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Research Article

Comparison of 2 Types of Bioabsorbable Implants Performing The Chevron Osteotomy to Treat Hallux Valgus Deformity: A Randomized Prospective Clinical Study

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Abstract

Background: Chevron Osteotomy is a treatment option for realigning a mild hallux valgus deformity. There are multiple different ways to fix this osteotomy. We compared prospectively two different types of bioabsorbable screws for the fixation of the Chevron Osteotomy.

Questions/purposes: The purpose of the study was to compare two types of bioabsorbable screws to stabilize the chevron osteotomy. In particular, we were interested in the stability of fixation, the absorbability of the implants without losing the initial angular correction of both IMA and HVA, complications with the hardware, and the healing process of both the osteotomy site and the soft tissue envelop, finally the patient satisfaction with the intervention.

Patients and methods: We included patients between 19-90 years old with a mild to moderate hallux valgus deformity (IM angle I/II -15 degrees). Between Nov. 2016 and Oct. 2017, 71 patients were randomly assigned to either the Mg group or the PLLA group. Clinical, radiographic, and pedobarographic examinations were performed preoperatively, four weeks postoperatively, and two years postoperatively.

Results: The clinical improvement measured by AOFAS, FFI, and FAOS was statistically significant for all patients in both groups compared to the preoperative values. We observed a significant statistically unchanged correction of both IMA and HVA in both groups throughout the entire observation period. There were no malunions or loss of correction in both groups. We observed a screw fracture in 8 cases four weeks postoperatively; despite this finding, it did not affect the IMA, and HVA achieved correction. In one case, we had to replace a PLLA screw intraoperatively with a classic titanium headless screw due to intraoperative loss of compression. We also had one superficial infection in both groups and a deep infection in the Mg group that required implant removal.

Conclusion: The Chevron osteotomy remains a sound and viable osteotomy correcting mild and moderate hallux valgus deformity. To our knowledge, this is the first study to compare Both resorbable screws and showed satisfying and comparable clinical and radiological midterm results. Screw fractures were observed with the magnesium-based implant. This occurrence could not be seen with the PLLA implant due to its biocomposite nature. Further research is needed with another radiological tool to understand the reason behind implant failure.

Introduction

Austin and Leventon first described the chevron osteotomy as a distal 60°angled V-shaped metatarsal osteotomy [1] Level 3-4 studies have shown good to excellent clinical results in mild to moderate hallux valgus deformities using this operative technique [2] Recent studies report a modification in the angle and length of osteotomy lines: the use of larger angles and horizontal osteotomy lines results in a larger contact surface but reduces impaction, i.e., the inherent stability of the entire osteotomy, requiring the use of osteosynthesis [3]. Most surgeons who perform chevron osteotomy to treat mild to moderate bunion deformity have opted to use fixation methods to reduce displacement and the likelihood of malunion [4-7]. K-wires, screws, staples, and plates are mentioned in many studies [8]. However, screw fixation remains mechanically superior to other fixation methods [9]. Non-degradable steel and titanium-based implants are commonly used in orthopedic surgery [10]. These implants provide maximum stability but may require a second surgery for removal [11]. In addition, the non-degradable implants also interfere with imaging techniques such as CT scans and MRIs [12]. The mechanical properties of the bone differ from those of steel or titanium, which can lead to an uneven load transfer, limiting the bone-healing process [13,14]. Therefore, using bioresorbable implants with Young's modulus close to that of cortical bone is appealing for the potential reduction of stress shielding [10].

The use of bioabsorbable implants for bone fixation was first reported more than 30 years ago, and their use expanded from the original application in ankle fractures [15] to the fixation of fractures and osteotomies throughout the rest of the body [16,17], including the fixation of osteotomies of the first metatarsal [18,19]. With this method, complications can occur due to osteolysis, sterile sinus formation, foreign body reaction, fluid collection, implant extrusion, and loss of mechanical stability [20,21]. However, the risk of complications does not appear to be significantly higher than in non-degradable implants [22]. Absorbable polyglycolide polymer-based implants are the most commonly used [23]. Recently developed magnesium-based implants demonstrate improved anticorrosive and mechanical properties compared to those used in the early 20th century, which exhibited high corrosion rates and lower mechanical stability [11,24,25]. Our clinical experience using bioabsorbable implants has shown that occasionally there is a loss of mechanical stability and implant fracture at the sight of osteosynthesis resulting in the dislocation of the distal fragment. The purpose of this prospective study was to evaluate the biomechanical stability of chevron osteotomy by comparing two different types of biodegradable screws. The screws were made of either magnesium (Mg) or Poly(L-lactic acid) (PLLA). Clinical, radiological, and pedobarographical assessments were conducted after a follow-up period of two years.

Patients and Methods

Patients

We included patients aged 18 - 90 years with mild to moderate hallux valgus deformity. An indication was determined based on symptoms, the severity of deformity (IM angle I/II 9-15°), and surgeon experience. Patients who refused to participate and patients with lower extremity comorbidities or diseases that precluded participation in the follow-up examinations were excluded. Pregnant women could also not be included due to radiation exposure. Between November 2016 and October 2017, 71 patients were recruited. They were randomly assigned to either the Mg group or the PLLA group. The patients were operated by three senior Surgeons of the Department.

Implants

Both materials used in the study were bioresorbable compression Herbert screws. These headless screws are inserted flush with the cortical bone. The Mg group was treated with a magnesium screw (MAGNEZIX® CS, Syntellix AG, Hanover, Germany) which was launched in 2013 and consists of a magnesium-based alloy MgYREZr according to DIN EN 1753. These screws are variable pitch cannulated headless screws (2.7 mm Ø), providing interfragmentary compression, similar to the Herbert screw PLLA-implant (Bio-Compression Screw 2.7 x 20 mm, Arthrex® Inc., Naples, USA), which was used in the PLLA group.

Surgical Procedure

Preparations and patient positioning were performed according to the usual standard methods. A medial approach of approximately 5 cm was performed, followed by medial capsulotomy incised in the same horizontal medial plane. The lateral release was then performed via the transarticular approach. After that, a thin medial wall bone cut was performed using an oscillating saw. Next, the drill wire was inserted in the middle of the metatarsal head to determine the correct trajectory for the osteotomy. The osteotomy was performed at an angle of approximately 60 degrees. After translating the distal fragment by approximately 5 mm and impacting it, provisional fixation was performed with a k-wire from the Lateral, proximal, and dorsal to distal, plantar, and medial directions. The bone was predrilled with the help of the fixation wire. According to randomization, the appropriate bioresorbable screw was inserted by hand. With good compression, the newly formed pseudoexostosis could be removed. The medial capsule was closed under tension to reduce the sesamoid bones. Finally, the skin was closed with an Allgöwer suture. From the first postoperative day on, according to pain intensity, full weight-bearing was allowed exclusively using a Hallux Valgus shoe, which allowed load relief of the forefoot. This shoe had to be worn for four weeks. Early physiotherapy for MTP joint mobilization and gait training was recommended and prescribed to all patients after four weeks postoperatively and prior to radiological bony consolidation of the osteotomy.

Evaluation

Clinical, radiographic, and pedobarographic examinations were performed preoperatively, four weeks postoperatively, and two years postoperatively. The Clinical survey included the patient's overall satisfaction, determination of the range of motion (ROM) in the first metatarsophalangeal joint (MTPJ-1), AOFAS-Score (American Orthopaedic Foot and Ankle Society), FFI (Foot Function Index) and FAOS (Foot and Ankle Outcome Score). Intermetatarsal I/II and Hallux Valgus angles were measured on weight-bearing x-rays in dorsoplantar projection. For pedobarographic examination, the emed®-x (Novel GmbH, Munich, Germany) measuring platform was used. To generate sufficient information, patients had to walk barefoot several times in a defined setup. For further analysis, only the forefoot, divided into medial, central, and lateral, and the toe box, divided into big toe, second toe, and third-fifth toe, were used. Peak pressure (N/cm 2), max force (N max), the contact surface (cm 2), and pressure-time-integral ((N/cm 2)*s) were chosen as the most informative parameters.

Results

A total of 71 feet were randomized between November 2016 and October 2017. We examined 62 feet 4 weeks, and two years after surgery, 32 in the PLLA group, 30 in the Mg group, and 9 feet were lost to follow-up. Demographical characteristics were similar between the two groups in terms of gender, age, BMI (kg/m^2), and Follow-up time (Table 1). There was also no significant difference in preoperative AOFAS, FFI, and FAOS scores between the two groups, except for the sports subcategory, which was slightly worse preoperatively for patients in the PLLA-group (Tables 2,3). The clinical improvement in terms of AOFAS, FFI, and FAOS was statistically significant for all patients in both groups compared with preoperative values. However, no difference was observed between the two types of screws, including all subcategories of the FAOS. 19 Patients were very satisfied, and 11 were satisfied in the Mg group. In the PLLA group, 25 patients were very satisfied, and seven were satisfied. None of the patients were dissatisfied with the intervention. There was no statistical difference between the groups concerning the preoperative Intermetatarsal angle I/ II(IMA) and the Hallux Valgus angle (HVA). All patients with a moderate deformity. We observed a significant statistical correction of the IMA and HVA in both groups. The parameters showed no statistically significant difference between the two types of screws (Table 4). Bony consolidation was detected radiologically four weeks postoperatively. There were no malunions in our series. Loss of correction was also not observed at the last follow-up two years after surgery compared to the one-month postoperatively measurements. No recurrence (HVA>20/ IMA>9) was found in either group. We observed a screw fracture in 8 cases on the X-ray follow-up four weeks postoperatively in the Mg group. All screw fractures were located at the sight of the osteotomy. Despite this finding, no radiologically significant difference was measured in these cases concerning IMA and HVA, and no loss of correction was measured compared with the other patients in the Mg group. In one case, we had to replace a PLLA screw intraoperatively with a classical titanium headless screw due to intraoperative loss of compression. We observed one superficial infection in both groups and a deep infection in the Mg group that required implant removal. All patients were encouraged to start physiotherapy six weeks postoperatively. There was no statistically significant difference in the ROM of the first MTP joint between the two groups after two years. The pedobarographical analysis showed higher contact time, peak pressure, contact surface, and pressure-time integral of the big toe and the medial forefoot in favor of the PLLA group. However, these differences were not statistically significant. Subgroup analysis with the broken Mg implants showed no pedobarographically statistical difference from the other feet in the Mg group at the last follow-up (Figures 1,2).

Figure 1: Magnesix screw broken 1 month postoperative.

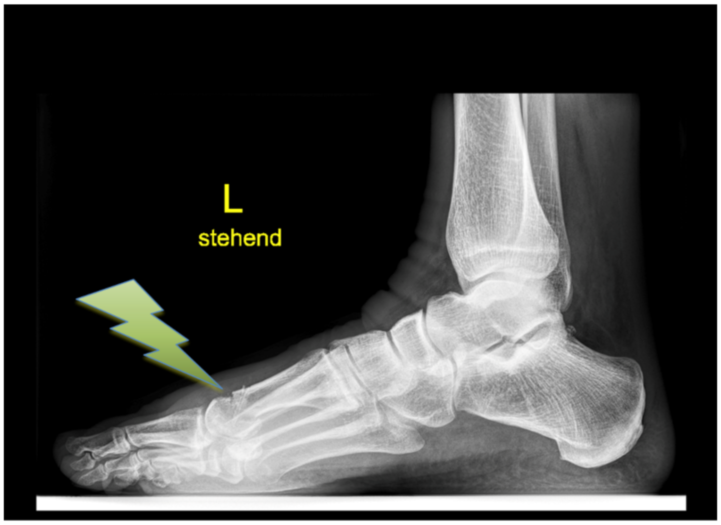

Figure 2: Magnesix-screw broken, 1 month postoperative.

	Magnezix	**Biokomp**	**total**	p-value*
Number of patients	30	32	62	-
Gender (Female/Male)	28 / 2	27 / 5	55 / 7	-
Age (Years)	52.2 (±13.5)	52.6 (±12.4)	52.4 (±12.9)	0.913
BMI (kg/m^2)	22.9 (±4.2)	23.9 (±3.9)	23.4 (±4.1)	0.334
Follow-up (Months)	26.4 (±2.9)	25.8 (±2.8)	26.1 (±2.8)	0.413

BMI, body mass index, (*), number in bracket is standard deviation; * unpaired (two sample) t-test;

Table 1: Summary of preoperative patient’ demographics.

	AOFAS pre	**AOFAS post**	**FFI pre**	**FFI post**	**ROM**
Magnezix	56.0 (16.8)	89.9 (8.7)	21.8 (17.3)	2.4 (3.8)	75.8 (16.7)
Biokomp	55.1 (12.4)	91.2 (10.0)	27.4 (15.3)	2.3 (4.4)	79,.0 (15.8)
p-value*	0.855	0.595	0.214	0.975	0.471

AOFAS, American Orthopaedic Foot and Ankle Society; ROM, Range of Motion; FFI, Foot Function Index; (*), number in bracket is standard deviation; * unpaired (two sample) t-test, α=0,05;

Table 2: Summary clinical scores and functional outcome before and 2 years after Chevron-Osteotomy and comparison between both screws.

	FAOS preoperative					**FAOS postoperativ**				
	Symptoms	**Pain**	**ADLs**	**QoL**	**Sport**	**Symptoms**	**Pain**	**ADLs**	**QoL**	**Sport**
Magnezix	76.9 (21.0)	74.1 (18.2)	86.6 (14.0)	54.2 (19.4)	68.6 (19.7)	87.9 (11.5)	93.2 (7.9)	96.1 (6.0)	78.4 (14.4)	85.2 (17.7)
Biokomp	77.2 (17.1)	65.7 (14.2)	76.7 (17.0)	52.0 (21.3)	53.0 (22.2)	85.2 (13.6)	93.7 (9.8)	96.6 (5.9)	82,3 (14.9)	88.5 (15.9)
p-value*	0.960	0.061	0.021	0.696	0.011	0.435	0.832	0.779	0.321	0.496

FAOS = Foot and Ankle Outcome Score; ADLs, activities of daily living; QoL, quality of life; (*), number in bracket is standard deviation

Table 3: “Foot and Ankle Outcome Score” before and 2 years after Chevron-Osteotomy.

	Magnezix	p-value*	**Biokomp**	p-value*
IM pre	11.7 (1.9)		12.2 (2.6)	
IM post	5.7 (2.6)	0.000	6.2 (2.2)	0.000
HV pre	25,3 (8,0)		24.4 (7.6)	
HV post	9,3 (6,1)	0,000	9.2 (7.5)	0.000

pre, preoperative; post, postoperative; IM, Intermetatarsal angle; HV, Hallux-Valgus-angle; (*), number in bracket is standard deviation; * paired sample t-test, α=0,05003B

Table 4: Correction.

Discussion

Chevron osteotomy is a good and reliable operation method for correcting mild to moderate hallux valgus deformity. This procedure is frequently performed due to the high incidence of hallux valgus deformity [10,26]. Osteotomy fixation has been shown to prevent long-term recurrence and allow early weight-bearing [4]. It is standardly and routinely performed with metal implants such as screws, k-wires, and staples [3,6,7,15,16,18,19,24,27-35]. Many recent studies have focused on the advantages of resorbable magnesium polymers in fixing metatarsal osteotomies compared with standard titanium screws [10,25,36]. PLLA implants were also widely used in the past for osteotomy fixation but were abandoned due to foreign body reactions and soft tissue irritation after implant loosening [31]. However, recent studies have shown that the new generation of implants provides excellent and reliable results in hallux valgus surgery [26] (Figure 3).

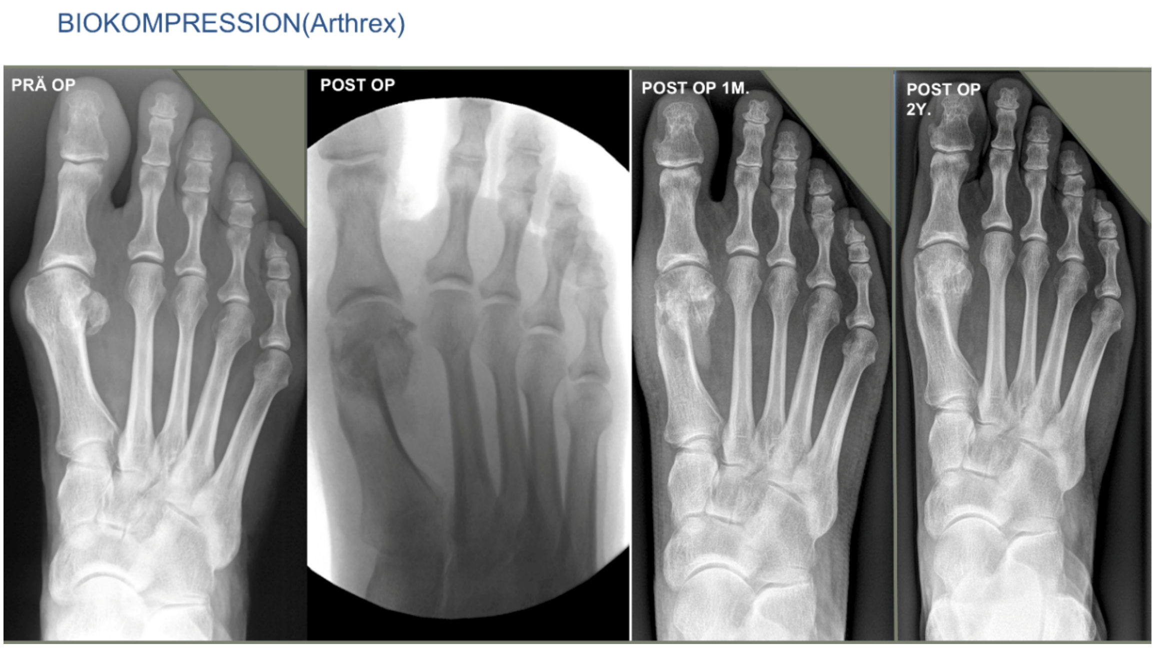

Figure 3: PLLA-Biokomression-screw.

In the present prospective randomized study, we could show similar results for Magnesium and Poly(L-lactic acid) implants regarding patient satisfaction and objective clinical and radiological outcomes. To our knowledge, this study is the first report which compares these two types of resorbable implants. The clinical outcome after chevron osteotomy in hallux valgus surgery is very good regardless of the type of implant used for fixation [19,32]. Windhagen et al. observed in their series an excellent improvement of the AOFAS- score and a drastic reduction of the VAS score after surgeries with no statistical difference between the group with the titanium screw and the group with the magnesium screw fixation [10]. Our series found a statistically improved AOFAS compared with preoperative measurements. However, the results did not differ between the two groups. The FFI and VAS scores also decreased with no remarkable difference between the two screws. The motion of the first MTP joint plays an important role during ambulation. Usually, a mild decrease in joint motion is very well tolerated, but joint motion below 40 degrees of dorsiflexion is associated with difficulties in the push-off phase [30,25]. After the corrective surgery, patients had to cope with an average loss of motion of around 25 to 30 degrees [30]. In this prospective randomized study, we observed a ROM of 75.8° (±16.7) in the Mg group and 79.0° (±15.8) in the PLLA group. However, this difference was not statistically significant. The Hallux valgus deformity leads to unphysiological biomechanics of the forefoot and, consequently, increased pressure beneath the first, second, and third metatarsal head [28, 37]. This study analyzed and compared the plantar pressure distribution of bioabsorbable magnesium and Poly(L-lactic acid) screws. Pedobarographic analysis revealed no statistically significant difference between the groups in peak pressure, contact time, and contact surface measurements in the Hallux region and central forefoot. Nevertheless, slightly higher pedobarographic values were measured in the central forefoot, the first and second toe in the PLLA – group, which could indicate a more pronated forefoot during ambulation and, thus, a recurring near-to-normal gait pattern. In the Mg group, we observed eight screw fractures out of 30 patients during the 4-week follow–up. These eight patients expressed great satisfaction and had no complaints postoperatively; none had to be reoperated. The intraoperative assessment showed high osteotomy stability, so we suspect that the screw fractures resulted from early full weight-bearing. This observation stands contrary to the current literature, in which screw fractures of magnesium-based implants in Hallux valgus surgery are not common [10,28,38]. Windhagen et al. state that Mg-based implants should be less vulnerable to stress shielding because Young's modulus is closer to the human cortical bone [10]. Klauser et al. observed one screw fracture in 100 patients due to a traumatic incident [28]. Choo et al. and Windhagen et al. reported high stability of the magnesium screw without fractures during their follow–up period [10,38]. The new generation of magnesium-based implants has fewer corrosive activities and, therefore, fewer gas-forming cavities, which are associated with a loss of mechanical stability [10]. We can confirm this finding as no such phenomenon occurred during our follow-up period of 2 years. Although pedobarographical analysis of the screw fracture subgroup showed no statistical difference, the reason for the slightly worse plantar loading could be the patients' knowledge of the screw fracture, which may have led to an automatically more supinated forefoot during ambulation compared to the other groups. Also, no statistically significant differences in HVA and IMA were observed during the 2-year follow-up period compared to the remaining magnesium – implants. They showed no change in the readings during the entire follow-up period. Interestingly, we observed a statistically significant improvement in HVA from 4 weeks(9.9°) to 2 years (7.3°) postoperatively ($p=0.012$) in the Mg group. Compared to the PLLA group, no statistically significant difference was found in the radiological measurements. The clinical and radiological evaluation shows the high stability of both screw types. In a single case in the PLLA group, intraoperative compression loss occurred, requiring the surgeon to implant a conventional titanium screw to achieve adequate fixation. PLLA- screws were associated with complications such as foreign body reactions and soft tissue irritation due to a nonphysiologic degeneration process [7,14]. Recent studies have shown that the new generation of PLLA implants causes fewer foreign body reactions and equivalent or fewer infections compared to conventional titanium screws [7,29]. The occurrence of giant-cell granuloma, nonunions, and avascular necrosis secondary to foreign body reactions have also been described in various studies after PLLA screw implantation [14,18]. In our study, there was no diagnosis or clinical suspicion of a giant–cell granuloma. No signs of avascular necrosis or nonunion were noted during the follow–up period. We observed one superficial infection in both groups, which was resolved with local dressings and oral antibiotics. One deep infection requiring implant removal occurred in the Mg- group. The validity of this study is limited by the fact that PLLA screws are not visible in standard radiographs. Further imaging, like MRI, was not possible to conduct, due to high costs – and time management. This circumstance may have affected the comparison between the two screw types regarding the radiological verification of the mechanical strength of the screws. The stability and comparison with the magnesium-based screw are only possible if the radiographs are evaluated for the alignment of the distal fragment, i.e., the HVA and IMA [39]. In summary, The reliability and reducibility of the Chevron Osteotomy have made it one of the first solid choices for many surgeons worldwide to correct mild to moderate Hallux valgus deformity. In our study, we compared in a prospective randomized manner the two types, as mentioned earlier, of bioabsorbable implants. We thus determined their outcomes based on several rigid parameters considering the stability of the fixation, which reduces the nonunion rate, allowing for the patient's immediate safe postoperative weight-bearing. Further clinical studies are needed to assert whether the bioabsorbable screws can be a well-grounded and dependable alternative for the more traditional steel or titanium implants.

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