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Biomechanical characteristics and functional results of cortical suspension systems used for surgical treatment of hallux valgus

THESIS SUMMARY

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Introduction

Hallux valgus is one of the most frequent chronic medical conditions affecting the human foot. The financial and psychosocial burden imposed by the management of this disease can reach a considerable magnitude. Along with the functional impairment caused by the resulting metatarsalgia and the aesthetic concerns, hallux valgus amplifies the risk for traumatic injuries among the elderly population and brings the threat of new complications for patients with peripheral neuropathy caused by type II diabetes mellitus or other chronic conditions.

Considering the aging tendency of human population and the high prevalence of peripheral neuropathy in the setting of modern society diseases (type II diabetes mellitus, thyroid disfunction, autoimmune diseases), research and development of hallux valgus management has a significant importance, even at present [1].

The evolution of hallux valgus treatment was disrupted by numerous changes and controversies, researchers and medical professionals trying to develop a scientific, evidence-based approach, sometimes resembling a logical flow diagram, adapted to specific factors to establish the ideal indication for different surgical techniques. Unfortunately, none of the advanced approaches succeeded to become a generally adopted standard of management, current surgical treatment still being affected by a high incidence of complications and recurrence of the deformities [2].

The challenges in optimizing surgical management of hallux valgus are generated foremostly by a lack of a consensus and adequate knowledge about the etiopathogenesis and biomechanics involved in the initiation and progression of the specific deformities. Therefore, researching all sides of this condition, remains an important endeavor to be undertaken, with the aim of bringing new and useful information, which can improve prevention, diagnosis and treatment of hallux valgus.

I. General part

The first section of this work contains essential information required for the understanding of hallux valgus as a distinct condition and of the analyzed surgical technique, dedicated to the surgical correction of the characteristic deformities.

Because the structure and consequently, the function of human foot implies a very high level of complexity, a description of the anatomy adjusted to the specifics of this condition and its treatment was primarily performed. Also, for a better understanding of the specific factors involved in the etiopathogenesis, diagnosis and treatment of hallux valgus, a series of applied biomechanics details were presented. This information was bestowed considering the biomechanical adaptation and specialization involved by human foot development, as well as first ray and hallux instability, perhaps the most debated and scrutinized biomechanics principle in literature.

The unique deformities of hallux valgus addressed by classification and surgical treatment, include positional changes of first ray and of the whole foot in all three anatomical planes, relative to the ground, but also in relation to one another. These changes must be appreciated and described in a three-dimensional way, this requiring a close examination of the terminology and anatomical positions and their importance for the management and stratification process of this condition.

The next chapter incorporates fundamental information required for understanding the management of hallux valgus, which demands considering its etiopathogenesis, epidemiology, pathoanatomy, diagnosis, severity stratification and treatment options. All this knowledge creates an up to date background necessary for an efficient investigation of the selected surgical technique, considering the high level of intricacy implied by the management and its past challenges.

To develop a virtual model for the implementation of the finite element analysis of the biomechanical system formed by the first two metatarsal bones and the corresponding cuneiforms, but also of the components required by the studied surgical technique, a set of essential data regarding the methodology for computerized analysis of biomechanical structures was presented in this last chapter of this part.

II. Special part

1. Medium-term outcomes after hallux valgus surgical correction based on cortical suspension systems

1.1 Working hypothesis and objectives

Hallux valgus presents as a medial painful proeminence, with the apex at the first metatarsophalangeal joint and as a disruption of the first ray's ability to physiologically support body weight during the push-off stage of human gait cycle. This biomechanical imbalance is expressed in a clinical setting as transfer metatarsalgia, a painful medial proeminence conflicting the shoewear and aesthetical concerns. Management of hallux valgus usually starts with a course of non-surgical measures, which cannot alter the progression of the deformities and usually with modest results. When this approach fails, the indication for surgical treatment ensues. Although there are many types of surgical procedures developed for surgical correction, they are merely variations of the same basic principles [7-9].

A non-invasive correction procedure included in the novel techniques category is the Mini TightRope® technique. This correction method is the main focus of this work, which investigates different aspects of the postoperative results and also the specifics of this surgical technique. The first research course was directed towards perioperative management, surgical technique details, complications and the postoperative results. Radiological evaluation of the results and also a subjective assesment performed by the patients must be essential objectives for any study analyzing a surgical treatment method for hallux valgus that has not stood the test of time [10].

Another objective of this study was to advance any observations that can lead to the improvement of clinical and functional results evaluation process or to the enhancements of specific evaluation scores. Concerning the surgical technique, the aim was to identify any planning, perioperative management or surgical metod details that could be improved or altered, therefore ensuring better results, lower complication rates and a smoother learning curve.

An important element that must not be overlooked is patients' satisfaction, which is very much affected by the aesthetical outcomes and the ability to return to the preffered shoewear, denied by the painful symptoms. In order to adress this problem, we included the assessment of postoperative satisfaction with local aesthetics, pain severity or footwear restriction levels, in the results evaluation process.

1.2 Patients and methods

For this study, the hallux valgus cases diagnosed and treated in our department using the MTR® technique during a five year period were followed up and the resulting data analyzed. An indication for surgical correction was established after a first course of non-surgical treatment did not lead to favorable results, with persisting painful symptoms and functional impairment.

23 patients were included in this study, with only one case of unilateral procedure, and all the other bilateral corrections performed simultaneously. As a result, a total of 45 separate procedures were assessed.

The correction technique combined a soft tissue procedure performed at the first metatarsophalangeal joint (modified McBride with the preservation of the peroneal sesamoid), followed by the reduction and fixation of the first intermetatarsal angle using two cortical suspension systems for each foot, provided in a sterile kit by the manufacturer, each system comprising of two metalic buttons and high strength wires (2.0 FiberWire®) [10].

Radiological results evaluation was done by processing and analyzing data provided by specific angles measurements of the first intermetatarsal angle (IMA) and the hallux valgus angle (HVA), accomplished using the anatomical axis of the corresponding bones. The follow-up period was at least three years for the patients under observation after surgery, repeated foot radiographic examinations being completed for these cases. Bone mineral density was assessed using preoperative DEXA (dual X-ray absorptiometry) scans, to diagnose osteopenia or osteoporosis.

Quantitative variables collected for statistical testing were angle measurements defining the specific deformities, age, bone mineral density (BMD) determined for lumbar spine and bilateral femoral neck and the T score, resulted from processing the recorded values of BMD.

Qualitative variables (ordinal variables) compiled for determining functional results were the perceived aesthetics of the feet, pain severity levels and footwear restrictions. For the assessment and recording of these variables we developed a subjective evaluation form, administered to the patients under follow-up for at least one year after surgery.

Testing for data normality was performed using the Shapiro-Wilk test. The distribution analysis of the specific angles measurements (IMA and HVA) was applied for every determination point, considering these moments as dependent observations used for statistical analysis of the correction potential. The radiographic evaluation moments were before (T0) and right after surgery (T1), at minimum one year after (T2) and at least three years after surgical correction.

Follow-up and comparative analysis of the radiological parameters between different observation moments were accomplished using Wilcoxon signed-rank test for dependent samples. The same test was used for comparing functional results expressed as ordinal variables, between different observation points in time. Correlation between variables was calculated using Kendall's tau-b statistical test, which determines the strength and direction of association between two ordinal variables. The independence analysis between the second metatarsal fracture, considered the main specific complication, and bone mineral density deficiencies (osteopenia or osteoporosis) was performed by running Fisher's exact test, which can calculate if there is an association between two dichotomous variables [11].

1.3 Results

The mean age of the patients included in our study was 46 years (±9,68), with a follow-up period of minimum 12 months for most of the cases, spanning up to 62 months after surgery.

Normality testing results for specific angle measurements, using the Shapiro-Wilk test revealed normal distributions for most of the data sets ($p>0,05$), with two exceptions represented by the HVA values before correction (T0) and at one year (T2) after surgery. The cause for these asimetrical results is the inclusion of two cases with severe bilateral HVA distortion at (T0) and the occurence of three complications at (T2), in the form of HVA severe deformity recurrence.

During the follow-up period, a fair maintenance of the correction for the specific angles was recorded, up to at least three years after surgery, with a variable loss of initial correction that did not cause any significant functional impairment, requiring revision procedures (Table 1.1.).

Table 1.1. Specific angles measurements recorded during the postoperative follow-up period

	IMA (degrees)		**HVA** (degrees)	
observation moment	mean value (SD)	median	mean value (SD)	median
T0 (N=45)	13.19º (2,69)	13,28º	30,63º (9,01)	30,01º
T1 (N=45)	6,40º (2,98)	6,68º	15,89º (8,34)	15,32º
T2 (N=37)	9,02º (2,11)	9,17º	23,95º (10,96)	20,78º
T3 (N=20)	10,43º (2,57)	10,06º	25,92º (8,37)	23,76º

After applying the Wilcoxon test, a correction of IMA median value of 6,6º was calculated between (T0) and (T1), a statistically significant difference (Z = -5,84; p<0,001) (Fig. 1.1.).

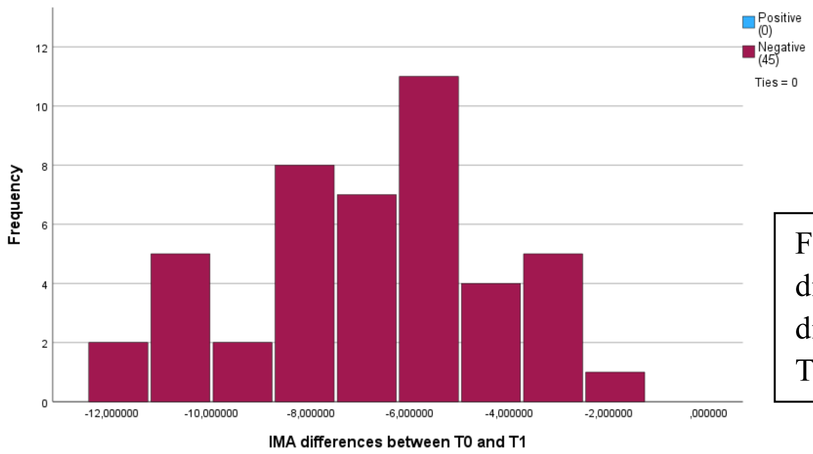


Fig. 1.1. Symmetrical distribution of the differences between T0 and T1 for IMA

A statistically significant correction of HVA median value equal to 14,69º was detected for the same observation moments (Wilcoxon test; Z = -5,75; p<0,001). There was a positive difference for one HVA measurement, which could be explained by the radiographic examination deficiencies of that case (Fig. 1.2.).

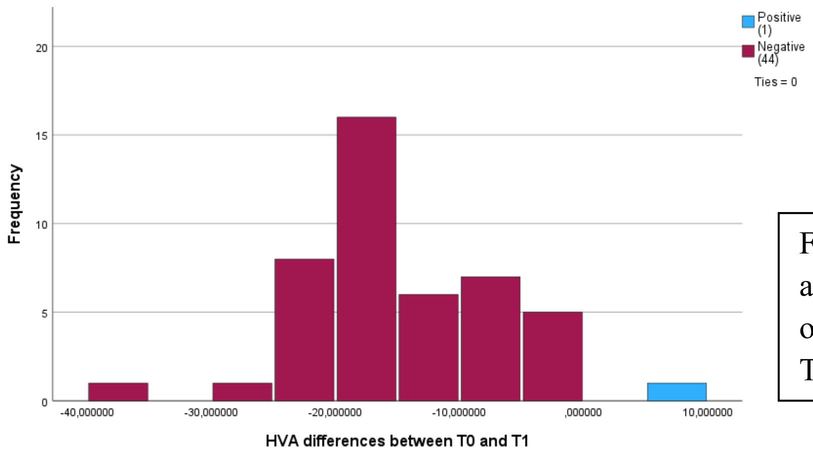


Fig. 1.2. Slightly asymmetrical distribution of the differences between T0 and T1 for HVA

The radiological results recorded at one year after surgery (T2) for the remaining patients under follow-up (N_2=37) showed a loss of IMA correction by 2,62º (38,58% from T1 correction) and by 8,06º for the HVA (54,68º from T1 correction).

There was a statistically significant correction of IMA median value, with a 4,11º difference between (T0) and (T2) moments, and a perfectly symmetrical distribution of differences (Wilcoxon test; Z = -5,3; p<0,001) (Fig. 1.3.).

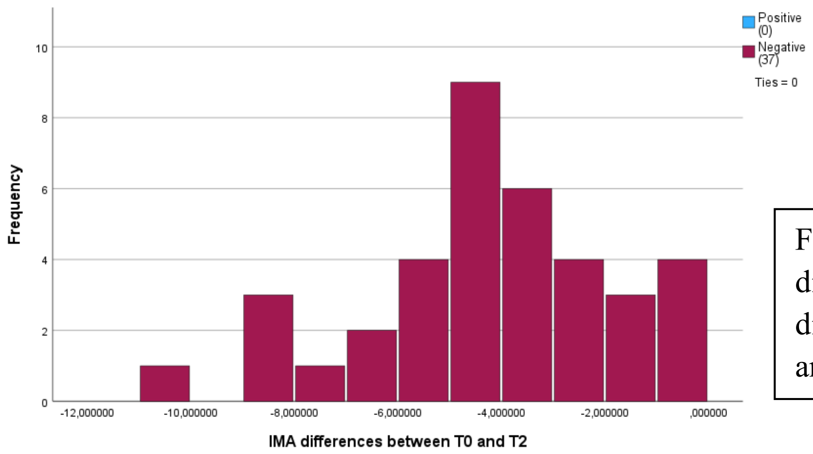


Fig. 1.3. Symmetrical distribution of the differences between T0 and T2 for IMA

Median HVA correction at (T2) was 9,23º (Wilcoxon test; Z = -4,08; p<0,001), with an abnormal distribution of differences. The asymmetry was caused by 7 recurrences of HVA deformity, representing 6 positive differences compared to the preoperative value and one case that defined by the recurrence of a severe deformity (Fig. 1.4.).

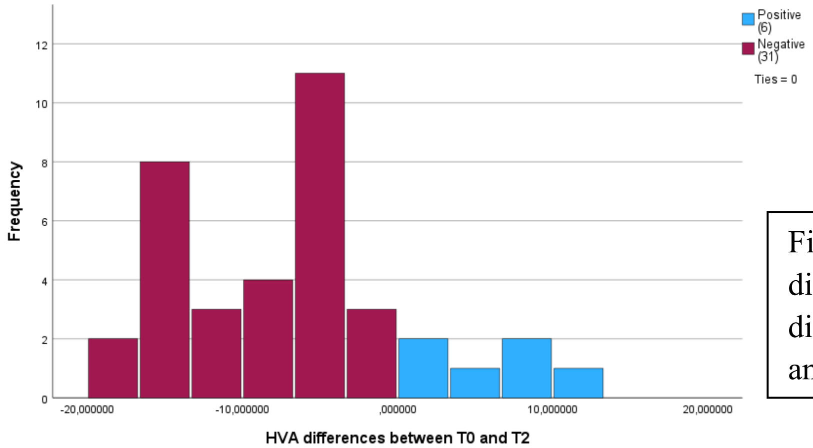


Fig. 1.4. Asymmetrical distribution of the differences between T0 and T2 for HVA

At the last radiographic evaluation performed (T3) on the 10 patients with bilateral interventions (N_3=20), an additional increase of 1,4º of the average IMA values (33,65% of the T2 correction) and of 1,97º for average HVA values (29,49% of the T2 correction) was observed.

There was a statistically significant reduction in median IMA value by 3,22º between the time points (T0) and (T3). The absolute symmetry for the differences two observation moments confirmed the sustainability of IMA correction for the MTR® technique on the medium-term (Wilcoxon test; $Z = -3,9$; $p<0,001$) (Fig. 1.5.).

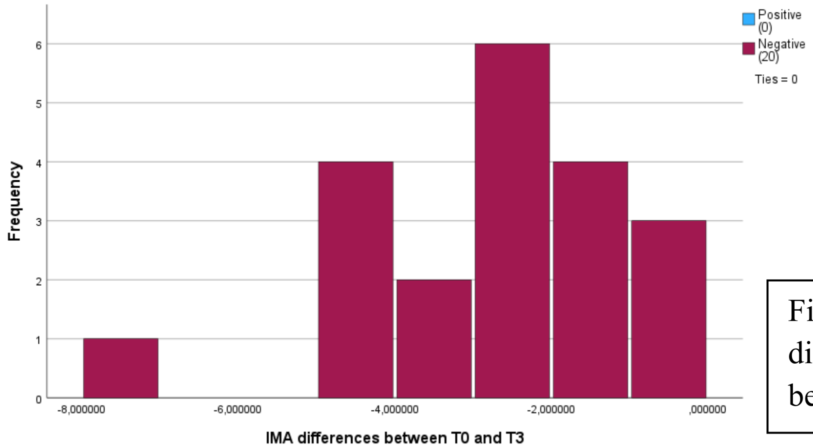


Fig. 1.5. Symmetrical distribution of the differences between T0 and T3 for IMA

A statistically significant reduction of 6.25º (Wilcoxon test; $Z = -3,28$; $p=0,001$), of the median HVA value, was recorded at least 3 years postoperatively (T3) (Fig. 1.6.).

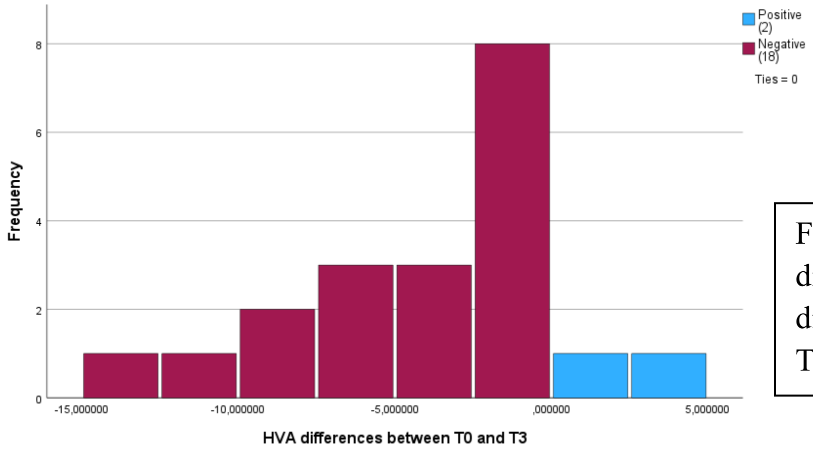


Fig. 1.6. Asymmetrical distribution of the differences between T0 and T3 for HVA

Compared with immediate postoperative values (T1), at least three years after this moment (T3), a mean increase of 2,76º was observed in the IMA values, which lost 4,03º (59%) of the initial correction, and a mean increase of 14,74º in HVA values, with a loss of 10,03º (68,04%) from the initial correction (Fig. 1.7.).

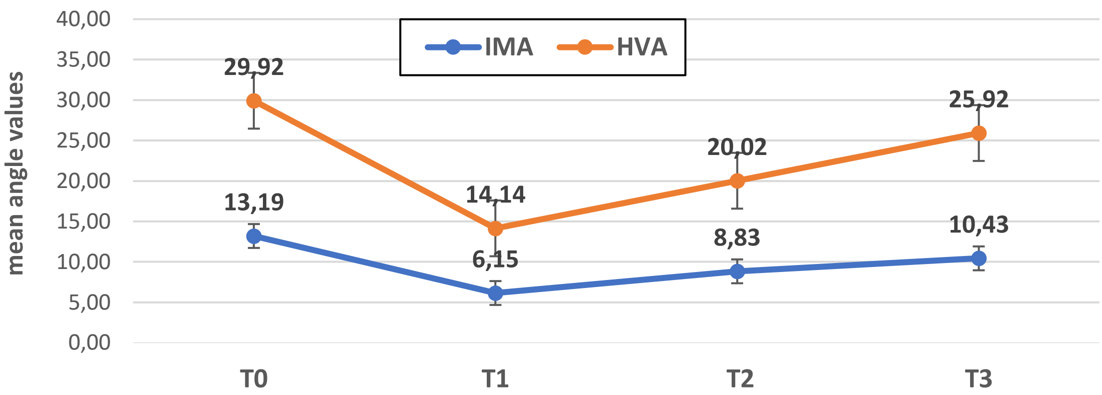


Fig. 1.7. The evolution of IMA and HVA for the 10 patients (N=20) remaining under follow-up for at least three years, expressed as average values

The IMA, which was preoperatively affected in 78% of cases by moderate and severe changes, was corrected to normal values immediately after surgery or equivalent to a mild deformity, for all cases (Fig. 1.8.).

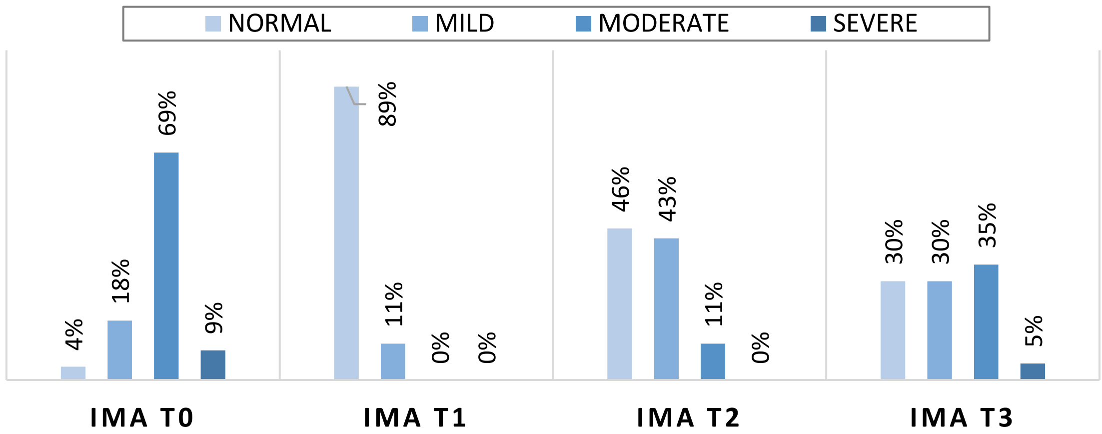


Fig. 1.8. Evolution of deformation severity for IMA expressed as percentage

If the potential for correction and maintenance of results was clear for the IMA, in the case of HVA the radiological results generated by the MTR® technique were not as reliable (Fig. 1.9.).

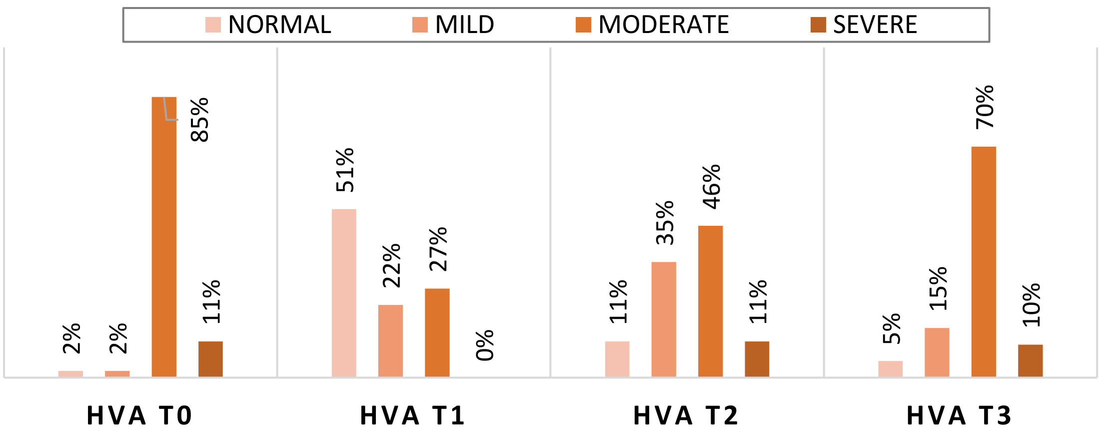


Fig. 1.9. Evolution of deformation severity for HVA expressed as percentage

With the exception of one patient who described no differences, at (T2) the disappearance of pain or just a minimal level was recorded for 95% of cases (Fig. 1.10.).

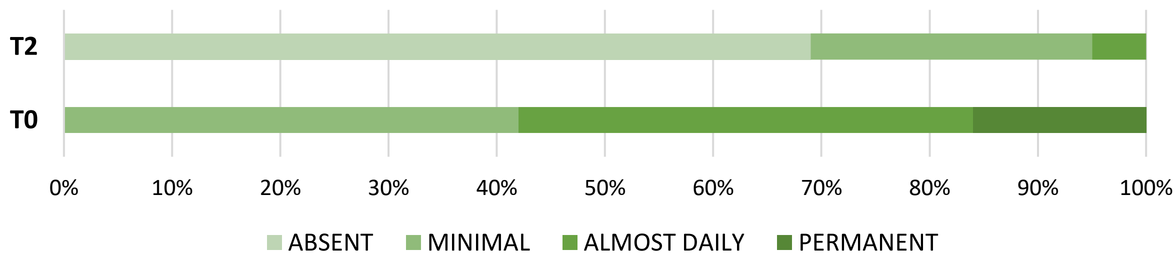


Fig. 1.10. Evolution of pain severity expressed as percentage (T0)-(T2)

Statistically, there was a significant decrease (Wilcoxon test; Z = -3,84; p<0,001) between the perceived pain level at one year post-correction (T2) compared to the preoperative moment (T0). Most patients experienced an improvement in pain symptoms, with at least one level of improvement (95%) according to severity stratification.

From the total of 19 cases, 7 patients (37%) did not describe an improvement in the ability to use the footwear prohibited by the pain symptoms, which were troubling the patients before surgery (Fig. 1.11.).

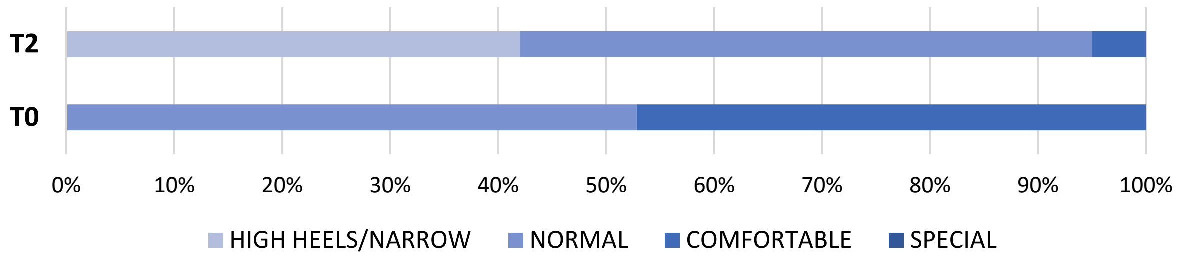


Fig. 1.11. Evolution of footwear restrictions severity expressed as percentage (T0)-(T2)

The level of footwear restriction showed a significant decrease at one year (T2) (Wilcoxon test; Z = -3,17; p=0,001). There was an improvement of at least one level in 63% of cases, with no patients mentioning any increases in limitation. 8 patients (47%) described the resulting local aesthetics as excellent, 7 patients (37%) claimed the aesthetic result was satisfactory and only 3 patients (16%) described it as unsatisfactory.

There was a strong negative (inverse) correlation between the level of satisfaction with aesthetics and pain severity recorded at one year after surgery (T2), with proper statistical significance (Kendall's test; τb = -0.719; p = 0.001) (Table 1.2.).

Table 1.2. Correlation between satisfaction with aesthetic results and pain level

		Aesthetic results	**Pain level**
Aesthetic results	Correlation coefficient	1,000	**-0,719**
	Sig. (2-tailed)		**0,001**
	N	19	19

A moderate negative correlation could be observed between the level of satisfaction with aesthetic results and the severity of footwear restrictions at least one year after the surgical correction (Kendall's test; τb = -0,537; p = 0,015) (Table 1.3.).

Table 1.3. Correlation between satisfaction with aesthetic results and footwear restrictions

		Aesthetic results	**Footwear restrictions**
Aesthetic results	Correlation coefficient	1,000	**-0,537**
	Sig. (2-tailed)		**0,015**
	N	19	19

No correlation was detected between the severity of pain symptoms and the degree of restriction for footwear at one year after the surgical correction (T2) (Kendall's test; τb = 0,05; p = 0,795) (Table 1.4.).

Table 1.4. Correlation between pain level and footwear restrictions

		Pain level	**Footwear restrictions**
Pain level	Correlation coefficient	1,000	**+0,057**
	Sig. (2-tailed)		**0,795**
	N	19	19

The analysis of correlation between the IMA values and functional results determined preoperatively (T0) and one year after the correction (T2) did not reveal significant results (Table 1.5.).

Table 1.5. Correlation between IMA values and functional parameters

Observation moment	Functional parameter	Correlation coefficient with IMA (tau-b)	*p* value
T0	Pain	-0,233	0,230
	Footwear restrictions	-0,127	0,534
T2	Pain	-0,009	0,963
	Footwear restrictions	+0,113	0,571
	Satisfaction with aesthetic results	-0,105	0,591

There was only one case of positive, statistically significant correlation between the HVA value and pain severity (Kendall's test; $\tau b = +0,396$; $p = 0,047$) (Table 1.6.).

Table 1.6. Correlation between IMA values and functional parameters

Observation moment	Functional parameter	Correlation coefficient with HVA (τb)	*p* value
T0	Pain	+0,024	0,901
	Footwear restrictions	-0,054	0,790
T2	Pain	**+0,396**	**0,047**
	Footwear restrictions	+0,269	0,177
	Satisfaction with aesthetic results	-0,298	0,126

9 patients were diagnosed with osteopenia, with only one case of second MTS fracture (3%), recorded at least one year after the correction (T2). We did not detect a statistically significant association between bone density impairment and the occurrence of postoperative fractures (Fisher's test, p=1,00) (Fig. 1.12.).

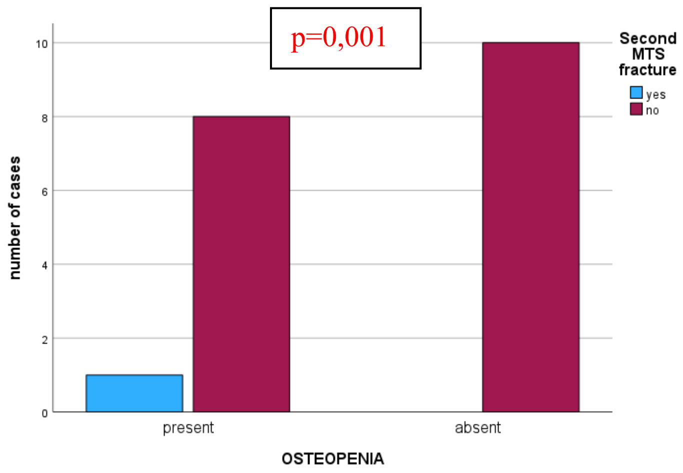


Fig. 1.12. Association analysis between bone density impairment and second MTS fracture at (T2)

Although no statistically significant association could be demonstrated between the presence of severe preoperative HVA deformities and their recurrence after surgery (Fisher's test, p=0,88), this subject has be taken into account regarding the ability and limitations for HVA correction of the studied technique (Fig. 1.13.).

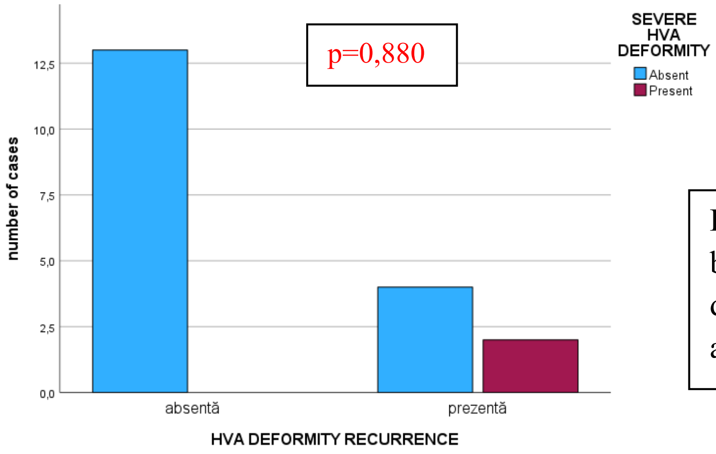


Fig. 1.13. Association analysis between severe preoperative HVA deformities and their recurrence at one year after surgery (T2)

A total of 12 complications was recorded, representing 27% of the total number of interventions under follow-up. The most common complication was the recurrence of deformities (23%), followed by second MTS fracture (2%) and soft tissue reactions (2%). No revision surgeries were required for the management of the recurrence or any other critical complications.

1.4 Discussions

The main objective of deformities correction, using the Mini TightRope® technique or any other procedure, is to optimize foot biomechanics, which is essential for normal gait kinetics and kinematics, while avoiding all the severe complications associated with osteotomies [12,13].

For an adequate analysis of our series, we performed a systematic review of data presented by papers based on the MTR® technique, published between 2010 and 2022. In terms of follow-up time, our study exceeded any work that evaluated the results of techniques based on this type of implants, most of the procedures reported in literature relying on a single MTR® system for IMA fixation and metatarsal bone tunnels with a diameter of 2.7 mm, which may increase the risk for metatarsal fractures.

The reported complications rates in literature show high variability, with an average of 24%, which is similar to our results (27%). The difference was the order of complication types, the literature data reporting the second MTS fracture (10%) as most frequent complication, followed by the recurrence of deformities (6%), hypercorrection (3%) and soft tissue complications (3%). The paper published by Dayton et al. in 2015 performed a meta-analysis of possible complications reporting a similar order, the most common being second MTS fracture (13.6%) followed by recurrence of deformity (7.6%) and hypercorrection (3.8%). Our results revealed the recurrence of deformities as the most frequent type of complication, especially for the hallux valgus angle (HVA), with a percentage of 23% [13].

The advantages suggested by the MTR® technique are the preservation of bone integrity, which can be useful in case a revision procedure is required, and limitation of invasive procedures performed on soft tissues, therefore reducing the risk of infection and facilitating postoperative recovery [14-15]. The statistical analysis of data showed that the studied technique effectively corrects the angle values, with functional results similar to other techniques, despite a partial loss of the initial correction. Graphical and numerical statistical evaluation confirmed the correction potential, which was clearly better for IMA, consistent with other published series. Regarding HVA correction, the potential for reduction and maintenance was lower and it is based on an indirect effect of biomechanical realignment at the level of the first metatarsophalangeal joint, for which a soft tissue procedure was applied. Mean angular values obtained from our analysis and those reported by relevant studies published in literature were almost equivalent, both for the preoperative and postoperative moments [14-25].

In literature, the percentage of deformities recurrence is 6%, identified rather in association with other complications, while our results placed this complication first, with a percentage of 23%. Although in most cases, not causing any significant functional impairment, we believe that a more accurate description of the diagnostic criteria for recurrence, supported by objective parameters such as angular values, is necessary for a more effective diagnosis [13].

Thus, we can state that the main problem of the MTR® technique is represented by the high risk of HVA deformities recurrence that can be attributed to the use of only a soft tissues procedure for the correction at this level. Recurrence of deformities may or may not be associated with the loss of fixation provided by the suspension systems and may occur independently of the aforementioned causes, the reduction of the angles showing a decrease even without any associated complications. We believe that this complication is not specific to the MTR® technique, as all HAV surgical correction interventions have significant recurrence rates of up to 50-70% [14-25].

To reduce the risk of second MTS fracture, a series of changes regarding the surgical technique or its indication have been suggested. A pattern of association between older age, expressed as decreasing bone density, and a higher incidence of fractures does not seem to exist, which means that the surgical technique details or implant design play a greater role in determining the fracture risk.

The main factors on which the patient's satisfaction and the perceived postoperative results depend are pain mitigation, ability to use the desired footwear and aesthetics. To evaluate the clinical results, we developed a simplified evaluation form starting from the AOFAS model, which kept three main components represented by pain, footwear restrictions and the level of satisfaction given by the aesthetic appearance and quality of life. Most studies report radiological outcomes or complication rates, but this approach focuses more on the surgeon's perspective and less on the subjective feedback from the patients tailored to their needs and wishes. We support the crucial role of pain symptoms in describing and evaluating functional and clinical outcomes following correction, regardless of the used technique [14-26].

Our results showed a positive statistical correlation between the amplitude of the HVA and pain severity, an interesting observation, considering that the recurrence of HVA deformities shows the highest incidence and associates unfavorable outcomes. Nevertheless, there was a weak level of positive correlation between the two. This observation highlighted the importance of the HVA deformity effect on the results and the need to optimize correction and its reliability, especially in the setting of HVA deformations recurrence as the main specific complication detected in our series.

According to our analysis, the general decrease in shoewear restrictions level, recorded before surgery, reached a statistically significant level. None of the relevant studies published in recent literature have evaluated and specifically discussed this parameter. However, we believe that this element must be addressed during the management of hallux valgus, because it plays an important role in maximizing the perceived result.

Moreover, we found that there was a strong negative correlation between satisfaction with aesthetic result and pain symptoms, which confirmed the high level of subjectivity and complexity involved in the assessment of postoperative satisfaction and the extremely important effect that pain exerts on this process. Among the reviewed papers, only one explicitly assessed the level of postoperative patient satisfaction [14].

With a carefully formulated indication, the MiniTightRope® technique generates comparable results to those of established surgical techniques for mild or medium cases of hallux valgus. Our conclusions corresponded to those reported in literature, with good functional results and a low level of medium-term complications.

2. Finite Elements Analysis of hallux valgus surgical correction technique based on cortical suspension systems

2.1 Working hypothesis and objectives

Complementary to experimental studies, the computational analysis method has nowadays become an important technique for studying and understanding the etiopathogenesis and biomechanics of musculoskeletal disorders. The evaluation of potential variations of biomechanical parameters can provide useful information for the optimization of preoperative planning, implants or surgical technique and prevention of complications.

In the case of the ankle and foot, computational studies carried out through finite element analysis and applied to virtual three-dimensional reconstructions have generated data that help the understanding of normal biomechanics, traumatic injuries or the pathogenesis of chronic conditions, therefore contributing to the improvement of implant design or surgical techniques, but also external orthopedic devices, such as adapted footwear [27,28].

Using computational analysis, hallux valgus has been investigated regarding its pathogenesis and the role of risk factors, the variations of surgical correction techniques or implant types [29-31]. The HAV correction technique based on cortical suspension systems presents a series of specific complications. Among these, the second MTS fracture has been reported in literature as the most frequent type of specific complication, with an incidence of 10% [13]. Several factors have been associated with fracture risk of the second metatarsal, which that can occur intraoperatively, immediately after surgery, or later.

The present chapter presents the development, validation and implementation of a biomechanical model created with the aim of analyzing the relationship between variations in bone density, the geometry of implants or bone tunnels and the fracture risk, by simulating the effect of hallux valgus correction on the stresses induced in the second metatarsal during the push-off phase of gait cycle. The goal was to assess the fracture risk encountered in clinical setting by studying the influence of some characteristics such as the impairment of bone mineral density, the increased diameter of bone tunnels or design of the metal buttons, which the cortical suspension system uses for fixation.

2.2 Materials and methods

This chapter presents the steps required for the development of a finite elements model based on the first two metatarsal bones and the corresponding cuneiforms, as well as the implants necessary for surgical correction of hallux valgus using the Mini TightRope® technique.

2.2.1 Geometrical reconstruction

A virtual reconstruction technique from computerized tomography scans was used for modelling the bone geometries. Thus, following the segmentation process, three elements corresponding to the geometries of all four bones necessary for the biomechanical model creation resulted [32].

The conception of the virtual model was based on the tomographic images acquired through the preoperative scan for one of the patients included in the study. The 36-year-old patient required bilateral correction of the specific hallux valgus deformities, which was performed during a single stage. The metal buttons were reproduced to their actual dimensions using the Design Modeler application, from the ANSYS Workbench suite, 2022 R1 version. The resulting geometries were exported to Materialise MIMICS image processing software and positioned according to the surgical technique details provided by the implant manufacturer [10].

2.2.2 Creation of a biomechanical model

A biomechanical model is the computational model comprised of the four bones (first and second metatarsals together with the medial and intermediate cuneiform bones), the metal buttons, the ligaments, the suspension wires, the imposed interaction conditions between elements, the loading forces and boundary conditions [33].

Biomechanical model creation and finite element analysis were performed using the ANSYS simulation software, 2022 R2 version. The following stages were completed, which are essential for obtaining the computational model:

1) Discretization of volumetric components (bones and metalic buttons).
2) Defining the interaction between the components.
3) Modeling the ligaments.

4) Modeling the suspension wires.
5) Setting boundary conditions.
6) Pretensioning of wires.
7) Modeling of plantar forces.

2.2.3 Material properties

A homogeneous distribution of the Young's modulus was adopted throughout the model (identical for all bones), and was determined by equating the structural stiffness (Young's modulus) of a heterogeneous distribution model variant, based on the radiodensities analysis method.

Only the second metatarsal was extracted, for which material properties were defined according to the radiodensities analysis results, within the MIMICS software, resulting in heterogeneous distributions of density and Young's modulus [34]. To equate the structural stiffness, a static finite element model was then created using the ANSYS software, for which the discretization and distribution of material properties were imported from MIMICS. The result was a model with a heterogeneous and overall anisotropic structure, developed using radiodensities analysis of the patient's bone structure CT scans.

Part of the model, corresponding to the second cuneiform, was set in a fixed position, to simulate the interaction with the other unmodeled bone elements. All the degrees of freedom for motion were blocked on the interaction surfaces with these unmodeled elements, resulting in the complete immobility of the bone element base. A resultant force was applied for setting the loading conditions, calculated for the second metatarsal by equating the subject's weight, based on the use of a recognized static model [35].

Similar models were then developed, but with homogeneous Young's modulus distributed throughout the bone volume. The initially chosen value was 7000 MPa (according to data from literature), which led to a higher structural stiffness compared to the heterogeneous material distribution [29-31,36]. An equivalent Young's modulus value of 3720 MPa was determined through repeated sensitivity analysis.

2.2.4 Analyzed variants and comparison criteria

There is a real interest in studying the influence of bone density variations or the geometry of implants and bone tunnels on the risk of second metatarsal fracture, especially since this complication is reported as the most frequent one.

Thus, the comparative study was carried out relying on three criteria:

1 - bone density variation; three models were developed, which differ in Young's moduli, E1, E2 and E3.

2 - the use of two standard buttons or an oversized button (SBP®) for the second MTS. The comparison was made between two models, with the same Young (E1) modulus, which differed only in the type of second MTS buttons.

3 - different dimensions of the tunnels diameter. In this case, the comparison was made between two models with two standard buttons, the E1 Young modulus, but which differed in the tunnels' diameter (1.1 mm or 2.7 mm).

To carry out the mentioned comparisons, five models were developed, for which the following abbreviations were adopted, for simplification:

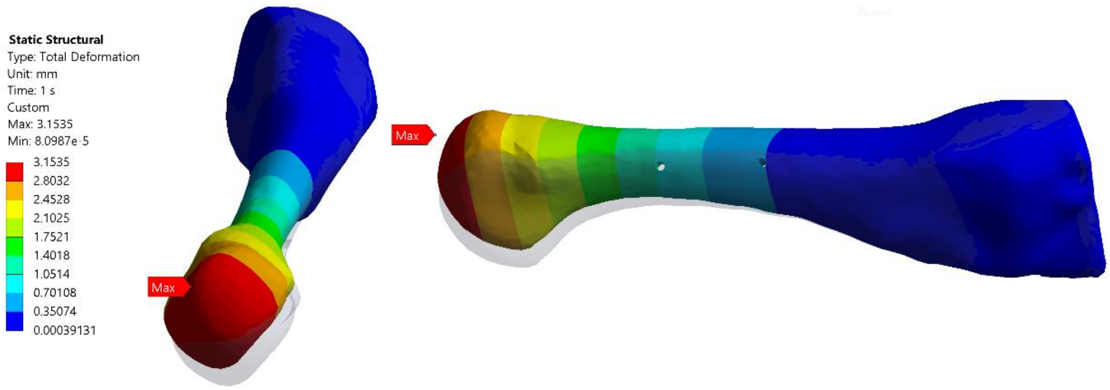
- MBE1d, MBE2d and MBE3d - models with two buttons, E1, E2, E3 Young's moduli and the small tunnel's diameter (d = 1.1 mm).
- MPE1d - model with an oversized button (SBP®), E1 Young's modulus and small tunnel diameter (d = 1.1 mm).
- MBE1D - model with two buttons, E1 Young's modulus and large tunnel diameter (D = 2.7 mm).

2.3 Results

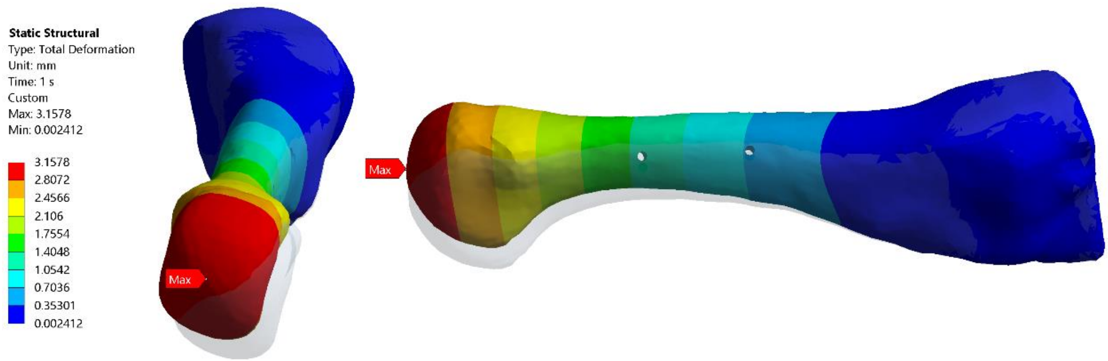
2.3.1 Equating the Young modulus

Fig. 2.1. presents the total displacements, using two views, corresponding to the aforementioned variants of Young's modulus distribution: heterogeneous (Fig. 2.1.a.) and homogeneous equivalent (Fig. 2.1.b). It can be seen that the details of the deformed geometries were similar and the maximum displacements were equal to the second decimal place (3.15 mm). It was therefore accepted that the value of 3720 MPa for Young's modulus in the homogeneous model structurally equated the heterogeneous distribution of bone density,

obtained by the radiodensities analysis method. This value was used to define material properties, for performing the comparative analyzes between the models with homogeneous structure.



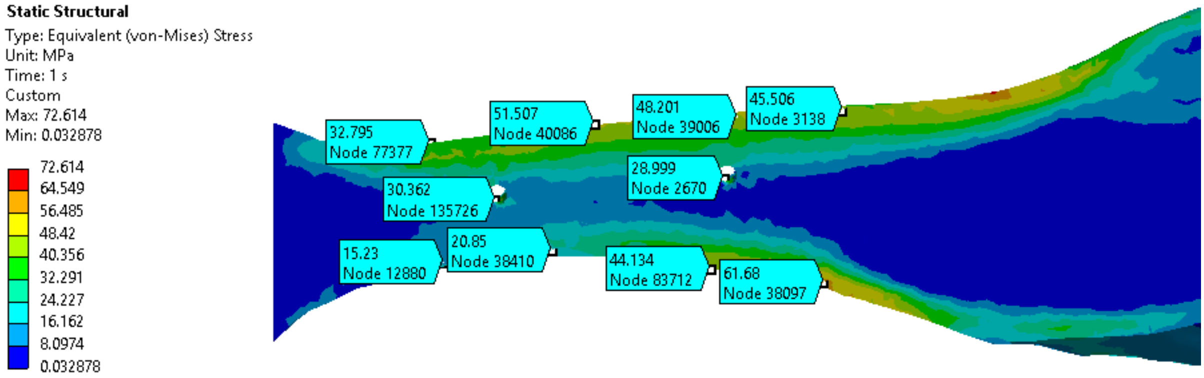
(a)



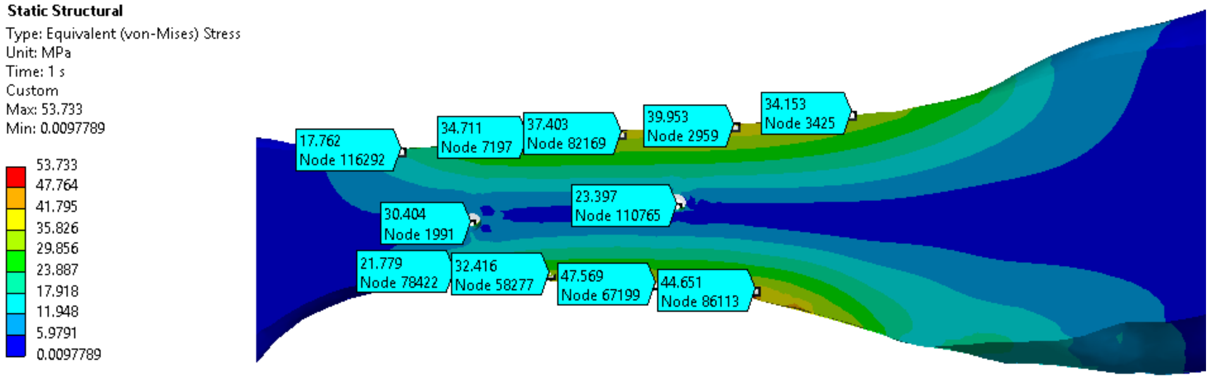
(b)

Fig. 2.1. Total displacements for heterogeneously distributed (a) and homogeneously distributed (b) Young’s modulus

Considering that the aim of developing this biomechanical model was to evaluate bone tunnels von Mises stress, which is dependent on stiffnesses distribution, it is necessary to compare the stress distribution between the equivalent heterogeneous and homogeneous cases in the second metatarsal diaphysis (Fig. 2.2.). It resulted that, indeed, the stress was higher for heterogeneous distribution, inside the bone cortex. Therefore, at cortical level, the homogeneous model underestimates the stress, by about 25%. In the tunnels, however, the stress was much lower. For the distal bone tunnel, the stress was almost the same for both models (30.362 MPa for the heterogeneous distribution and 30.404 MPa for the homogeneous one).



(a)



(b)

Fig. 2.2. von Mises stress in longitudinal midsection of the second MTS bone for heterogeneously distributed (a) and homogeneously distributed (b) Young's modulus

2.3.2 Validation of biomechanical models

C1 criterion analysis. Fig. 2.3. shows the force values emerging in the suspension wires, determined for all models under two loading conditions (wire pretensioning only or plantar force loading). It can be seen that, in both wires, the forces are similar, in all models and for both loading conditions.

According to literature data, if a single wire is used, it will be tensioned by 4.1 N for each degree of IMA correction, and the average force developed in the wire after applying the plantar load would be 33 newtons [37]. In our case, if a single wire were to be used, according to the aforementioned data and considering the 5,45^{o} required for IMA correction, specific to our patient who was the basis for model creation, a resulting force of 22,35 N would be generated in the wire after pretensioning.

If it is assumed that by using two wires they withstand equal forces (in reality, the proximal wire is tensioned less), it results that the force for a single wire would be 11.175 N. Compared to this value, the resulting forces in the two wires after prestensioning were higher, but within an acceptable margin considering the involved degree of approximation (Fig. 2.3.). Factors such as bone stiffness, wire characteristics, metatarsocuneiform joint details, the tunnels positioning and soft tissue, could affect the differences between resulting forces.

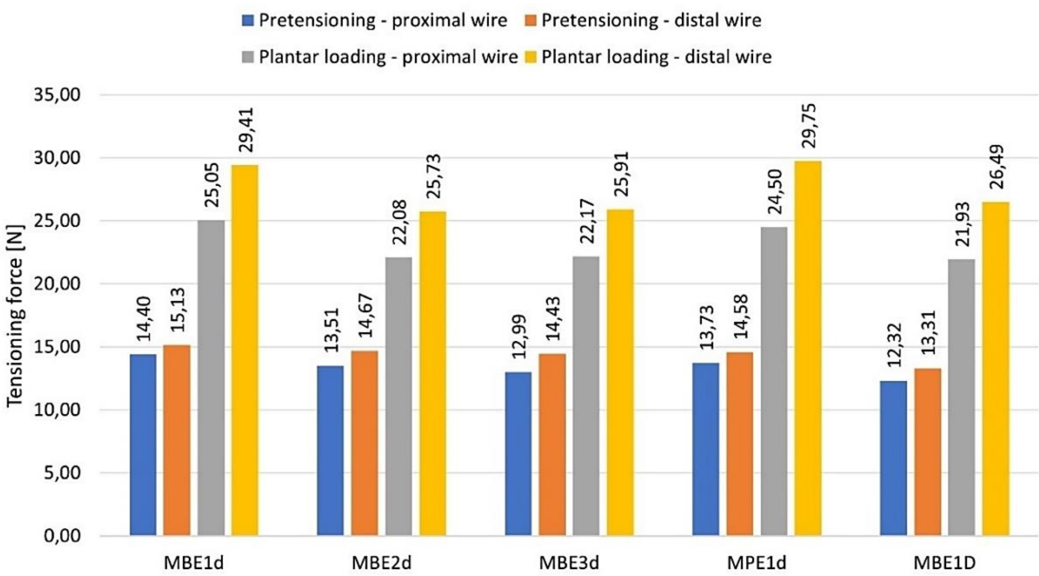


Fig. 2.3. The resulting tensile forces in the suspension wires for the two loading conditions (wire pretensioning only and plantar forces loading) for all models

Considering MBE1d as a reference model, the relative deviations of the other models results were determined (Table 2.1.). The maximum deviation resulted was 14.44%, which corresponded to the proximal wire of the MBE1D model. This value was admissible considering the variability of biomechanical models, for which differences of up to 25% are allowed. It was shown that large deviations (over 10%) occur for models with different Young's moduli (MBE2d and MBE3d) compared to the benchmark model and also for the MBE1D model. For density variation, the result can be justified by stiffness differences, which significantly manifest in the second metatarsal, with plantar loading. In the case of MBE1D (tunnel diameter 2.7 mm), the differences were caused by the characteristics of this model, which involved small differences, especially in terms of discretization, compared to the reference model.

The MBE1d model was chosen as the standard instead of the literature data, as the validation process was based on equivalence between the created computational models. The deviation from literature data was greater, due to significant differences of the models developed for this work and the characteristics of the experimental determinations in literature, used for equating wire tension forces [37]. Therefore, a quantitative comparison in this sense was not justified, the values reported in literature being considered as reference only, and as an order of magnitude of the resulting forces.

Table 2.1. Deviations of the resulting wire tensile forces compared to those resulting from the MBE1d reference model

Model	**Deviation [%]**			
	Pretensioning		Plantar loading	
	Proximal wire	Distal wire	Proximal wire	Distal wire
MBE2d	6,18	3,04	11,86	12,51
MBE3d	9,79	4,63	11,50	11,90
MPE1d	4,65	3,64	2,20	1,16
MBE1D	**14,44**	12,03	12,46	9,93

C2 criterion analysis. In fig. 2.4., the maximum values of total displacement resulting in the biomechanical model are presented, both after wire pretensioning and after the application of the plantar forces. These highest values were extracted from the distributions of total displacements for the biomechanical model. The following results were deduced:

- For the first loading situation, which involved only the pretensioning of the wires, it resulted that the total displacements decreased with the Young's modulus. This result can be justified by the fact that the total displacement is the cumulative result of the component elements deformation and the rigid body motion (predominantly rotation) of the first metatarsal, due to its mobile contact (joint) with the first cuneiform. Therefore, for the maximum stiffness case (MBE1d), the second MTS deformed less, forcing the first MTS to rotate more so that the displacement generated by the wires shortening was ensured. The decrease in stiffness led to larger deformation in the second MTS, which caused a reduction in the rigid rotation of the first metatarsal bone. As a result, the maximum displacement in these cases, which occurs predominantly at the level of the distal extremity of the first metatarsal, decreased with Young's modulus.
- For the models with identical Young's modulus, but with geometry differences, pretensioning of the wires led to overall displacements with relative deviations below 1% (Fig. 2.4.). This result validated the similarity between the analyzed models.

- For models with different Young's modulus, the addition of plantar forces led to the decrease of total displacement for the medium Young's modulus model (MBE2d) compared to the other two models (MBE1d and MBE2d). The effect can be justified by the way displacement is being distributed in the volumes of the two bones, because of different stiffness. For the stiffest model, the highest displacement was found in the distal end of the first MTS, for the one with medium stiffness the displacement being almost equally distributed between both bones, and for the one with minimum stiffness, the second metatarsal deformation and displacement increased considerably.
- For the models with equal Young's modulus, plantar forces produced similar displacement distributions (Fig. 2.4.). Between models MBE1d and MPE1d, the difference was insignificant (relative deviation of 1.87%), being caused by small differences in the application of plantar forces, on the one hand, and by the differences between the contact of the metallic implants with the second metatarsal bone (two buttons in the case of MBE1d and one plate in MPE1d), on the other hand. A larger maximum displacement resulted in the MBE1D model (10% deviation from the MBE1d model), caused by differences in discretization, contact at the first metatarsocuneiform joint, and orientation of the plantar forces. The latter depends on the selected surface of each element where the force was applied, which can present small differences resulting from the discretization.

According to the arguments in relation to C2 criterion, the models were validated.

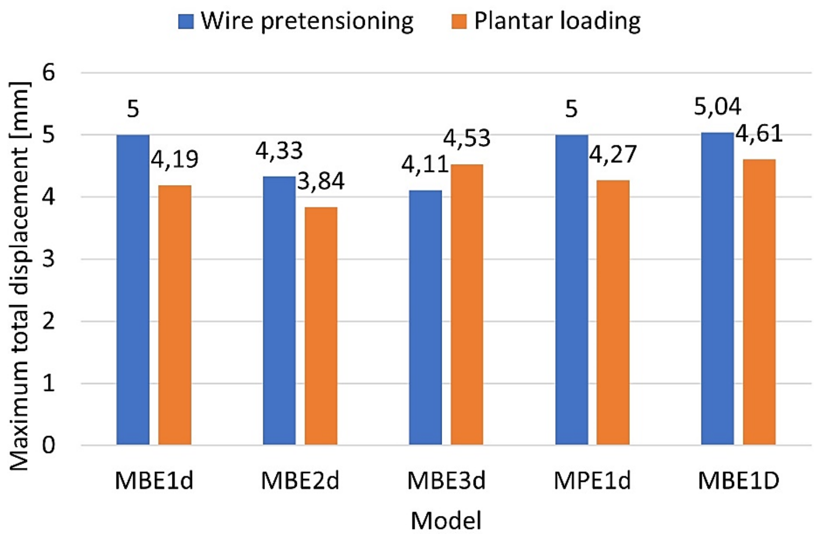


Fig. 2.4. Maximum total displacements in the biomechanical model corresponding to both situations (wire pretensioning only and plantar forces loading) for all models

C3 criterion analysis. Fig. 2.5. shows the maximum values of resulting displacements of the second metatarsal, for all models. These were extracted from the distributions of total displacements. The following conclusions were drawn:

- For both loading situations (wire pretensioning only and plantar forces loading), the maximum displacement increased with decreasing Young's modulus.
- In the case of models with equal Young's modulus, the maximum deviations of displacements, compared to the reference model (MBE1d), were 2.17% for wire pretensioning and 17.72% for plantar loading. The larger deviation in the second case was caused by the differences between the plantar force application surfaces on the second metatarsal. However, this variation was below the accepted threshold of 25%.
- The directions of second metatarsal movements were predominantly in the transverse plane, for wire pretensioning, and in the sagittal plane when plantar forces were added. The loading directions were thus validated.

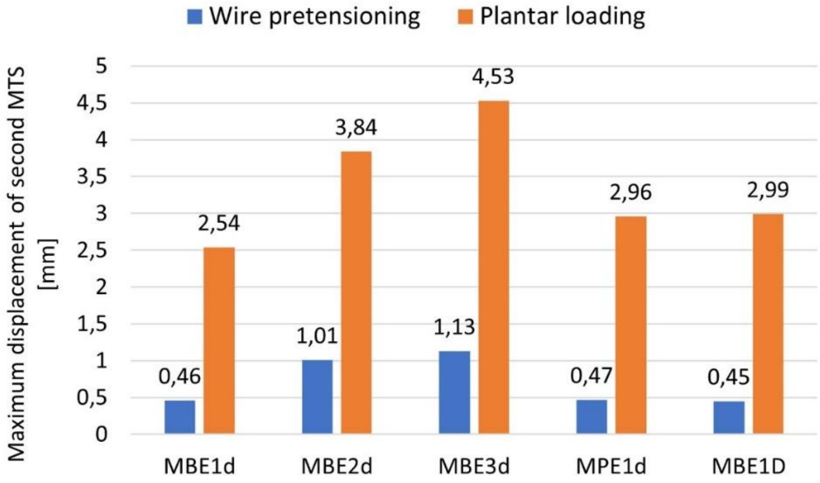
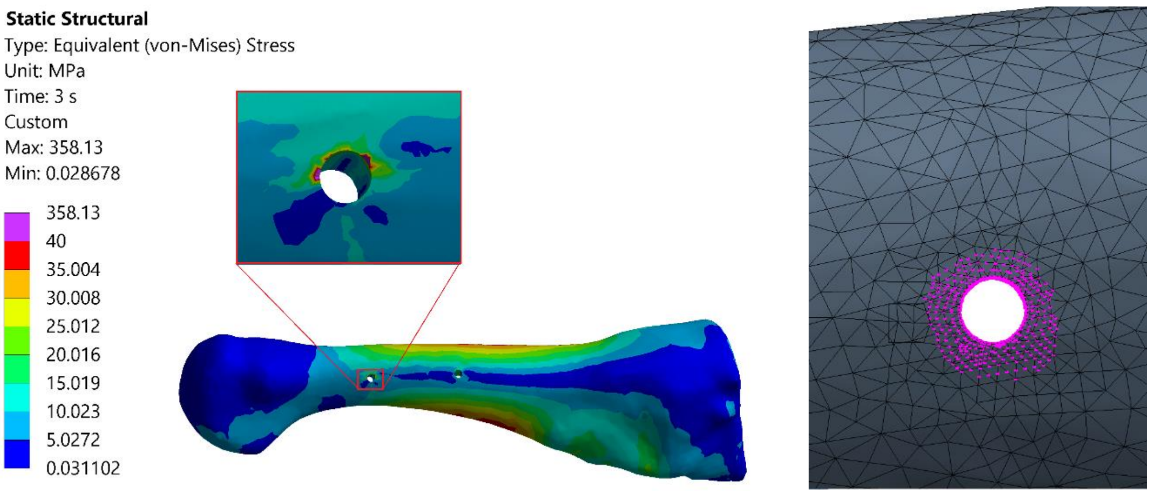


Fig. 2.5. Maximum second MTS displacements in the biomechanical model corresponding to both situations (wire pretensioning only and plantar forces loading) for all models

2.3.3 Stresses around bone tunnels

According to the Saint-Venant's principle, the difference between the effects of two different, but statically equivalent loads (which have the same resultant and produce the same contact reactions) becomes very small at adequately large distances from the loading area [38]. Within the analyzed models, Saint-Venant's principle is applicable for the diaphyses of the two metatarsals, therefore also in the area of interest (in the second metatarsal bone tunnels). In the contact areas (in the metatarsocuneiform joint and the intercuneiform joints), the defined boundary conditions do not accurately reproduce reality for local force distribution, but they recreate it as a resultant. Therefore, in these areas the resultant stress is unrealistic, but the distant effect is not affected. All this shows that the stress distribution in the second metatarsal diaphysis was practical, so the stress analysis in the bone tunnels is justified.

For all models, in the bone tunnels walls of the second metatarsal, the highest stress resulted in the distal tunnel, as shown in fig. 2.6. Therefore, the stress assessment was limited to this area. To extract the stress values in the aforementioned region, the nodes along the distal tunnels walls were selected, with an adequate radius of the selected area, to accurately reflect stress distribution and maximum values (Fig. 2.6.b.).



(a) (b)

Fig. 2.6. Distribution of the equivalent von Mises stress in the second metatarsal, for MBE1d model: (a) global view with distal tunnel details; (b) selected nodes along the distal tunnel

In fig. 2.7. the maximum values of the von Mises stress developed in the distal tunnel walls are presented, for comparison between all the analyzed models. The following conclusions were drawn:

- For models with different Young's modulus, after wire pretensioning, the stress decreased insignificantly along with Young's modulus. The result was acceptable, considering the decrease of wire tensioning forces with the Young's modulus. In this study, the equivalence of Young's moduli was carried out in relation to stiffness, and it was admitted that in the areas where stress was analyzed, the global stiffness did not influence it, since, upon prestressing, the second MTS behaves as a statically determined system, working under small displacements (total displacements are much smaller than bone dimensions). It is known that, in such systems, stress does not depend on stiffness.

- For models with different Young's modulus, after applying the plantar load, there are differences of about 13.5% between the maximum stresses obtained for the stiffest model and the other two. For the latter two, the values are approximately equal. However, the maximum values are not enough to characterize the stress state since the maximum value develops locally and may depend on singularities. Therefore, the stresses were compared using the volume of material in which it exceeded the limit of 30 MPa, chosen for a better visualization. Thus, from fig. 6.24., it can be deduced that although the maximum values in the MBE2d and MPE3d models were equal, the stresses exceeded 30 MPa on a smaller volume of material in the latter model. Also, the volume of material affected by stresses above 30 MPa was greater in the maximum stiffness model. Therefore, as with the pretensioning situation, it shows that stress decreases with stiffness, but not significantly.
- A significant decrease compared to the reference model was found for the MPE1d model, which involved the use of the supplementary, oversized button. The result demonstrated the obvious contribution of the additional button (SBP®), which distributed the pressure of with bone over a larger area.

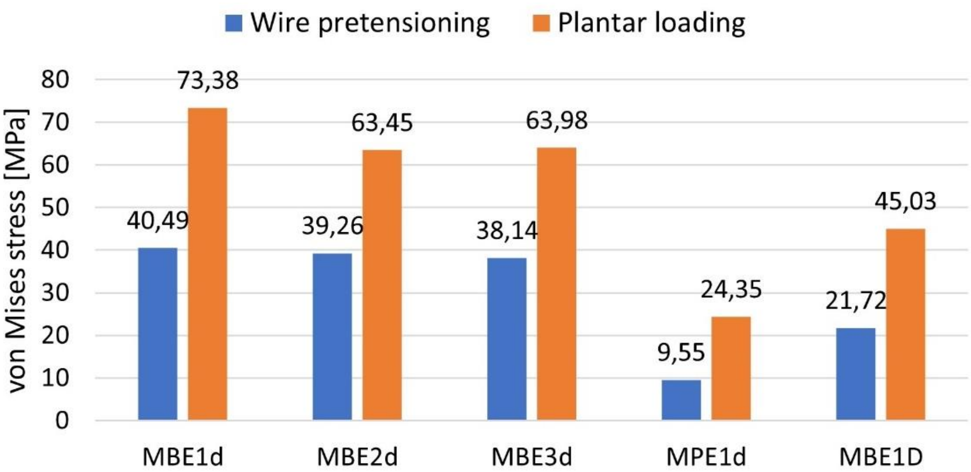
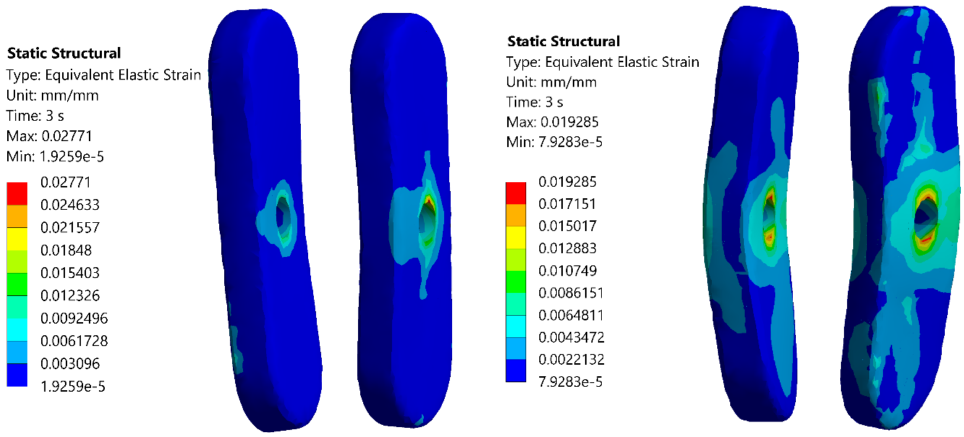


Fig. 2.7. Maximum von Mises stresses in the distal tunnel walls of the second metatarsal corresponding to the two different loading situations for all models

A debatable result was obtained for the MBE1D model, with lower stress levels than for the reference model, although the effect of stress concentration was expected to be more pronounced at larger diameters of the bone tunnels. However, the stress concentration effect produced by bending caused by plantar forces was small, regardless of the tunnel's diameter, since these forces act in the neutral plane (longitudinal plane, horizontal in this case, which contains the centroids for the diaphysis cross sections, where bending stresses is zero). Therefore, the stress difference between the two different bone tunnels diameters did not come from the stress concentration effect.

The differences were caused by the way the metal buttons rest on the bone surface and by the way they transmit the load into the bone, on the edge of the tunnel (Fig. 2.8.). For the MBE1D model, the button deformed more over a larger volume in the tunnel area, with a more pronounced bending tendency. However, the maximum strain was higher in the button corresponding to smaller diameter tunnels and was located closer to the tunnel. Therefore, locally, the button placed over the small diameter tunnel deformed more, around the area of the tunnel edge, where the maximum stresses were identified. For the larger diameter tunnel, the contact was spread on a larger circumference and under the area with smaller deformations of the implant. The effect discussed in this work is model dependent because button deformations over the tunnels are determined by the constraint equations required for defining the connection with the suspension wires. In reality, the wires transmit the local stress to the buttons differently. Therefore, the comparison regarding the influence of tunnel diameter based on this study cannot be quantitatively conclusive. However, it can be concluded that the presented results raise the interest for more detailed studies on the influence of the tunnels diameter.



(a) (b)

Fig. 2.8. Distribution of specific von Mises stress in the distal button placed on the second metatarsal bone (strain amplification factor = 10): (a) MBE1d model; (b) MBE1D model

2.4 Discussions

Finite element numerical simulations are tools capable of providing detailed insights into the behavior of biomechanical structures, as they can reproduce, with enough accuracy, biomechanical interaction scenarios beyond the clinical and experimental possibilities of investigation. Therefore, in the present work, numerical studies were carried out analyzing the mechanical interaction occurring at the level of the first two metatarsals, generated by surgical correction of specific hallux valgus deformities through the MTR® technique. According to clinical reality, among the factors influencing the risk of second metatarsal fracture, bone mineral density, the type of metallic buttons and bone tunnels diameter have been suggested. Conclusions deriving from the numerical analyses targeting the aforementioned factors are further discussed in this chapter.

Comparative criterion 1 – Bone density variation

The von Mises stresses decreased slightly with the decrease of the Young's modulus, both because of the pretensioning of the suspension wires and because of plantar loading, corresponding to the push-off phase of the gait cycle. Although this reduction in material stress could be considered a positive aspect, the effect is not at all beneficial in the case of low-density bones, as they have lower physiological stress limits. According to the Frost mechanostat, the limit value of 60 MPa of the pathological threshold of microdamage accumulation was determined for a Young's modulus of 20 GPa. For lower Young's moduli, these physiological limits decrease [39].

In addition, the determination of the stress limits in the Frost mechanostat based on Young's moduli imposed as homogeneous equivalents is not accurate. In reality, in the cortical area of the bone, where the maximum stresses were identified, the Young's modulus is close to 20 GPa for patients with normal density and decreases, in the case of those with affected density (osteopenia or osteoporosis), towards quantitatively unknown limits. For their estimation, additional studies are needed, which transcend the scope and objective of this work. Therefore, the stress values obtained in the present work were correct, within the limits of modeling approximations, but cannot be compared with known limiting values for bone. Thus, the variation in bone density does not significantly influence the level of stress in the wire tensioning stage, but the risk of fracture is greater in the presence of lower bone mineral densities, as the physiological limits decrease.

The microdamage threshold defined by the Frost mechanostat (MESp) does not represent the static yield stress of the material. This threshold refers to a stress limit at which damage begins to accumulate faster than can be compensated by bone regeneration through the remodeling process, if physical activities or trauma which exceed this limit are maintained excessively, without allowing the bone to regenerate. A relevant example is represented by second metatarsal stress fractures encountered in athletes or military recruits. This stress limit corresponds to a specific strain level, indicated by Frost, of 3000 µm/m. Experimental measurements have determined specific deformations above this threshold in the case of vertical jumps with landing on one or both lower limbs [40]. It was therefore accepted, for this study, that the determined stress levels were within normal limits, considering the ability of bones to continuously remodel under conditions of normal activity.

Considering the incidence reported by literature, the percentage of second MTS fractures ranks first, with a value of 10% of the total case number. The risk for developing this complication has been attributed to the influence of several factors, among which the damage to bone density has also been greatly discussed [13-25].

If we acknowledge the stress obtained in the present work to be correct, within the limits of the modeling approximations, the discussion remains open regarding the physiological stress limits, extrapolated in this work from the Frost mechanostat, and how these limits change with the decrease in bone mineral density. Even in the absence of a concrete objective demonstration, from the reported clinical data and the results obtained by the finite elements analysis, the idea of variable stress limits emerges, which most of the time ensures a favorable interval for the body to compensate through bone remodeling. Thus, we consider that by optimizing perioperative factors and surgical technique, the risk of second MTS fracture secondary to procedures using MTR® systems can be kept within acceptable limits to further support its implementation.

Comparative criterion 2 – Normal buttons versus oversized button

Most authors believe that the initiation point for a fracture line is located at the level of the bone tunnels, below the metal button, an area where the implant would generate an increased pressure on the bone cortex, already weakened by the drilling of the tunnel, thus concentrating high stresses in the bone mass.

The suggested methods to mitigate this risk are an increased attention to centering the initiation point of the bone tunnel at the level of the second MTS diaphysis, at an equal distance between the plantar and dorsal cortex, at a proper distance from the metatarsal neck, which must be of at least 5 millimeters, but also the use of an additional oversized button (Syndesmosis Buttress Plate®) positioned below the two normal buttons, with the role of redistributing the pressure on a larger surface of the cortex. The first two aspects relate to the surgical technique and can be significantly improved by optimizing the learning curve and informing the surgeon as best as possible about these details. Because there is only one paper in literature reporting the use of an extra oversized button, with no results supporting a clear advantage, a comparative analysis with the standard technique was performed.

As shown in section 6.3.3, the oversized button (SBP®) induces considerably lower stresses in bone than smaller metal buttons, due to a distribution of contact pressure over a larger surface area. It is obvious, according to the study presented here, that this variant is more effective in mitigating the risk of second metatarsal fracture. Thus, the use of an additional oversized second metatarsal button in current surgical practice implementing this technique or its variations is unquestionably supported.

Comparative criterion 2 – Bone tunnels diameter

This comparison criterion was chosen considering the information derived from the reviewed papers, which included 85% studies based on correction variants using MTR® systems and bone tunnels of 2.7 millimeters in diameter. These papers analyze the results of 152 surgical correction procedures, representing 80% of the total cases included in the systematic review, and report a total of 16 cases of second MTS fracture, representing 84% of the total number of fractures.

In contrast, in our study, clinical outcomes determined at least three years postoperatively showed a much smaller number of second MTS fractures, only 2% of all interventions. This discrepancy between the data and the introduction of a surgical technique modification by the manufacturer, with the reduction of the bone tunnels diameter from 2.7 millimeters to 1.1 millimeters, with the stated aim of mitigating the fracture risk required a comparative analysis between the two variations of diameter and on their influence on resulting local stress.

Following the finite element analysis, lower stresses were recorded in the tunnels with increased diameters. This was due to the way the buttons transmitted the load to the bone through contact pressure. The effect discussed in this work is model dependent, however, the button deformations at the holes are determined by the constraint equations required for designing the connection with the suspension wire. In reality, the wires distribute the local stress in the buttons (in the tunnels) differently. Therefore, the comparison regarding the influence of tunnel diameter based on the study in this work could not be quantitatively conclusive. However, it can be concluded that the presented results raise the interest for more detailed studies on the influence of the tunnels diameter. By introducing a higher level of detail in the geometry modeling of the buttons and the contact with the metatarsal bone, this effect could be reanalyzed, and the importance of this comparison criterion determined more precisely in future studies.

3. Conclusions

1. The algorithm used for selecting the technique for surgical correction requires an individual approach, considering the severity of specific deformities, joint congruence, bone anatomy, osteoarthritis or accompanying deformities, especially pes planus and foot hyperpronation, tarsometatarsal mobility, pain location and associated conditions.
2. The leading indication of MiniTightRope® technique for surgical correction of deformities is mild to moderate hallux valgus, with a correctable first intermetatarsal angle, for which performing just a soft tissue procedure holds an unacceptable risk for postoperative recurrence and osteotomy techniques bear a high risk for severe complications.
3. The primary objective for developing this technique is bone stock preservation, which would improve results of a future revision surgery, and also mitigation of invasive procedures performed on bone and soft tissue, resulting in a reduction of infection risk and facilitation of postoperative rehabilitation.
4. Another important advantage promised by the studied technique is risk mitigation for major complications associated with osteotomies, complications that can lead to the development of severe functional impairment and require a challenging management.
5. The reported incidence rate for complications in literature is highly variable, with a mean of 24%, percentage similar to the one recorded for our series, with 27% out of the total number of procedures followed by complications.
6. The particularity of our results is provided by the frequency ranking for all types of complications, showing a 23% deformity recurrence rate, especially for the hallux valgus angle as leading complication.
7. Concerning radiological results, a statistically significant level of correction for the first intermetatarsal and hallux valgus angles was achieved and maintained on short and medium-term, which confirms the therapeutic potential of the MTR® technique.
8. Mean recorded values for the specific angles resulted from our study are similar with the ones reported by various authors during the last decade, with the papers presenting these results based on the analysis of different MTR® surgical technique variations.
9. The information stemming for our experience suggests a greater potential of the MTR® technique for reducing and maintaining the correction of first intermetatarsal angle (IMA),

similar with other published series, all these supporting the use of this technique especially for those cases with an abnormal IMA as chief and most important deformity.

10. The MTR® technique potential for correcting and maintaining the reduced HVA is inferior to its capability to manage the IMA deformity, and it is based on an indirect effect provided by the realignment of the first metatarsophalangeal joint, augmented by the soft tissue procedure.
11. The absence of a system or a single implant that can maintain the HVA correction combined with a well-known risk for recurrence after using soft tissue procedures demand further development and implementation of technique modifications for addressing these disadvantages and for adjusting the indication criteria, nonetheless avoiding osteotomies.
12. There is no statistically significant association between a high severity of HVA deformity recorded before surgery and an increased incidence rate for recurrence postoperatively, this conclusion supporting the importance of a proper surgical technique for a reliable correction.
13. Defining recurrence of the specific deformities after surgical correction of hallux valgus poses a series of challenges, a better and accurate description of diagnostic criteria supported by objective parameters being required for an efficient follow-up and diagnosis of complications, despite an identifiable cause for correction loss.
14. Regardless of how it is identified, recurrence does not lead in most cases to significant functional impairment that may require revision surgery or negatively affect the daily activities of the patient, as it did before the surgery.
15. Postoperative recurrence of deformities is not a complication unique to the MTR® technique, all the other procedures developed for surgical correction of hallux valgus reporting similar rates of recurrence.
16. A pattern of association between aging or other factors that can negatively affect bone density and an increased risk for fractures after surgery cannot be supported.
17. The percentage of second metatarsal fractures identified in our series represents 2% of all included procedures, a much lower rate than the one reported in recent literature.
18. No significant statistical correlation was identified between the preoperative IMA measurements or the ones extracted at one year and the functional results assessed for the same moments in time, therefore questioning the extent to which the radiological parameters are influencing the clinical outcome.
19. A mild positive correlation was statistically confirmed between HVA measurements and pain severity registered at minimum one year after surgery, confirming the important effect

of this deformity on the final results, and considering that we have identified recurrence as the most common medium and long-term complication.

20. The statistically significant reduction of pain level confirms a good therapeutic potential of the studied technique and the essential role of pain in assessing and defining the outcome for all hallux valgus correction techniques.
21. The issue of footwear restrictions must always be discussed with the patient during hallux valgus management, with the aim of maximizing the perceived results and, this parameter must become a part of any algorithm for the assessment of postoperative results.
22. A strong negative correlation, with statistical significance was detected between the satisfaction with aesthetics and pain perception, confirming the high degree of complexity and subjectivity involved in the evaluation of postoperative patient satisfaction and the crucial role pain symptoms play in this assessment process.
23. The level of satisfaction with foot aesthetics is the parameter influenced the most by all the other factors involved in determining the postoperative results and must be a part of the assessment process.
24. With proper indication, the MiniTightRope® technique can provide results similar to the other generally accepted and established procedures, and to their published outcomes, while maintaining a low level of postoperative mid-term complications.
25. Some specific details of this technique need further investigation and management, to improve its results, especially the correction of HVA, enhancement of implant durability, maintenance of correction after implant removal, the proper indication and best time for removal, the effect on adjacent joints and the learning curve for this procedure.
26. The numerical results stemming for the Finite Element Analysis presented in the paper have a qualitative significance, comparing different particularities of hallux valgus surgical correction using the MTR® technique. The quantitative validations presented in the present work demonstrated that the analyzed parameters, such as stresses and deformations, fall within the limits identified in literature, validating the biomechanical models.
27. The comparative analysis of bone density effect on stresses in the metatarsal tunnels, translated into stiffnesses from a modeling perspective, demonstrates that the risk of second metatarsal fracture increases due to the lower resistance of low-density bones, not due to the stress level, which is basically the same regardless of density.
28. The oversized button (SBP®) significantly reduces the risk for metatarsal II fracture, by distributing the contact pressure more evenly with the bone, over a larger area, thus ensuring local stress values that will fall below the bone microdamage threshold.

29. The diameter of the tunnels influences the stress level inside and around their walls, but the limitation regarding the detailed modeling of the contact between the buttons and the bone surface does not allow a definite conclusion.

Personal contribution

- Carrying out a systematic analysis of the data reported by published papers during the last 12 years, which included surgical procedures based on the studied technique or its variations.
- To evaluate functional clinical results, we developed a simplified evaluation form starting from the AOFAS model, with three main components.
- Starting from the images obtained by computer tomographic scanning of a foot affected by moderate hallux valgus, we created a series of virtual biomechanical models, with the aim of developing a platform for computational analysis of some characteristics of the studied surgical technique.
- We introduced for the first time quality of the bone mass as a study parameter, objectively measured by the bone density test to diagnose any decrease manifested as osteopenia or osteoporosis, and we analyzed its relationship with other factors.

References

1. Hetherington V, editor. Hallux valgus and forefoot surgery. Churchill Livingstone; 1994.
2. Wong, Duo. (2013). Biomechanics of Hallux Valgus and Evaluation of Interventions. 10.13140/RG.2.2.36341.60643.
3. Sarrafian S. Sarrafian’s anatomy of the foot and ankle: descriptive, topographic and functional, vol. 507– 508. Philadelphia: Lippincott Williams & Wilkins; 2011. p. 507–8.
4. Coughlin MJ, Jones CP. Hallux valgus: demographics, etiology, and radiographic assessment. Foot Ankle Int. 2007;28:759–77.
5. Richie, Douglas. (2021). Pathomechanics of Common Foot Disorders. 10.1007/978-3-030-54201-6.
6. Perera, A. M., Mason, L., & Stephens, M. M. (2011). The Pathogenesis of Hallux Valgus. The Journal of Bone & Joint Surgery, 93(17), 1650-1661.

7. Nica M, Creţu B, Ene R, Şerban B, Cîrstoiu C. Review of current hallux valgus management options. Romanian Journal of Orthopaedic Surgery and Traumatology. 2019;2(2): 130-138.
8. Deenik A, Verburg A, Louwerens J-W, de Waal Malefijt M, de Bie R. Evidence of treatment algorithms for hallux valgus. Hallux valgus. 2015;57.
9. Coughlin MJ, Saltzman CL, Mann RA. Mann's surgery of the foot and ankle E-Book: Expert Consult-Online. 2013 Sep 6, Elsevier Health Sciences.
10. Comprehensive Solutions for Forefoot and Midfoot Surgery using the Mini TightRope® System. Retrieved from: https://www.arthrex.com/resources/brochures/sjjj_vkEEeCRTQBQVoRHOw/comprehensive-solutions-for-forefoot-and-midfoot-surgery-using-the-mini-tightrope-system *(accesat în 23.05.2022).*
11. Laerd Statistics (2015). Statistical tutorials and software guides. Retrieved from https://statistics.laerd.com/ *(accesat în 12.12.2022).*
12. Nica M, Panaitescu C, Cretu B, Zsombor P, Tecu C, Semenescu A, Ene D, Soare G, Cirstoiu C, Ene R. Results of Hallux Abducto Valgus Surgical Correction Using Two 1.1mm Mini TightRope Constructs. Rev. Chim.[internet]. 2020 Feb;71(2):52-57.
13. Dayton P, Sedberry S, Feilmeier M. Complications of metatarsal suture techniques for bunion correction: a systematic review of the literature. The Journal of Foot and Ankle Surgery. 2015 Mar 1; 54(2):230-2.
14. Cano-Martínez JA, Picazo-Marín F, Bento-Gerard J, Nicolás-Serrano G. Treatment of moderate hallux valgus with a Mini TightRope® system: a modified technique. Revista Española de Cirugía Ortopédica y Traumatología (English Edition). 2011 Sep 1;55(5):358-68.
15. Holmes Jr GB. Correction of hallux valgus deformity using the mini tightrope device. Techniques in Foot & Ankle Surgery. 2008 Mar 1;7(1):9-16.
16. El Attar M, El Naggar A, Samir FF, Fathi H. Short term results of osteotomy-sparing technique in management of moderate hallux valgus using TightRope system. Journal of Orthopaedics. 2018 Jun 1; 15(2):721-5.
17. Holmes Jr GB, Hsu AR. Correction of intermetatarsal angle in hallux valgus using small suture button device. Foot & ankle international. 2013 Apr;34(4):543-9.
18. Kayiaros S, Blankenhorn BD, Dehaven J, Van Lancker H, Sardella P, Pascalides JT, DiGiovanni CW. Correction of metatarsus primus varus associated with hallux valgus

deformity using the arthrex mini tightrope: a report of 44 cases. Foot & ankle specialist. 2011 Aug;4(4):212-7.

19. Kemp TJ, Hirose CB, Coughlin MJ. Fracture of the second metatarsal following suture button fixation device in the correction of hallux valgus. Foot & ankle international. 2010 Aug;31(8):712-6.
20. Mader DW, Han NM. Bilateral second metatarsal stress fractures after hallux valgus correction with the use of a tension wire and button fixation system. The Journal of Foot and Ankle Surgery. 2010 Sep 1;49(5):488-e15.
21. Ponnapula P, Wittock R. Application of an interosseous suture and button device for hallux valgus correction: a review of outcomes in a small series. The journal of Foot and Ankle Surgery. 2010 Mar 1;49(2):159-e21.
22. Gonzalez TA, Smith JT, Bluman EM, Ready LV, Ciurylo W, Chiodo CP. Treatment of Hallux Valgus Deformity Using a Suture Button Device: A Preliminary Report. Foot & Ankle Orthopaedics. 2018 Dec 8;3(4):2473011418806951.
23. Weatherall JM, Chapman CB, Shapiro SL. Postoperative second metatarsal fractures associated with suture-button implant in hallux valgus surgery. Foot & ankle international. 2013 Jan;34(1):104-10.
24. West BC. Mini TightRope system for hallux abducto valgus deformity: a discussion and case report. Journal of the American Podiatric Medical Association. 2010;100(4):291-5.
25. Angthong C, Kanitnate S, Angthong W. Hallux valgus correction using a Mini TightRope device: a report of the short-term outcomes in 3 feet. J Med Assoc Thai. 2011 Dec 1;94(Suppl 7):S66-72.
26. Mulok HJ, Goh TC, Bajuri MY, Apandi HM, Aiman F. Outcome of Modified Technique Using Mini Tightrope Device for Hallux Valgus Surgery: A Case Series.
27. Wang Y, Wong DW, Zhang M. Computational models of the foot and ankle for pathomechanics and clinical applications: a review. Annals of biomedical engineering. 2016 Jan;44(1):213-21.
28. Cheung JTM, Yu J, Wong DWC, Zhang M. Current methods in computer-aided engineering for footwear design. Footwear Sci. 2009;1:31–46.
29. Wong DWC, Zhang M, Yu J, Leung AKL. Biomechanics of first ray hypermobility: An investigation on joint force during walking using finite element analysis. Med Eng Phys. 2014; 36(11): 1388-93.

30. Wong DW, Wang Y, Chen TL, Yan F, Peng Y, Tan Q, Ni M, Leung AK, Zhang M. Finite element analysis of generalized ligament laxity on the deterioration of hallux valgus deformity (bunion). Frontiers in bioengineering and biotechnology. 2020 Sep 8;8:571192.
31. Guijun L, Xiaohui F, Weifeng K, Xiaoqing Y, Rongzhong J, Jun Y. Finite element analysis of the treatment of hallux valgus deformity by microplate combined with super strong suture elastic fixation. Chinese J. Tissue Eng. Res. 2022; 26(6): 938-42.
32. Sandu M, Sandu A, Nuțu E. Rezistența materialelor. Editura Printech, Bucureşti. 2019, ISBN 978-606-23-0953-4.
33. E. Nuțu. Îndrumar de laborator în modelarea computerizată a structurilor biomecanice. Editura MATRIXROM. 2019, ISBN 978-606-25-0490-8.
34. Trabelsi N, Milgrom C, Yosibash Z. Patient-specific FE analyses of metatarsal bones with inhomogeneous isotropic material properties. J. Mech. Behav. Biomed. Mater. 2014;29:177–189.
35. Jacob HA. Forces acting in the forefoot during normal gait–an estimate. Clinical Biomechanics. 2001 Nov 1;16(9):783-92.
36. Helgason B, Perilli E, Schileo E, Taddei F, Brynjolfsson S, Viceconti M. Mathematical relationships between bone density and mechanical properties: A literature review. Clin Biomech. 2008; 23: 135-47.
37. Feldman V, Nyska M, Marom N, Slavin O, Brin YS, Farkash U, Palmanovich E. Measurement of transverse forces between the first and second metatarsals: a cadaveric study. Journal of Orthopaedic Surgery and Research. 2016 Dec;11:1-6.
38. Saiyan S, Paushkin A. Generalization of Saint-Venant principle to kinematic boundary conditions for beams. InAIP Conference Proceedings 2023 May 4 (Vol. 2497, No. 1). AIP Publishing.
39. Frost HM. Bone's mechanostat: a 2003 update. The Anatomical record part a: discoveries in molecular, cellular, and evolutionary biology: an official publication of the american association of anatomists. 2003 Dec;275(2):1081-101.
40. Milgrom C, Finestone A, Sharkey N, Hamel A, Mandes V, Burr D, Arndt A, Ekenman I. Metatarsal strains are sufficient to cause fatigue fracture during cyclic overloading. Foot & ankle international. 2002 Mar;23(3):230-5.

Published papers

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2. Nica M., Creţu B., Ene R., Şerban B., Cîrstoiu C.. Review of current hallux valgus management options. Romanian Journal of Orthopaedic Surgery and Traumatology. 2019;2(2): 130-138. Available at: https://doi.org/10.2478/rojost-2019-0024