Biodegradable vs. Conventional Implants in Skeletal Traumatology: A Study of Load Capacity in the Inner Ankle Region

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Abstract: This study investigates the use of biodegradable implants in skeletal traumatology. The focus is on evaluating the cyclic loading of intraosseous implants in the inner ankle region and comparing the load capacity of conventional and biodegradable implants in healthy tissue. Mechanical testing and retrospective analysis were conducted on chromium nickel and magnesium implants to assess their strength and stability. Laboratory testing involved simulating ankle fractures and analyzing the performance of different implants. The results show significant differences in fatigue capacity, with the biodegradable implants demonstrating lower ultimate stress but sufficient load-bearing capacity under actual stress conditions during the healing process. These findings contribute to our understanding of implant performance in skeletal traumatology and highlight the potential of biodegradable implants as a viable alternative in reducing invasiveness and improving patient outcomes.

Keywords: Biodegradable implants; Skeletal traumatology; Cyclic loading; Ultimate fatigue capacity

1 Introduction

In the field of skeletal traumatology, when conservative treatment is not feasible, the primary objective is to minimize the invasiveness of surgical interventions. Presently, in addition to conventional implants, absorbable and biodegradable implants can be utilized for osteosynthesis. The integration of these absorbable materials into the therapeutic procedure mitigates certain side effects associated with osteosynthesis, particularly the need for a secondary surgical intervention for implant removal. This considerably reduces the overall surgical risks, such as general anesthesia, infection, embolism, and also alleviates the economic burden on the healthcare system. Consequently, the utilization of biodegradable and resorbable materials can be perceived as a minimally invasive approach [1].

Certain types of biodegradable materials possess the capability to degrade and be absorbed by the body without adversely affecting the bone tissue. Their crucial mechanical property lies in maintaining static stability, ensuring the strength of the implant over a specific duration, particularly during the healing of bone tissue (e.g., fracture healing). During the initial phase, the fracture stability is upheld by the osteosynthetic material, enabling bone healing to occur. Subsequently, the integrity and stability of the bone tissue are restored (bone callus is formed), and it is during this phase that the process of biodegradation accelerates [2]. The specific type and chemical properties of biodegradation are influenced by the composition of the implant itself.

Currently, the predominant material used for biodegradable implants is poly-L-lactide (PLLA) due to its exceptional mechanical properties, stability, natural biocompatibility, and, importantly, ease of processing [3]. However, the degradation process of PLLA in the body takes approximately 14 to 36 months, which does not align with the timeframe required for the healing of living bone (8 to 12 weeks) [4]. Moreover, the acidic by-products resulting from PLLA degradation often incite a local inflammatory response that hinders tissue regeneration [4]. PLLA also lacks osteogenic activity and can even impede osteogenic proliferation and differentiation due to its hydrophobic nature [4]. Consequently, alternative materials with improved characteristics are actively sought in the field of orthopedics and skeletal traumatology.

One alternative is the utilization of novel polymeric materials such as polyglycolide (PGA), polycaprolactone (PCL), or their combination with PLLA [5]. These materials exhibit faster degradation rates and elicit more favorable biological responses compared to PLLA. Additionally, they demonstrate the ability to promote osteogenesis and facilitate bone regeneration [6]. Another option involves the use of osteosynthetic materials based on hydroxyapatite (HA) or tricalcium phosphate (TCP), which significantly enhance ossteointegration and can expedite bone healing. However, TCP's biomechanical properties render it brittle and prone to disintegration. Studies indicate that this material is not advantageous for osteosynthesis and is instead primarily employed for bone cyst filling [7].

Another category of materials applicable in bone surgery comprises biodegradable implants based on magnesium alloys. The initial attempts to employ magnesium in bone surgery date back to the early 19th century, exemplified by Lambotte's pioneering operation [8]. The notable advantage of magnesium alloys lies in their modulus of elasticity and strength, which closely match those of bone tissue, unlike common materials used in osteosynthesis such as stainless steel or titanium. For instance, the modulus of elasticity of bone ranges between 3 and 20 GPa, while that of magnesium falls within 41-45 GPa, and titanium alloy exhibits a range of 110-117 GPa [9].

Due to the desirable properties and biodegradability of magnesium alloys, it is possible to minimize undesirable effects such as stress shielding, soft tissue irritation, loosening, or osteopenia that can occur with standard implants [9]. One notable innovative material based on magnesium alloys is an osteosynthetic material called Magnezix (Syntellix AG, Hannover, Germany). Introduced in 2013, Magnezix was the first magnesium implant approved for human use [10]. The chemical composition of this magnesium alloy, known as MgYREZr or "WE43," comprises magnesium, zirconium, and rare earth elements (REEs) such as yttrium, gadolinium, and others [7]. Through this metallurgical process and alloying, the material achieves high strength and a certain degree of stability during degradation via corrosion processes [11].

Upon implantation into bone tissue, Magnezix undergoes resorption and degradation through corrosion, releasing hydrogen gas according to the equation: $Mg + 2H2O \rightarrow Mg(OH)2 + H2$ [9]. Subsequently, it is gradually replaced by new bone tissue. Studies have also demonstrated a certain degree of osteoinductive potential associated with this material. Complete degradation of the material occurs within one year, although radiographic evidence of degradation can be observed earlier [12,13]. Magnezix implants are available in four types: compression screws (Magnezix CS/CSc), pins (Magnezix Pin), cortical screws (Magnezix CBS), and implants for bone fusion (Magnezix StarFuse).

Therefore, this study investigates the cyclic loading of ankle implants and compares the load-bearing capacity of conventiona) and biodegradable implants in relation to the physiological loading experienced by healthy tissue.

2 Methodology

2.1 Preparation of Specimens and Implantation of Fixation Screws

In our laboratory study, we conducted a comparative analysis of the stability and properties between Magnezix CBS screws and standard cortical screws (ISO 58321E implant steel) for medial malleolus fractures of the ankle. Medial malleolar fractures are very common among the adult population and constitute approximately 9% of all fractures [14]. Surgical treatment, specifically open reduction and internal fixation, is widely recommended in recent literature for dislocated ankle fractures [13]. The common technique employed involves operative fixation using two cannulated screws for medial malleolus fractures [15]. However, other studies have indicated that the stability of medial malleolus osteosynthesis performed with fully pre-drilled cortical screws did not significantly differ [16].

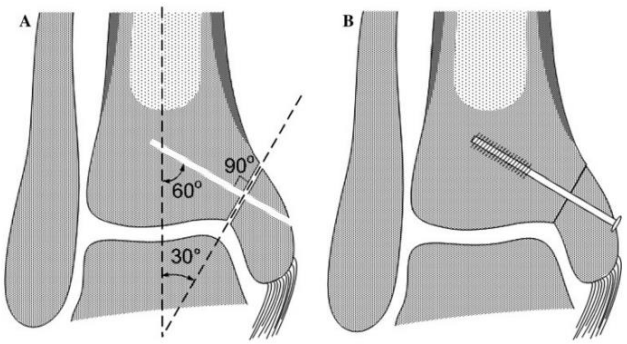


Fig. 1 A schematic representation of the osteotomy and osteosynthesis procedure.

Cadaveric bone, specifically the fresh-frozen distal third of the tibia, was utilized for this study. X-rays were conducted to confirm the absence of bone defects or traumatic focal changes in the tibial skeleton. The oblique osteotomy technique (Fig. 1) was selected as it closely simulates the characteristics of medial malleolus fractures and also serves as an approach to the talus articular surface. The osteotomy line was guided between the tibial plateau cartilage and the articular facet of the medial malleolus. Pre-drilled holes for future insertion of cortical screws were created using a 2.7 mm drill bit at a 60° angle relative to the tibia's long axis. Subsequently, the medial malleolus osteotomy was performed using an oscillating saw with a thin saw blade (0.4 mm width) to minimize bone loss. The saw osteotomy was guided at a 30° angle to the tibia's long axis, near the subchondral bone, and completed with an osteotome and thin chisel [12].

Next, osteosynthesis was carried out using two cortical screws, 40 mm in length and 3.5 mm in diameter. Each preparation was fixed using either two standard self-tapping cortical screws or two Magnezix CBS screws (38 or 40 mm length depending on the preparation size) with a diameter of 3.5 mm. The osteosynthesis was examined, and anteroposterior and lateral projection radiographs were obtained (Figs. 2 and 3).

Fig. 2 CT scan of applied screws into the tibial bone.

Fig. 3 Bone specimen with implanted screws.

2.2 Mechanical Testing of Biological Samples

The cyclic testing itself was conducted using a LiTeM machine at a frequency of 4 Hz. The amplitude of the applied forces was selected in accordance with previous studies by other authors [17,18], ranging from F_{min} = 10 N to F_{max} = 50 + X*25 N, where X represents the cycle number (0, 1, 2, ...). Each cycle consisted of 10,000 repetitions. The number of cycles continued until mechanical failure of the implants (Fig. 4) or the attainment of the maximum displacement of bone fragments, particularly in the case of chromium-nickel implants.

During the mechanical testing, the sample was placed in a custom-made holder and fixed using three screws at the epiphyseal region and a pair of screws at the diaphyseal region. The securely fastened sample within the inner housing was then stabilized in the optimal position using an outer housing and inserted into the jaws, ensuring overall system stability (Fig. 5).

Fig. 4 Final destruction of a magnesium implant.

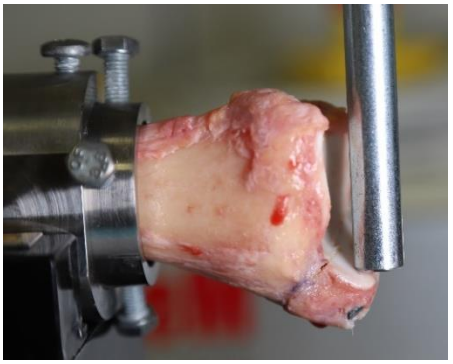


Fig. 5 Picture of real loading in the LiTeM machine.

Loading was generated based on a sinusoidal function, as depicted in Fig. 6. The mean value of the load was automatically increased during each loading cycle, corresponding to the starting position for the respective cycle. The loading direction is derived from studies focusing on fractures in the ankle region and considers the risk loading pattern [19].

3 Results

Mechanical testing revealed significant differences in the ultimate strength of fixation screws. As the testing was conducted on non-living specimens, the resulting values relate

solely to the mechanical properties of the implants and the quality of the corresponding bone material. The obtained graphs illustrate an increasing displacement of diverging fragments, attributed to partial compression and bending of the screw, resulting in progressive separation along the osteotomy line.

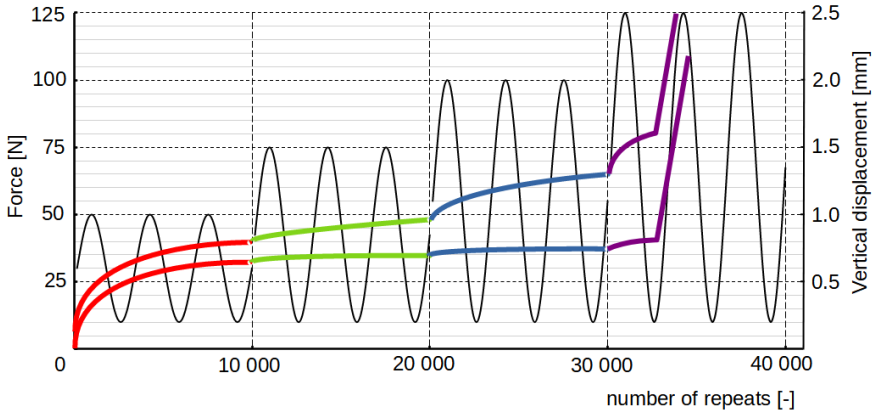


Fig. 6 A diagram depicting the cycles in relation to the applied load.

Fig. 6 presents a diagram depicting the cycles in relation to the applied load. The gradual increase in deformation is evident from Fig. 6, represented by the colored curve. This displacement was calculated based on local minima and maxima of the displacement function obtained from the load machine's displacement sensor. It should be noted that this displacement does not represent the absolute separation perpendicular to the osteotomy plane (Fig. 7). The analysis encompassed a total of six specimens, with three utilizing biodegradable screws (samples 1-3) and three employing chrome-nickel screws (samples 4-6).

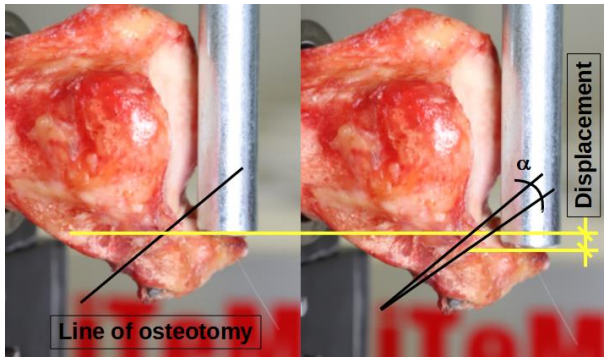


Fig. 7 The photographs of the loaded samples, indicating the osteotomy line, displacement, and the angle α representing the deviation of the fragment from the osteotomy line. The left image depicts a lower applied force compared to the right image, hence the noticeable non-zero displacement.

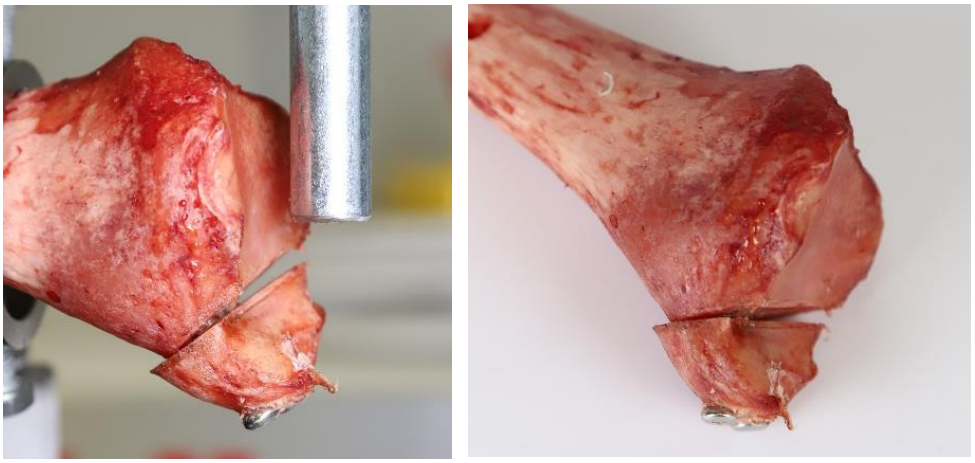
Table 1 summarizes the results of cyclic loading. For each cycle (10,000 repetitions), the maximum displacement value at the beginning and end of the respective cycle is provided. The table also presents the difference value between the initial and final displacement values in the respective cycle. However, the average value supplemented with the standard deviation is only informative due to the significant variation in the density of biological material.

Table 1. The final value for each sample represents the overall displacement for that particular specimen. For each cycle, the displacement values at the beginning and end of the cycle are provided.

material	sample	cycles 1	2	3	4	5	6
		Displacement [mm]					
Magnezix	1	1.08 1.67	1.91 1.96	2.84 3.49	* after ~ 21800 cycles		
	2	0.48 0.75	1.07 1.17	1.23 1.38	1.43 1.68	* after ~ 32500 cycles	
	3	1.05 1.28	1.61 1.81	2.53 3.06	* after ~ 21400 cycles		
	average difference	0.36 ± 0.16	0.12 ± 0.06	0.44 ± 0.21	0.25 ± x		
Stainless steel	4	0.39 0.78	1.05 1.27	1.54 1.83	2.13 2.52	2.83 4.14	4.73 5.32
	5	0.75 2.45	2.97 5.89	# after ~ 6800 cycles			
	6	1.22 2.19	2.87 6.43	6.82 8.27	# after ~ 12400 cycles		
	average difference	1.12 ± 0.67	2.23 ± 1.45	0.87 ± 0.58	0.39 ± x	1.31 ± x	0.59 ± x

* – implant failure due to fracture; # – failure due to excessive displacement

Results demonstrate that the evaluation of biological specimens requires a comprehensive approach, taking into account the varying quality of bone. Biodegradable samples 1 and 3 endured a similar number of cycles, with failure (Fig. 4) occurring at a displacement of approximately 3 mm. Sample 2, implanted in denser bone, exhibited significantly lower displacement values and a higher maximum number of repetitions. Greater differences were observed with the conventional screw application. Sample 6 failed after 20,000 repetitions, where no fatigue fracture of the screw occurred, but rather the loosening of the implant within the bone (Fig. 8). Similar failures were observed with samples 4 and 5, resulting in loss of screw fixation. Overall, implant failure in all cases occurred at a displacement of ~3 mm, with biodegradable implants achieving this displacement consistently over the course of repetitions.



(a) (b)

Fig. 8 Sample 4 after failure of the fixation in the osteotomy line, leading to implant embedding into the bone and significant fragment collapse.

Conclusion

This study revealed a significant difference in the fatigue strength between the conventional and biodegradable implants. The biodegradable implant withstands substantially lower

fatigue loads, but considering the actual load at the application site, its strength is sufficient throughout the healing process. Furthermore, the lower material stiffness positively influences the degree of surrounding bone tissue compression, resulting in less pronounced displacements compared to conventional implants. During the healing period, bone stress is lower compared to the physiological state, and the lower implant strength proves to be adequate. It can be assumed that stress gradually transfers from the implant to the bone during the healing process. Biodegradable screws present an intriguing alternative, but a larger sample size would be beneficial for further study. To confirm this study, it will be necessary to expand the number of samples tested. However, considering the availability of biological samples, this is a long-term process.

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