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Correction of Hallux Valgus through Minimally Invasive Percutaneous Techniques: The WOS Procedure - Long-term Efficacy and Application Across Different Age Groups

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Reply Letter

Dear Editor,

Thank you for your email and for the constructive feedback provided on our manuscript entitled "Correction of Hallux Valgus through Minimally Invasive Percutaneous Techniques: The WOS Procedure - Long-term Efficacy and Application Across Different Age Groups" (Minerva Orthop-4443).

We greatly appreciate the reviewers' comments and the consideration given to our work. The authors have carefully addressed all the suggested revisions and have made the necessary corrections to the manuscript. We believe these changes have significantly improved the clarity and quality of our paper.

We remain open to any further suggestions or corrections that might be required and sincerely hope that our revised manuscript will meet the standards for publication in Minerva Orthopedics. We are committed to ensuring the highest quality of our work and are eager to see it published in your esteemed journal.

Thank you once again for your time and consideration.

Best regards,

Dr. Alessandro Cattolico

Università Degli Studi Della Campania – Luigi Vanvitelli

Correction of Hallux Valgus through Minimally Invasive Percutaneous Techniques: The WOS Procedure - Long-term Efficacy and Application Across Different Age Groups

Running title: Minimally invasive correction of hallux valgus with WOS technique efficacy

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Abstract:

Background: Hallux valgus (HV), characterized by lateral deviation of the big toe, presents a significant orthopedic challenge. The Without OsteoSynthesis (WOS) technique, a minimally invasive percutaneous approach, has been proposed as an effective treatment option. This study assesses the efficacy and safety of the WOS technique in a fouryear follow-up of 260 patients, derived from an initial cohort of 642, categorized by age.

Methods: Key parameters including the hallux valgus angle (HVA), intermetatarsal angle (IMA), range of motion (ROM) of the big toe, and the American Orthopaedic Foot & Ankle Society (AOFAS) score were evaluated at baseline, six months (T1), and four years (T2) postsurgery. Patients were divided into five age-based groups for analysis. Statistical evaluations involved paired t-tests for pre and post-operative comparisons at T1 and T2, and one-way ANOVA for age-related analysis, supplemented by Turkey's post-hoc analysis.

Results: Significant improvements were observed in HVA, IMA, ROM, and AOFAS scores at both T1 and T2 across all age groups, demonstrating the effectiveness of the WOS technique. Notably, patients aged 60 to 80 years showed a reduction in ROM, suggesting age-specific considerations are necessary. Complications were minimal, highlighting the safety of the procedure.

Conclusions: The WOS technique offers a promising solution for HV treatment, ensuring long-term benefits in deformity correction, patient satisfaction, and pain reduction. Despite its efficacy, further research is recommended to optimize outcomes, particularly for elderly patients, thereby enhancing functional benefits and minimizing complications.

Key words: MIS , Minimally invasive surgery, Hallux Valgus

Introduction

Hallux valgus (HV) is a prevalent foot deformity predominantly identified by the lateral deviation of the hallux, or big toe, in the direction of the second toe, concomitant with the medial deviation of the first metatarsal.

This misalignment culminates in the emergence of a noticeable bony prominence on the medial aspect of the first metatarsal head.

This prominence, clinically recognized as an exostosis, can be a significant source of discomfort. Individuals afflicted with HV often report symptoms ranging from localized pain and tenderness to broader functional limitations in daily activities, often compounded by associated aesthetic concerns.

The pathogenesis of HV is intricate, underpinned by a multifactorial etiology. Current research suggests that this deformity arises from an interplay of genetic predispositions, external environmental factors such as footwear choices, and underlying biomechanical abnormalities. Given its complex nature, a comprehensive understanding of HV is crucial for developing effective therapeutic interventions.

Environmental factors, such as footwear and occupational activities, have also been implicated in the development of HV. High-heeled shoes, narrow-toed shoes, and tight-fitting shoes have been shown to increase the risk of HV, presumably by altering the loading patterns on the foot and promoting abnormal foot postures (Nix et al., 2010)

Occupations that necessitate prolonged periods of standing or walking, such as nursing and teaching, have been implicated in the development and exacerbation of foot disorders. Specifically, these professions have been associated with an elevated risk of HV. The sustained pressure and stress on the feet, inherent to these roles, may contribute to the biomechanical alterations predisposing individuals to HV. Understanding the

occupational risk factors for HV is pivotal for preventative strategies and tailoring therapeutic interventions for those in high-risk professions.

Abnormal gait patterns, such as toe-out gait and increased knee valgus, have also been associated with an increased risk of HV, possibly due to altered biomechanical stresses on the foot (Shibuya et al., 2020)

The diagnosis of HV is primarily grounded in a comprehensive clinical assessment of the patient. Hallmark manifestations include the notable presence of a deviated big toe, concomitant pain, and associated functional impairment. While the clinical presentation provides essential insights, radiographic imaging plays an instrumental role in the diagnostic journey. Not only does it offer a quantitative assessment of the degree of deformity, but it also serves as a valuable tool in guiding therapeutic decisions, enabling clinicians to tailor interventions based on the severity and specifics of the malalignment observed, as well as on the degree of Metatarso-Phalangeal osteoarthritis.

In more advanced cases of HV, surgical intervention may be deemed necessary. Traditional surgical approaches, such as open osteotomy with internal fixation, have historically been the gold standard. However, these procedures come with notable downsides including significant morbidity and extended recovery durations. With advancements in surgical techniques, minimally invasive percutaneous methods have come to the fore.

Minimally invasive or percutaneous designs have been described for distal firstmetatarsal osteotomy, with or without osteosynthesis (Carvalho et al., 2016)(Kadakia et al., 2007).

Minimally invasive percutaneous techniques for HV correction, in general, offer a gentler approach, minimizing damage to the soft tissues and the aforementioned joint, and thereby lower the potential for wound-related complications.)

Techniques such as the Without OsteoSynthesis (WOS) stand out for their reduced trauma to soft tissues and the first metatarsophalangeal joint, consequently diminishing wound complication risks.

This multicentric study aimed to assess the effectiveness of the Without OsteoSynthesis (WOS) technique for HV correction

Materials and methods

Study Design

. The study included a cohort of 260 patients, segmented into five age-based groups of 52 individuals each. A follow-up period of four years was conducted to evaluate the medium-term efficacy of the technique across a diverse age range of 30 to 80 years.

From an initial pool of 640 patients who underwent minimally invasive percutaneous correction for HV between January 2014 and December 2018, a subset of 260 patients was selected. Inclusion criteria mandated that all subjects had undergone primary correction for HV. Patients requiring supplementary interventions, such as for metatarsalgia, were also included, provided their HV was of mild to moderate severity. Severe cases, particularly those with a preoperative AOFAS score below 50, were excluded.

To ensure the integrity of the study, several exclusion criteria were applied. Patients with rheumatic diseases, such as rheumatoid arthritis, seronegative spondyloarthropathies, and gout, were excluded. Individuals with conditions affecting

bone metabolism, including hyperparathyroidism and renal insufficiency, were also excluded. Additionally, patients who experienced significant incidents such as accidents, fractures, or traumatic events in the year before or after the intervention were not included. Subjects who did not complete the four-year follow-up period or required revision surgery during the study were excluded, as were cases involving ligamentous laxity necessitating temporary wire usage. Finally, patients receiving surgical treatments deviating from the WOS technique were excluded.

Outcomes of interest encompassed AOFAS score, Range of Motion (ROM), Hallux Valgus Angle (HVA), Intermetatarsal Angle (IMA), with a special emphasis on discerning any age-influenced differences in these outcomes.

Surgical Procedure

All patients underwent the same first-ray procedure performed by three expert surgeons, following the methods described by Isham and De Prado et al. (2005). The surgical technique employed was the WOS. This technique is carried out through two small incisions of approximately 2-3 mm each. One incision is made proximal to the metatarsal head, while the other is located at the first phalanx of the first ray. Through the first incision, exostectomy and osteotomy of the first metatarsal are performed to translate the metatarsal head. The second incision allows for the osteotomy of the phalanx, as described by Akin. The entire procedure is conducted under continuous fluoroscopic guidance.

Image 1

Radiographic and Clinical Evaluations

For accurate assessment, radiographic measurements were performed twice, 2 to 4 weeks apart, with the mean of the two measurements used for statistical analysis (Magnan et al., 2005). Portable X-ray fluoroscopy was employed to minimize radiation exposure, leveraging the skill of the operator to optimize outcomes.

Data Collection

Clinical and radiographic parameters evaluated included the Hallux Valgus Angle (HVA), Intermetatarsal Angle (IMA), Range of Motion (ROM) of the big toe, and the American Orthopaedic Foot & Ankle Society (AOFAS) score (Leigheb et al. 2019) . Data were collected at three key time points: pre-surgery (T0), six months post-surgery (T1), and four years post-surgery (T2).

Patient Demographics

The study cohort consisted of 232 females and 28 males, with an age range of 30 to 79 years and an average age of 64 ± 16.09 at the time of intervention (T0).

Stratification

For better analysis, patients were stratified into five distinct age brackets, each containing 52 participants. The groups were defined as follows: Group 1 (30-39 years), Group 2 (40-49 years), Group 3 (50-59 years), Group 4 (60-69 years), and Group 5 (70-79 years). These meticulous steps and criteria were carefully chosen to minimize variables that could compromise the study's findings and ensure the reliability of the results.

STATISTICAL ANALYSIS

For the statistical assessments, we employed the renowned IBM SPSS software. The Student's t-test was instrumental in gauging the statistical significance of the data shifts, comparing the T1 data against the preoperative findings, and the T2 data with the preoperative baseline. Further, the One Way ANOVA test was utilized to decipher overlaps in outcomes across age groups. A subsequent post-hoc analysis (Turkey HSD) was conducted to probe into statistically significant variances among the groups.

Through the amassed data, our intention is to critically assess the efficacy of the minimally invasive percutaneous surgery for HV correction devoid of internal fixation. Additionally, this study aims to elucidate the technique's applicability and effectiveness across varied age spectrums.

Results

Table 1

AOFAS score, HVA, IMA and ROM were evaluated at three distinct time intervals: pre-surgery (T0), six months post-surgery (T1), and four years post-surgery (T2).

Statistically significant changes were observed in the overall cohort from pre-surgery to both six months and four years post-surgery ($p<0.05$). Significant improvements in all parameters, including ROM, were recorded at T1 and T2 compared to T0.

Following the evaluation of the general population, a further statistical analysis was conducted on patients segmented by age groups. Using the ANOVA test to compare preoperative AOFAS scores, no statistically significant differences were found in the initial scores across all five groups (p=0.48). Similar consistency was observed for HVA, IMA, and ROM, with no statistically significant differences in initial values across the groups (HVA p=0.32, IMA p=0.65, ROM p=0.34). Thus, all groups had comparable baseline parameters preoperatively.

The AOFAS score, HVA, and IMA remained similar and comparable across different age groups at both six months and four years post-operation. However, this similarity was not evident for ROM. While ROM remained consistent in groups 1, 2, and 3, groups 4 and 5 displayed a significantly reduced ROM in the post hoc analysis compared to younger patients. A significant variance in ROM was detected among patients aged 60 to 80 years, which was markedly inferior compared to other age brackets.

Discussion

The findings of this study endorse the WOS technique as an effective surgical approach for the correction of HV. Noteworthy improvements in the AOFAS score, HVA, and IMA were observed at both six months and four years post-surgery, indicating the technique's enduring outcomes. These results, in terms of improvement in the parameters examined, are comparable and similar to those already present in the literature. However, there are no studies like ours that have analyzed the effectiveness of this technique by comparing it across different age groups.

The diminished ROM noted in patients aged 60 to 80 years necessitates further research to discern underlying factors and potential interventions to enhance results within this age bracket. While the WOS technique showcases promising outcomes in treating HV, with statistically significant enhancements in key parameters, clinicians should be wary of the potential decline in ROM in older patients. When selecting the most suitable surgical intervention for this demographic, age-related functional requirements should be taken into account.

Future studies might delve into factors influencing ROM outcomes, such as possibly reduced functional demands or decreased movement post-operation, and explore potential strategies to augment the efficacy of the WOS technique in elderly patients. Although postoperative ROM in patients over 60 is lower compared to other age groups, the overall AOFAS score remains consistent across the five examined groups. Hence, this clinical parameter doesn't impact the patient's overall satisfaction.

The complication rate recorded with this minimally invasive percutaneous technique for correcting HV is very low, and among these complications are recurrence of the HV deformity or development of the opposite deformity (hallux varus), malunion, nonunion, head metatarsal necrosis, clawed hallux, and transfer keratotic lesions that cause pain, as well as other complications. (Arauz et al 2017)

Conclusions

HV should only be addressed surgically with joint preserving

Procedures [12] (Nix et al., 2010). The outcomes of our research endorse the WOS technique as a proficient surgical strategy for the rectification of HV. The rise in the AOFAS score, HVA, and IMA at six months and four years post-surgery indicates the method's prolonged efficacy.

However, clinicians should remain alert to the diminished ROM discerned in the 60-80 year age category. This discrepancy necessitates additional inquiry to discern its root causes and to identify potential strategies to bolster outcomes for this particular demographic.

In summation, the WOS technique exhibits commendable results in addressing HV, marked by statistically significant enhancements in pivotal metrics. When determining the optimal surgical intervention for their clientele, medical professionals should factor in the likely decline in ROM among the elderly, bearing in mind the age-related functional requirements. Prospective investigations might probe into factors—such as potentially diminished functional demands or reduced post-surgery movement—affecting ROM results and feasible measures to amplify the success rate of the WOS method in senior patients.

Even though patients above 60 display a reduced post-operative ROM relative to other age segments, the cumulative AOFAS score is consistent across the five scrutinized groups. This implies that this specific clinical metric does not sway overall patient contentment.

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Conflicts of interest.— NO CONFLICT OF INTEREST

Authors' contributions

This study represents a collaborative effort among several dedicated professionals, each contributing their unique expertise to the research. Their contributions are as follows:

Alessandro Cattolico: As the initiator of the study, Alessandro Cattolico played a pivotal role in conceptualizing the research framework and methodology. As an expert surgeon, he also contributed significantly to the surgical procedures and provided critical insights into the interpretation of the results.

Fabrizio Sergio and Ottorino Catani: Both renowned as expert surgeons, Fabrizio Sergio and both were instrumental in executing the surgical interventions, ensuring the highest standards of precision and care were upheld throughout the study.

Angela Lucariello: Specializing in the methodological rigor of the study, Angela Lucariello was responsible for designing the materials and methods section, conducting the statistical analysis, and translating complex findings into accessible language for a broader audience.

Giovanni Cautiero: As an expert surgeon, Giovanni Cautiero contributed his surgical expertise, particularly in the nuanced aspects of the WOS technique, enhancing the study's overall execution and fidelity.

Alessia Boemio: In addition to her role as an expert surgeon, Alessia Boemio played a vital role in the translation process, making the study's findings accessible to a non-Italian speaking audience, thereby extending its reach and impact.

Luigi Aurelio Nasto and Enrico Pola: Both esteemed as expert surgeons, Luigi Aurelio Nasto and Enrico Pola brought their extensive experience and technical proficiency to the study, significantly contributing to its surgical success and the precision of its outcomes.

Fabio Zanchini: As a leading contributor, Fabio Zanchini was not only pivotal in patient recruitment and data collection but also played a central role in the analysis and interpretation of the data, ensuring the study's findings were robust, reliable, and of the highest scientific merit.

Each author's contribution is a testament to the collaborative spirit and dedication that underpins this research, showcasing a commitment to advancing medical knowledge and improving surgical outcomes for patients suffering from hallux valgus.

TABLES

Table I.— *RESULTS OF THE STUDY*

Table 1	*T0 (baseline)*	*T1 (6 months)*	*T2 (4 years)*
HVA	22.56° ± 5.37	11.16° ± 1.93	12.06° ± 1.35
IMA	12.58° ± 0.98	8.15° ± 1.34	8.96° ± 1.34
ROM	99.87° ± 11.23	102° ± 9.75	105.18° ± 7.64
AOFAS	62.17 ± 6	86.09 ± 8.34	89.32 ± 6.39

Legenda: Values are expressed as mean ± SD
HVA: Hallux Valgus Angle
IMA: Intermetatarsal Angle
ROM: Range Of Motion
AOFAS: American Orthopaedic Foot & Ankle Society Score

image 1: Surgical Technique

Supplementary Digital Material

Download supplementary material file: Minerva Orthop-4443_Supplementary Digital Material1_V1_2024-06-09.doc