Investigation of Biomechanical Characteristics of Orthopedic Implants for Tibial Plateau Fractures by Means of Deep Learning and Support Vector Machine Classification

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Abstract: An experimental comparative study of the biomechanical behavior of commonly used orthopedic implants for tibial plateau fractures was carried out. An artificial bone model Synbone1110 was used and a Schatzker V type tibial plateau fracture was created in vitro, then stabilized with three different implant types, classic L plate, Locking Plate System (PLS), and Hybrid External Fixator (HEF). The stiffness of the bone—implant assembly was assessed by means of mechanical testing using an automated testing machine. It was found that the classic L plate type internal implant has a significantly higher value of deformation then the other two implant types. In case of the other implant types, PLS had a better performance than HEF at low and medium values of the applied force. At high values of the applied forces, the difference between deformation values of the two types became gradually smaller. An Artificial Neural Network model was developed to predict the implant deformation as a function of the applied force and implant device type. To establish if a clear-cut distinction exists between mechanical performance of PLS and HEF, a Support Vector Machine classifier was employed. At high values of the applied force, the Support Vector Machine (SVM) classifier predicts that no statistically significant difference exists between the performance of PLS and HEF.

Keywords: tibial plateau fractures; orthopedic implants; biomechanical characteristics; deep learning; support vector machine

1. Introduction

Trauma orthopedic implants are the golden standard in the surgical treatment of complex skeletal injuries. The main goal of orthopedic implants is to secure the bone fragments in the anatomic position and to ensure the conditions for the bone healing process during the reparative and remodeling phases of the fracture healing. Restoring the stability and anatomic alignment of the fractured bone and avoiding damage to the adjacent soft tissue is another important goal of orthopedic implants. Not any bone fracture requires surgery but fracture fixation with implants becomes increasingly common as it was proven that proper bone alignment and limb functionality are superior in case of surgical treatment with orthopedic implants.
1.1. Schatzker Tibial Plateau Fracture Classification

Tibial plateau—the proximal tibia surface on which the femur rests—is a complex anatomic structure. Due to the combination of compression and bending stresses at the level of this region occurring during an orthopedic trauma (fall from height, car accident, etc.) several types of fractures of the tibial plateau can be encountered. The Schatzker classification system is a method commonly used to classify tibial plateau fractures in order to optimize the treatment approach:

- Schatzker I: Lateral tibial plateau fracture, wedge-shaped with less than 4 mm depression or displacement
- Schatzker II: Lateral tibial plateau fracture, wedge-shaped with a depressed component (same as Type I but with a significant depression)
- Schatzker III: Pure depression of the lateral tibial plateau
- Schatzker IV: Split of the medial tibial plateau, wedge-shaped
- Schatzker V: Bicondylar tibial plateau fracture where integrity of the epiphysis—diaphysis junction is maintained
- Schatzker VI: Bicondylar tibial plateau fracture with complete dissociation of the epiphysis—diaphysis junction

A schematic representation of Schatzker classification system is presented in Figure 1 [1].

![Figure 1. Schatzker classification system of tibial plateau fracture types—from [1].](image)

1.2. Fracture Healing Process

Fracture healing is a complex process, (described in detail in [2]), which is triggered by the inflammation phase. Inflammatory response reaches a peak approximately 24 h following the injury releasing inflammatory mediators, which recruit inflammatory cells and promote angiogenesis. Proper fracture healing requires two key conditions, as follows:

I. Proper blood supply through the nutrient artery (80%) and periosteal vessels (20%), which triggers the release of growth factors, stimulates local angiogenesis (which is another key process in bone healing [3]), vasodilation and ultimately, formation of new bone tissue. It has been shown [4] that blood supply not only provides nutrients but is also a source of mesenchymal stem cells that ultimately differentiate into osteoblasts. It is known that metaphyseal bone section heals significantly faster than diaphyseal bone because of a more intense vascularization of the first.

II. Mechanical stability of the fracture. Relative displacement of bone fragments interrupts the development of new bone tissue and may cause malunion.

Bone healing is a physiological process of proliferative nature. Depending on the relative position of the bone fragments created by the fracture line, the following types of healing process occur:

1. Primary healing occurs when the bone fragments are rigidly fixed in correct anatomic position with no gap in between [5]. Primary healing consists of remodeling of lamellar bone, the Haversian canals and the blood vessels without callus formation. The process can last from months to years.

2. If a gap of less than 0.01 mm the healing mechanism—contact healing—is slightly different. In this case, cutting cones, consisting of osteoclasts from across the sides of the fracture line, generate cavities at a rate of 50–100 µm/day, which subsequently are filled up with the Haversian system.
and osteoblasts lay down new bone tissue. Cutting cone mechanism occurs in diaphysis region of the bone (cortical tissue) and not in metaphysis region (such as tibial plateau).

(3) In fractures with larger gaps (0.8–1 mm) the fracture region is filled by osteoclasts and then by lamellar bone orthogonal to the axis of the bone. The process is known as gap healing.

(4) Secondary healing consists of endochondral ossification (which is one of the two fundamental mechanisms of bone tissue formation during fetal development of the mammalian skeletal system) and is the healing process most frequently encountered. Secondary healing occurs in cases where fracture is treated using orthopedic cast, or external or internal fixation.

1.3. Implant Device Effect on Fracture Healing Process

The duration and the outcome of the fracture healing process is significantly influenced by the implant device. Olivares-Navarrete [6] demonstrated that osteoblasts exhibit a differentiated phenotype when grown on grit-blasted titanium aluminum vanadium (Ti6Al4V) alloys with micron-scale roughened surface than in case of smooth surface Ti6Al4V or on tissue culture polystyrene. Krettek et al. [7] found that transcutaneous/transmuscular screws are beneficial to achieve primary fracture healing in closed fractures. Hente et al. [8] investigated whether compressive or distractive displacements have a more pronounced effect on new bone formation. It was found that cyclic compressive displacements were superior over distractive displacement enhancing periosteal callus formation. The influence of the osteotomy gap size and interfragmentary motion on the healing success was investigated by Claes et al. [9]. Increasing gap sizes delayed the healing process while increasing movement stimulated callus formation but not tissue quality. Gittens et al. [10] found that (i) differentiation of osteoblasts and the production of bone on the surface of the implant is a prerequisite of successful osseointegration and (ii) biological response can be modulated by the properties of the implant surface. Loi et al. [11] found that perfectly rigid fixation with no micromotion can lead to suboptimal bone regeneration. The reasons for this phenomenon are not fully understood. Some amount of motion is required for bone regeneration but what is the optimal amount of motion is yet to be established.

The implant material and surface condition are key factors influencing the dynamics and outcome of the healing process. Li et al. [12] modified titanium surfaces to produce smooth, micro, or nano-topographies. Experiments indicated that the nano-topography induced a stronger autophagic response, leading to degraded cytoplasmic YAP. With the lower levels of YAP, β-catenin transported and accumulated in the nucleus to activate TCF/LEF transcription factors, resulting in osteogenesis occurring at higher rate. Gao et al. [13] investigated a bio-functional magnesium coating deposited on porous Ti6Al4V scaffold. In vitro studies demonstrated that magnesium-coated Ti6Al4V co-culture with MC3T3-E1 cells can improve cell proliferation, adhesion, extracellular matrix (ECM) mineralization and ALP activity compared with pure Ti6Al4V cocultivation. A large number of studied (reviewed by Jia et al. [14]) demonstrated that poly-dopamine and its derivatives can be used for the surface modification of orthopedic implants to modulate cellular responses, including cell spreading, migration, tissue proliferation and differentiation, and may thereby enhance the function of existing implants.

Stress shielding occurs when Young moduli of the bone and implant differ significantly. Bone atrophy occurs in such cases resulting in a loose implant device and in the worst cases, refracturing the bone [15]. The higher the elastic admissible strain (defined as the strength-to-modulus ratio) is, the more suitable are the materials for such orthopedic implant applications [16].

1.4. Common Orthopedic Implant Devices, Materials and Biomechanical Characterization

Fracture healing process is closely related to the bone fixation stability and rigidity [17]. Two main types of fixation systems exist (Figure 2):

- Internal fixation (Figure 2a), which restores bone physiology and enable early mobilization of the limb. The function of the injured bones can be restored and full support for physiological
load is ensured by applying internal fixation. The vast majority of internal fixation systems are manufactured from stainless steel or titanium. A review of internal fixation systems and the fracture sites for which they are suitable can be found in [18] and [19]. By means of internal fixation, malunion is a very rare occurrence and mobilization of the patient is very fast. Internal fixation systems have disadvantages, however. The stiffness and Young modulus of the implant material are much higher than in the case of cortical tissue of the human bone. Fixation of the bone fragments with high rigidity materials prevents load transfer to the healing bone, which is unfavorable for fracture callus remodeling [20]. The necessity of surgical removal after the bone healing is another trauma the patient has to undergo.

- External fixation (Figure 2b) is considered flexible fixation. External fixator systems consist of elements such as pins, wires (Schanz screws, Steinman pins, Kirschner wires) and belts that are conventionally used as a dynamic fixation of fractured bones. External fixation approach is used for open fractures with massive soft-tissue injuries such as open Type II, Type III fractures (Type II and III are open fractures with a soft tissue laceration larger than 1 cm and 10 cm respectively, minor and severe comminution respectively and with simple and complex fracture pattern, respectively) and even in articular fractures, in which the surgical trauma to the limb during fixation is reduced [18].

![Figure 2. Internal fixators (a) and hybrid external fixator (b) used for fixation of tibial plateau fracture.](image)

Several milestones in development of internal fixation systems can be mentioned: Muller et al. [21] developed a plate with a tensioner to provide inter-fragmentary compression during tightening processing, called the dynamic compression plate (DCP); Perren et al. [22] developed another compression plate with limited bone surface contact, with the purpose of preserving the blood supply and protecting the periosteum; Wagner proposed a design of combined plate hole (described in [23])—a plate that possessed the advantages of both DCP and locking plate system. The modern locking compression plate design is based on the combined plate hole described in [23].

It is widely accepted that dual plating technique [24] ensures the best results in terms of mechanical stability and clinical outcomes. It was found that PLS plate system [21] provided a similar bio-mechanical resistance to static load in case of Schatzker V tibial plateau fractures.

The biomechanical properties of the bone—implant interface are the determinant requirements for implant stability [25]. A good quality of bone healing leads to: (i) direct contact between mineralized
bone tissue and the implant and (ii) an important proportion of the implant surface in intimate contact with bone tissue. Primary stability of the implant is a critical factor in the fracture healing success. Improper primary stability results in excessive interfacial micromotion following surgery [26,27], which may imply a higher occurrence of migration and implant failure [28].

The majority of implant systems employed in clinical practice have a complex geometry, which leads to three-dimensional complex, non-uniform, multi-axial stress fields [29]. The physiological gait pattern also applies a complex stress field on the implant device.

Due to the non-uniform stress distribution involving compressive and shear stress components, implant models have been developed in order to determine mechanical parameters under controlled and standardized conditions.

Stainless steel 316L is the most prevalent material for fabrication of implant devices for orthopedic surgery applications. It is highly resistant to the corrosive action of biological fluids due to the high chromium percentage (17–19%).

Titanium alloy is lighter than steel for the same strength but it can be easily contaminated when exposed to hydrogen, nitrogen, and oxygen, which make it unsuitable for some medical procedures.

The importance of orthopedic implants mechanical behavior becomes even more obvious if considered in the context of healing process types (Section 1.2). A significant number of studies exists on the micromovement of fractured bone components on the healing process. Yamaji et al. [30] conducted a study to identify the suitable amount of micromovement, location and timing of callus formation. It was found that in case of large micromovement, the amount of newly formed bone within the gap decreased with increasing gap size, suggesting a delay of bone healing. Stimulation of new bone formation by micromovement was mainly effective in the early healing phase (4 weeks postoperatively). Large gaps showed the least new bone formation at the fracture site and the lowest flexural rigidity. Kenwright et al. [31] presented a study in which 85 tibial fractures of comparable severity were divided into two groups and were fixed with highly rigid fixation (Group 1) and the same type of fixation with axial micromovement applied across the fracture site for 30 min per day (Group 2). It was found that the time to reach stiffness levels equivalent to clinical union was significantly lower in Group 1 than in Group 2 and the mean time to independent weight bearing was lower in Group 2 than in Group 1. Complications and failure of the procedure occurred mostly in Group 1 patients. It was concluded that axial micromovement contributed to improvement of the procedure outcome.

Implant devices wear and failure are important issues that must be considered. Gervais et al. [32] presented a case study investigating the failure analysis of a 316L stainless femoral orthopedic implant (locking compression plate fixed to the broken femur using locking and compression screws). The macro and micro fractographic analyses revealed that the failure mechanism was high-cycle fatigue and that the implant underwent approximately $10^6$ loading cycles before failure occurred. A Finite Element Analysis (FEA) of the assembly confirmed that the crack initiation sites were located in the region where the highest stress values occurred. Post-failure analysis indicated that the premature fatigue failure (less than 2 years) was most probably caused by walking (high-cycle fatigue). It was concluded that implant geometry and installation procedure could be optimized in order to redistribute the stress concentration.

Bone—implant device biomechanical behavior is one of the factors with the highest importance in the outcome of implant devices—based treatment of fractures. Gao et al. [10] reviewed the parameters that quantify the concept of biomechanical behavior for implant devices and the usual testing techniques. It is generally agreed that analytic modeling of the bone—implant device system is extremely difficult and can only be done for simple systems only. Commonly used techniques include FEA, experimental in vitro testing and recently, machine learning algorithms (MLAs). MLAs are extensively used in modeling complex processes with a significant random component. There is a wide range of applications for MLAs in healthcare: Wang et al. [33] proposed an intelligent scalp detection system based on MLAs, Miyagi et al. [34] developed a Support Vector Machine system to classify dysphagic swallowing sounds, Merrill et al. [35] employed Logistic Regression and Gradient Boosting
to predict short-term outcomes following open reduction and internal fixation of ankle fractures, Halilaj et al. [36] carried out a literature review of machine learning application in human movement biomechanics. Kang et al. [37] used a convoluted neural network to identify hip arthroplasty designs, Pandey and Panda [38] developed a model to predict temperature in orthopedic drilling based on a back-propagation neural network, Urban et al. [39] used deep learning algorithms to classify shoulder implants in X-ray images.

Support Vector Machine (SVM) algorithms are another set of MLAs commonly used in medicine, especially in diagnosis [40–43] as patient information repositories containing large amount of data become available. SVM algorithm is known for high classifying accuracy, high fault tolerance and generalization, as Jiang et al. [44] demonstrated by joining an SVM classifier with Rough Set Theory to classify digital mammography.

1.5. Objectives of the Study

Given the influence of mechanical stresses on the fracture healing process and outcome, discussed extensively in the Introduction section, the study presented in this paper attempts to differentiate between commonly used implant devices in terms of mechanical behavior, more precisely, the implant deformation as a function of axial force applied to a bio-mechanical assembly bone—implant device.

The main objectives can be concisely described as follows:

- Investigate experimentally the correlation between the compressive force applied axially to a bio-mechanical system bone—implant device and the deformation of the implant.
- Develop an MLA model that is capable of predicting the implant deformation as a function of applied force and implant type.
- Establish if in case of similar mechanical stress, different types of implant devices perform significantly different (in a statistical sense) in terms of micromovement at the fracture site.

An experimental model bone—implant device was built based on an artificial bone model in order to reproduce as closely as possible the mechanical behavior of the assembly. Three implant devices were studied by applying axial force to the bone—implant device assembly and measuring the deformation.

2. Materials and Methods

2.1. Bone Model

The bone model used for experiments was Synbone™ 1110, which mimics the shape and structure of cortical bone tissue, found primarily in the shaft of long bones and as outer layer around cancellous bone at the end of articulations and vertebrae (Figure 3). Artificial bones have widely been used for orthopedic implant devices testing [45]. Artificial bones are considered of questionable biocompatibility because (i) internal architecture and (ii) the resulting directional mechanical properties of the real bone are absent [46]. However, these specimens have identical size and accurate morphology, which results in a very low variability of strength [47]. These features may make them preferable to cadaver bone, which have high variability in their size and quality and are considered to have a high variability of strength. Only paired specimens from the same cadaver are considered to have comparable biomechanical characteristics to allow simultaneous comparison of two different implants [47].

The geometrical dimensions of the artificial bone used in the experiments were the following: length 387 mm, tibial plateau thickness 74 mm, diaphysis diameter 27 mm and medullary cavity diameter 8 mm.
2.2. Implant Devices

Three types of implant devices widely used in surgical treatment of complex tibial plateau fractures were considered in this study: (1) Classic L plate (Stryker)—Figure 4, (2) Locking Plate System (PLS)—Figure 5 and (3) Hybrid External Fixator (HEF)—Figure 6.
2.3. Fracture Stabilization Techniques and Implant Devices

2.3.1. L Plate

Two 6.5 mm cortical screws at the level of tibial plateau penetrating divergently the metaphysis all the way to the opposite cortical layer at approximately 2–3 mm from the joint region were used. To stabilize the plate, four cortical screws each of 40 mm traversing both sides of the cortical layer were used. All L plates used in the experiments had two holes on the metaphysis section and four holes on the diaphysis section.

2.3.2. PLS Plate

Three stabilizing 4.5 mm screws locked at the plate level (plate length was 75 mm) penetrating the metaphysis all the way to the opposite cortical layer were used. The screws penetrated the bone at 2 mm from the joint area of the tibial plateau. The screws were inserted by means of the threaded sheath tool from the orthopedic surgery instrument kit. The holes were bored using 3.7 mm drills. Standard plates with seven holes on the diaphysis section were used. Only three holes were occupied with unlocked cortical screws penetrating both sides of the cortical layer.

The implant material for all devices used in this study is stainless steel 316L 50% cold worked. (specifications AMS 5507 and ASTM A240). Type 316L stainless steel exhibits good corrosion resistance due to molybdenum addition. Mohamad et al. [48] investigated the corrosion characteristics of the cold work 316L stainless steel in simulated body fluids following ASTM G31–72. PBS solution and 0.9% NaCl solution were used as corrosive environments. It was found that corrosion occurred uniformly throughout the surface of the test specimen with higher resistance for steel with higher cold reduction. The corrosion rate measured was 0.23 mm/year for NaCl solution (0.9%) and 0.11 mm/year for PBS solution.

Typical values of the main mechanical properties of stainless steel 316L are presented in Table 1:

| Density | Tensile Strength (min) | Elastic Modulus | Hardness |
|---------|------------------------|-----------------|----------|
| 8000 kg/m³ | 485 MPa | 193 GPa | | 95 | 217 |

In contrast, the elastic modulus of human tibia ranges from 14.1 to 17.7 GPa [49].
2.3.3. Hybrid External Fixator

A hybrid fastening type has been used with a semi-circular ring at the level of the tibial plateau. The attachment to the diaphysis region was realized by means of two transfixing pins crossing both cortical layers, as follows: the proximal pin was inserted from anteromedial to posterolateral, and the distal one was inserted from anterolateral to posteromedial, establishing a four-point connection with the semi-circular ring. The pins used were 2.2 mm in diameter and located approximately 2 mm from the articular surface. The threaded elements were inserted as in the standard procedure, at 20 cm from the tibial plateau in the diaphysis region following a bi-cortical direction. This type of hybrid fastening involved an Ilizarov fixator in the metaphysis region and a Hoffman fixator in the distal tibia, both of which are interconnected with a stabilizing rod that was secured as parallelly as possible to the tibial diaphysis. Standard insertion positions of the pins and wires for distal and proximal insertion points were used. All models used in the experiments used the same fixator, changing only the pins and the Kirschner wires for every new model tested.

2.4. Test Machine and Assembly

A bi-axial tabletop servo hydraulic testing system test machine Instron 8874 (Instron, Norwood, MA, US) with capability of applying biaxial stresses both statically and dynamically was used. The machine can exert force in the range 1000–24,000 N with automated displacement data logging. The test assembly is presented in Figure 7.

Figure 7. Test assembly—PLS system (a) and hybrid external fixator (b).

The machine is driven by the computer software WaveMatrix, allowing several load programs, such as cyclic or multiaxial with various user-defined stop conditions.

2.5. Preparation of the Bone Model

All bone models were prepared by simulating a standard fracture - encountered frequently in the orthopedic surgery practice, Schatzker V—wedge fracture of both lateral and medial tibial plateau. To produce this type of fracture for all bone models used in the study, a 1 mm blade osteotomy oscillating micro-saw and a guidance plate secured in the tibial plateau region were employed, as presented in
Figure 8. Guidance plates were used in order to achieve a regular shape fracture with minimum bone tissue loss.

Figure 8. Guidance plate for the in vitro creation of tibial plateau fracture paths.

2.6. Bone—Implant Device Model Fastening System

The implant bone model was fastened in the test machine between the upper crosshead and the fixed inferior table by means of two elements (1) distal fastening element and (2) proximal element. From the viewpoint of the mechanical stress, the distal element is passive, in the sense it only fastens the bone model at the level of tibial diaphysis. The fastening element is presented in Figure 9. The element ensures fastening of the bone model both in the cortical region and medullary canal region (by means of the central pin). To maximize the contact area between bone model and fastening element and reduce the uneven axial stress, which can create a bending moment, the tibial diaphysis was sectioned in a plane orthogonal to the diaphysis axis.

Figure 9. Distal securing element.

The proximal element, presented in Figure 10, is active in the sense that it applies force from the upper crosshead of the test machine to the tibial plateau. The element was designed in such way that compression force is applied coaxially with the medullary canal and uniformly distributed across the two tibial plateaus.
3. Results

3.1. Test Procedure

Several 15 models were prepared for each implant type. The testing machine was set to apply progressive load to the model ranging from 1300 N to 3150 N with a constant increase rate of 2 N/s. The testing machine was set to record implant deformation automatically at every 50 N. End of test condition was either reaching the upper limit force value (3150 N) or damage of the model.

The 45 bone—implant models were conventionally included in three groups, as follows:

Group 1. 15 bone models with L plate implant
Group 2. 15 bone models with PLS plate implant
Group 3. 15 bone models with hybrid external fixator implant
Group 1. For 11 models the maximum force 3150 N was reached and for the rest the implant underwent damage, most frequently at the level of screws. Two models failed at 2800 N and the other two at 3000 N. Significant stability loss was observed in all cases.

Group 2. For 12 models the maximum load of 3150 N was reached and in three cases implant failure occurred. The damaged elements were the proximal screws (bending or displacement of the internal plateau). Failure occurred at force values of 3000 N.

Group 3. For 12 models the maximum load 3150 N was reached and for the other three failure occurred. Failure occurred at force values 3000 in one case and 3100 in the other two cases.

3.2. Preliminary Processing of the Raw Data

Statistical significance of the data was ensured by averaging the implant deformation (ID) values over all test specimens of the same type, for each value of the force applied. The extreme outliers (defined as points located beyond 3 interquartile range) were removed from the data set. For Group 1, two outliers were identified and for Groups 2 and 3 one outlier. Thus, several data points for each group were preserved. The data set considered for further analyzed consisted of 38 pairs of values (for each of the three types of implant) implant deformation (ID) versus applied force.

Raw data from each experiment is presented graphically in Figure 12a–c for L plate, PLS plate and HEF respectively in the form of box plots showing experiments where outliers were identified (‘+’ symbol in Figure 12a–c) and experiments where implant device failure occurred. The mean values of implant deformation for each experiment (after removing outliers and discarding failed experiments) are presented in Figure 12d.

Figure 12. Box plots of raw data for each implant device type (a–c) and processed data (d).
A preliminary statistical analysis was performed by calculating Pearson and Spearman coefficients in order to confirm the existence of a correlation implant deformation—force. Although both Pearson and Spearman correlation coefficients predict a strong correlation between applied force and measured implant deformation (Table 2), these values must be interpreted cautiously.

Table 2. Pearson and Spearman correlation coefficients.

| Implant Type            | Correlation Coefficient |          |
|-------------------------|-------------------------|----------|
|                         | Pearson                 | Spearman |
| L plate                 | −0.9989                 | −1.0000  |
| PLS plate               | −0.9993                 | −0.9996  |
| Hybrid external fixator | −0.9988                 | −0.9993  |

3.3. Development of the Artificial Neural Network (ANN) Model

Behavior of the mechanical system bone tissue—orthopedic implants under static and dynamic load is a complex problem and could not be reduced to a simple deformation under load problem due to the following considerations:

- Bone tissue is a material with complex mechanical properties, significantly different from those of the implant device (Young modulus highly anisotropic [50], shear and bulk modulus, elastic limit, homogeneity, and isotropy).
- Screw assembly between the bone and the implant introduces complex effects that cannot be fully accounted for analytically. Load is transferred between bone and implant device by means of screws, which undergo complex stresses, especially bending and shear. A complex stress field occurs in the bone tissue in the vicinity of the screw insertion region.
- L plate and PLS plate devices are somewhat similar regarding the implant deformation under load. However, the HEF is different in many aspects from the first two. On the other hand, PLS plate and HEF perform similarly from a mechanical point of view with the difference that PLS is an internal fixator, requiring open surgery while HEF is a minimally invasive implanting technique.
- Although standard implant insertion surgical procedures are in place, minor differences in terms of screw position, anatomic particularities of the bone, fracture particularities, surgeon experience and preferences and several other factors introduce a random component of the bio-mechanical behavior of the implant device—bone system.
- It appears from Figure 12a–c that the standard deviation (scattering of data points around mean value) tends to increase as the applied force increases. This is a clear indication that random factors with varying influence exist.

Due to the reasons presented above, the implant deformation as a function of compressive force cannot be reduced to a simple linear (or nonlinear) deformation under load problem. Instead, an algorithm that accounts for statistical variations is expected to produce more accurate results. Artificial Neural Networks (ANN) is considered a machine learning algorithm appropriate for this type of problem.

A standard ANN architecture with one input layer, one hidden layer and one output layer was selected with logistic sigmoid as activation function. Input parameters delivered to the ANN were (1) the force applied to the implant and (2) the implant type. The model output parameter was the implant deformation. The ANN training algorithm was Levenberg-Marquardt, which offers a trade-off between fast convergence and efficiency. MATLAB R2018a ANN toolbox was used to generate the ANN model.

The input data set was divided in 70% training, 15% validation and 15% testing. The performance criteria used in the training algorithm was selected Mean Squared Error. The minimum number of neurons in the hidden layer for which the network performed well was 5 and the learning rate was 0.5. The data set observed the general recommendations for designing the training set.
• Every class must be represented. The training data usually consists of several possible subgroups, each with its own central tendency toward a particular pattern. All such patterns must be presented to the ANN model during the training stage.
• Within each class, statistical variation must be adequately represented by including the relevant noise effects.

4. Discussion

4.1. ANN Model Results and Performance

The regression plots for training, validation and test of the ANN are presented in Figure 13 and the parameters of the ANN model are presented in Table 3.

Table 3. The main parameters of the ANN model.

| Data Set   | Number of Samples | Mean Square Error | Pearson Correlation Coefficient |
|------------|-------------------|-------------------|---------------------------------|
| Training   | 80                | 3.218E-3          | 0.9995                          |
| Validation | 17                | 6.330E-3          | 0.9902                          |
| Testing    | 17                | 2.738E-3          | 0.9852                          |

Figure 13. Training, validation and test regression plots.
In Figure 13, the coordinates of the markers are represented by the actual (experimental) values of the implant deformation ($x$ axis) and the ANN predicted values of the implant deformation ($y$ axis). The lines represent the linear fit of the actual value—ANN predicted value with the following parameters (Table 4):

Table 4. Regression model parameters performed on the ANN predicted values.

| Data Set         | Line Parameters |
|------------------|-----------------|
|                  | Slope     | Intercept |
| Training         | 1.0025    | 0.0023    |
| Validation       | 0.9960    | 0.0791    |
| Test             | 1.0018    | 0.0352    |
| Entire data set  | 1.0087    | 0.0192    |

To compare the actual (measured) values of the ID with the ANN predicted values, the ANN model was be used to generate a set of values (for the same set of input values) in such way that a comparison was made possible. In Figure 14a, the actual ID values and the ANN predicted values are plotted for the three implant types considered.

Figure 14. ID—actual values—ANN predicted values (a) and absolute error histograms (b).
The mean value and standard deviation of error (absolute values) are presented in Table 5.

Table 5. Mean and standard deviation of absolute error.

| Implant Type | Mean | Mean (Absolute Values) | Standard Deviation |
|--------------|------|------------------------|--------------------|
| LP           | 0.0228 | 0.0568                | 0.0423             |
| PLS          | 0.154  | 0.0421                 | 0.0307             |
| HEF          | −0.158 | 0.0450                 | 0.0345             |

From Figure 14b it can be inferred that the absolute error did not follow a normal distribution. This suggests some degree of bias, which can be quantitatively assessed by taking the mean of the absolute errors (Table 5, column Mean). For LP and PLS the ANN model overfits and for HEF it underfits the data. The extent of the bias was analyzed by taking the relative values of the errors. The relative error (in %), plotted in Figure 15, show that the highest value was reached in case of PLS type implant (approximately 5%). This is a small value, suggesting that although a certain degree of bias was detected, it was within acceptable limits.

4.2. Differential Analysis of Implant Deformation Data

In case of PLS and HEF implant types the deformation values were within 1 mm from each other as it can be observed in Figure 14. Moreover, this difference decreased as the applied force value increased, reaching approximately 0.5 mm at maximum force value. If other factors of random nature are taken into consideration such as bone—implant bonding and measurement error, it can be argued that no clear-cut distinction exists between the performance of PLS and HEF. This effect is better observed in Figure 16, where a box plot of implant deformation data for the three implant types is presented.
was selected. As the classifier operates best with normalized data, both columns were scaled to \(1\)×\(3 = 1\).

The three data sets (one for each implant type) were joined in one set consisting of 3 \(×\) 38 pairs of applied force—ID values. First 38 pairs correspond to LP type, the next 38 to PLS and the last 38 to HEF type. The categorical data—implant type was being provided as an input to the SVM classification. From Figure 16 it appears that ID data interquartile range overlaps significantly for PLS and HEF types with a difference between mean values of less than 0.8 mm. It is important to establish if such a small difference between PLS and HEF types is statistically significant or it is caused by random factors, meaning that PLS and HEF perform similarly. This matter is of utmost importance for the selection of the appropriate implant device. If it can be confirmed that no significant difference exists between PLS and HEF at high values of the applied force, then the mechanical resistance criteria can be ignored in selecting one implant type over the other, leaving in the selection balance only relevant differences, such as the level of trauma the patient has to undergo for each implant device type.

As the ANN model cannot provide an answer to this question, a machine learning classification algorithm was employed. The most suitable algorithm for this type of classification problem is Support Vector Machine.

4.3. Application of SVM Classification to Implant Deformation Data

The functional dependence ID—force applied was redefined introducing a categorical data, the implant type. In such way, the simple three-component regression problem (for three implant types) was be converted into a unique classification problem.

SVM classification was expected to settle bounds of the data set limits depending on the implant type and to establish if a statistically significant difference existed between PLS and HEF in terms of ID—force applied data. In other words, by reconfiguring a simple problem of ID as a function of applied force as a classification problem it was possible to answer the question whether or not a statistically significant advantage of PLS over HEF existed.

To implement an SVM classifier for the ID—applied force data set, the Python `sklearn` library was employed. The three data sets (one for each implant type) were joined in one set consisting of \(38 \times 3 = 114\) pairs of applied force—ID values. First 38 pairs correspond to LP type, the next 38 to PLS and the last 38 to HEF type. The categorical data—implant type was being provided as an input to the classifier as a column vector containing implant type information.

The data science platform Anaconda3 was used with Jupyter Notebook 6.0.3 and Python Kernel 3.7.6. Jupyter Notebook is an open source web application that allows creation and sharing of live code documents. The `sklearn` classifier regularization parameter C value was chosen 1.5 following the guidelines from [40]. Since a linear or quasi-linear separation was expected, the linear type kernel was selected. As the classifier operates best with normalized data, both X columns were scaled to the range \([-1,1]\). The scaled data is plotted in Figure 17 using marker color selected according to the categorical data.
The classifier established that HEF and PLS performed similarly in a statistical sense, meaning that no statistically significant difference exists between HEF and PLS at this value of the applied force (3150 N).

Figure 17. Data set categorized by implant type.

To render each region cluster as a distinct color 2-D region, a dense mesh of points was created and the classifier previously trained with the force—ID data set was applied to the dense mesh. The results are presented in Figure 18.

Figure 18. Data set and regions defined by the SVM classifier.

The classifier identified three distinct regions (defined in Figure 18 by three different color) and did not wrongly classify points belonging to one implant type to another region i.e., each implant device specific data set is placed in one region only. However, an obvious trend of the PLS points to approach the HEF region boundary can be observed. In fact, the PLS point corresponding to the applied force 3150 N (Figure 18, last point of the PLS data set) falls very close (or onto) the region boundary HEF—PLS. The data trend shown in Figure 18 can be interpreted as follows: As the applied force increased, the difference in terms of deformation between HEF and PLS decreased steadily, indicating that the advantage of PLS over HEF became statistically irrelevant. At the upper limit (3150 N), the classifier established that HEF and PLS performed similarly in a statistical sense, meaning that no statistically significant difference exists between HEF and PLS at this value of the applied force (3150 N).

The key conclusion that can be drawn from this observation: the maximum load that can be expected has to be also included in the implant device selection criteria.
5. Conclusions

A multi-objective comparative analysis was carried out in order to differentiate between mechanical stability characteristics of three commonly used tibial plateau fracture (type V Schatzker classification system) fixation systems: classic L plate, Locking Plate System and Hybrid External Fixator.

The L plate showed the lowest performance in terms of mechanical stability as shown previously in other similar studies (Faur and Niculescu [51]). The best performance was found in the case of the Locking Plate System. Hybrid External Fixator system provided a mechanical resistance only slightly lower than that of Locking Plate System plate. However, with the increase of the load, it was observed that the difference between the mechanical resistances of Locking Plate System plate and Hybrid External Fixator system becomes less significant.

The present study developed an artificial neural network model to predict the implant deformation as a function of load with the purpose of establishing if a significant functional dependence exists between implant deformation and applied force. Another objective of the analysis was to determine if the implant type has a significant influence on the implant deformation over the whole range of the applied force. As it was observed that the difference between the mechanical resistance of Locking Plate System type becomes comparable with that of the Hybrid External Fixator, a question was raised if a clear-cut distinction between implant deformation for Locking Plate System and for Hybrid External Fixator at higher force values, in other words if choosing PLS over Hybrid External Fixator has a significant advantage from the mechanical resistance standpoint when high loads are expected.

A machine learning algorithm—Support Vector Machine—was employed in order to analyse the implant deformation data and establish boundaries for data points depending on whether they belong to one or another implant type. It was found that the SVM classifier placed Locking Plate System data points increasingly closer to the Hybrid External Fixator region as the applied force increased. This is equivalent to say that no clear-cut distinction (statistically significant) could be identified between Locking Plate System and Hybrid External Fixator at high values of the applied force. However, at low and moderate values of the applied force, Locking Plate System performs better than Hybrid External Fixator.

The conclusions of the study can be synthesized in a recommendation: in cases where significant load is expected to be exerted on the implant device—bone assembly, other factors such as the extent of surgical trauma should weigh more in the medical decision since in such cases Hybrid External Fixator system performs similarly from a bio-mechanical point of view. As the micromovement at the fracture site is a key factor in the fracture healing process, it is critical to control its value, which is determined by the implant device type and the applied force.

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