WHITE PAPER - CONCLUSIONS STUDY FOR ABSORBABLE ACTIVAPIN™

50 cases with 2 years of follow-up.

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The study included 50 cases of hallux valgus surgery on 43 women and 7 men. The average age was 56 years and 1 month. Preoperative score (AOFAS Classification) was 48.

The surgery

The surgeries consisted of a minimally invasive distal dynamic metatarsal osteotomy in all cases, associated with phalangeal osteotomy in 46 cases. The metatarsal osteotomy was stabilized in 46 cases with a single pin (42 cases with a 2.7 mm pin and 4 cases with a 2.0 mm pin). In 4 cases the stabilization was made with 2 pins. In the 46 phalangeal osteotomies, only one pin was used (43 cases with 2.0 mm pin and 3 cases with 2.7 mm pin).

Postoperatively

At 4 months follow-up there was a single failure by nonunion requiring revision surgery for bone plate with a good result at 15 months (score 90). In this case the metatarsal osteotomy was fixed with a single 2.0 mm pin which according to my experience is a mistake. The failure seemed to result more from a lack of bone than granuloma resulting from intolerance to the pin. However we noticed the presence of painless granuloma in 5 radiological images. The average score increased to 78. In one case, the moving of a pin in metatarsal osteotomy required its removal under local anesthesia.

At one year follow-up on the 49 remaining cases, all 5 granulomas had disappeared. The average score was 88. The pain had disappeared in 39 cases, occasional pain was left in 9 cases and there was moderate pain in 1 case. Alignment was good in 42 cases and medium and asymptomatic in 7 cases. Mobility of the MTP was normal or subnormal in 14 cases, in 33 cases the mobility was limited and stiff in 2 cases. Mobility in plantar flexion of the interphalangeal joint was normal in 45 cases and in 4 cases it was limited. The shoes worn were normal in 45 cases and in 4 cases the patient used comfort shoes. There were no new pin movements. Good joint stability in 48 cases. No limitation of activity in 47 cases, limited activities in 2 cases.

At two years follow-up there were no moving pins. Improvements were noticed in 20 cases and stabile result in 28 cases. In one case there was a painful hallux varus between one and two years requiring plate fixation at 20 months (score 34). Complication was not related to the absorbable pin. The pain disappeared in 42 cases and there was occasional pain in 6 cases and major pain in 1 case. The case that remained painful was

associated with painful arthritis from deformation of bone. Alignment was good in 40 cases, medium and asymptomatic in 8 cases and bad in one case (revision surgery was needed). Mobility of the MTP was normal or subnormal in 14 cases, moderate (30 °) in 34 cases and poor in 1 case. Mobility in plantar flexion of the interphalangeal joint was normal in 48 cases and limited in one case. Shoes were normal in 48 cases and in one case wearing shoes was not possible. There was good joint stability in 48 cases and no limitation of activity in 48 cases, limited activities in 1 case. The AOFAS average score was 92. It was an improvement from 4 months (score 78) and 1 year (score 88) results.

Discussion

The benefits of absorbable ActivaPin™ is the good primary stability thanks to a grooved surface. Primary stability is an asset of using ActivaPin™ if necessary for creating compression or in significant shortening where necessary fixation is not possible without good stability of the implant. There is no need for a secondary operation as it is not required to remove the pins except in the case of nonunion. Also the insertion of the pin is made easy due to the conical distal tip of the implant.

The disadvantages of the absorbable ActivaPin™ were the implant package which is the same color for different sizes of pin as in the operation it was difficult to identify the correct size (a different color was beneficially implemented for different diameters in the outer package). It was not possible to remove the pin when it was inserted too deep in the bone. Packaging of the pin in a plastic container did not work well as in some cases it was not possible to remove the implant from the package. In my opinion, the packaging in a foil pouch would be sufficient instead of an aseptic plastic container as the implant must in any case be touched with hands when inserting in the bone. The small hole at the proximal end of the pin is not useful as quite often it does not pick the implant from the container and the small needle can break in the tip of the instrument. There is an empty foil pouch in each package that is useless and of great concern to the operation personnel.

Conclusions

The absorbable material of the implant was very reliable, no moving of the implants or the fixations was noticed and good biocompatibility at one year despite 5 cases of painless radiological granuloma at 4 months. There was very good tolerance of the material at 2 years. Good reliability of the reduction but persistence of a small defect in postoperative mobility in 60% of cases resulting from surgery and the presence of preoperative moderate osteoarthritis in one case. Disappearance of episodic pain in 3 additional cases was recorded between the first and second year. Good matching sizes of the metal K-wires to the absorbable pins. Of the 50 patients operated, two patients had complications but neither of them resulted from the use of absorbable pins themselves. The first patient presented a painful nonunion of bone due to poor technical quality (only one 2.0 mm pin was used, joint distraction and varus). This complication was not resulting from granulomatous reaction on the pin as the operative revision at 4 months was able to show. The second complication was due to progressive worsening during the second year of a small post-operative varus due to a technical error (hyper - reduction varus of the first metatarsophalangeal joint).