20 kg ($n=51$ and $n=27$ respectively), statistical correlations suggested that upward migration of the proximal fixation is more common in patients with weight range 1-10 kg ($p=0.023$).

Conclusions

Compared to first generation telescopic rods, the radiological complication rates for the F-D nail are similar quantitatively but not qualitatively. 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. Radiological observations such as apparent distal migration of the proximal thread, which accounted for almost half of the reported complications, do not alter the function of the nail, nor are they precursors to revision surgery. Thus far, the re-operation rate is significantly lower for the F-D rod than for first generation telescoping rods and none of the patients needed an arthrotomy of the knee joint. Accurate fixation of the F-D rod both distally and proximally is crucial to allow proper telescoping.

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 -that was one of the potential risks of the system- was observed. Finally, no infections were reported either.

Further studies and longer follow up are necessary to appreciate the full advantages of an implant such as the Fassier-Duval rod. More importantly, clinical outcomes would help prove the value of telescoping rodding in OI and may determine whether radiological imperfections are of clinical significance.

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