Applicability of Self-reinforced Polylactic Acid in Humeral Transcondylar Osteosynthesis

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The emergence of self reinforced polymers relaunched the osteosynthesis with resorbable materials, especially in the case of the long bone ends fractures. The improved mechanical resistance and the slow resorbtion are the main advantages compared with previous generations of bioresorbable materials. These qualities prompted us to conduct this study, which focuses on assessing the strength of new implants made of self reinforced polylactic acid (SR-PLA). The implants are designed for osteosynthesis of transcondylar fractures, one of the most common types of distal humerus fractures. Our innovation in terms of implants is to amend a malleolar bone screw so that it can be locked with a Kirschner wire or a thin screw. Thus, an assembly consisting of two screws of this type and a locking wire significantly increases the contact surface between the fragile epiphyseal bone and the implant. The study uses the finite element method and simulates the postoperative loading conditions of the bone-implant assembly. Two CAD models were created representing a stable and an unstable fracture fixed with these implants having the properties of SR-PLA. The models were imported, edited and analyzed in a state of the art finite element program. The evaluation of the interfragmentary displacements, normal stresses in bone and equivalent stresses in implants shows that the osteosynthesis of the stable fracture successfully bears the loads imposed on the entire arc of flexion-extension, while the unstable fracture fixation is fragile at the extremes of the range of motion. The weak point of both assemblies is the metaphyseal cancellous bone. For both models the screws made of SR-PLA held up very well in the given circumstances: the equivalent stresses were low relative to material mechanical resistance. SR-PLA appears as a suitable material for this type of osteosynthesis, but additional biomechanical studies are needed to confirm these results.

Keywords: self-reinforced polylactic acid, transcondylar fracture, finite element analysis

The distal humerus fractures are a critical part of the traumatology due to their incidence (roughly 2% of all limb fractures) and especially due to the challenges of their surgical treatment [19]. This treatment involves anatomical reduction and stable fixation, compatible with the early range of motion. The osteosyntheses with two parallel or perpendicular plates with screws are the current standard, mostly because they are highly effective in stabilizing complex fractures. For transcondylar fractures these osteosyntheses seem excessive, due to the aggressive approaches they necessitates, bulky implants and high cost. To address these drawbacks, we developed a new implant involving stabilization with two modified malleolar bone screws, which could be locked transversally by a Kirschner wire or a thin screw.

The two modified screws have almost identical configuration, the only difference being the length. Each screw has a proximal threaded end, an intermediate cylindrical body and a distal larger cylindrical end designed to accommodate the locking and guiding tools (fig. 1). The locking is achieved by means of a 3 mm Kirschner wire or a 3 mm screw which is guided through an oblong hole transfixing the distal end of the screw. One screw is inserted in each column of the distal humerus through a minimal incision and then locked. The locking Kirschner wire crosses the epiphysis and the two screws below the fracture line (fig. 2).

So far the assessment of this new method took into account only titanium alloy and 316L stainless steel

Fig. 1. The exterior aspect of the modified screw

Fig. 2. The anteroposterior X-ray image of a transcondylar fracture stabilized with two screws and a Kirschner wire

screws. The improvement of bioresorbable polymers (such as self reinforced polylactic acid) led us to evaluate their applicability for manufacturing the new type of implant we described above. One of the advantages of the bioresorbable materials over metals is the much lower risk of peri-implant demineralization due to their low Young modulus and also to their resorbtion which ranges between several weeks up to several years. The stress shielding is

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Fig. 3. Coronal section of model B

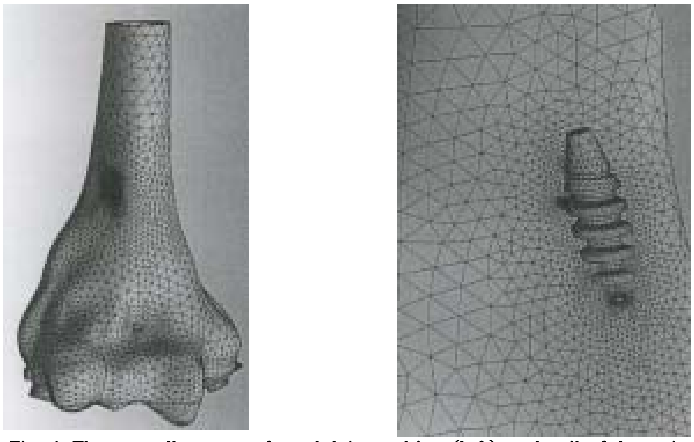

Fig. 4. The overall aspect of model A meshing (left); a detail of the exit area of the lateral column screw (right)

thus significantly decreased. The likelihood of diaphyseal humeral fracture is also diminished, as the humerus returns to its previous flexibility after the resorbtion of the implants (when metal implants are used the stress concentrations persist as long as the implants are not removed).

The self reinforced polymers like self reinforced polylactic acid (SR-PLA) are a significant advance over previous generations of biopolymers. They are especially useful in traumatology because of their improved mechanical resistance (with yield strength up to 789 MPa) [2, 8, 9, 24] and slow resorbtion (up to several years) [8, 9, 11]. The average healing time of a humeral transcondylar fracture is six to eight weeks. After eight weeks a screw made by SR-PLA exhibits minimal change of its mechanical properties.

Experimental part

The positive aspects mentioned above and the use of SR-PLA implants for the internal fixation of ankle fractures [4, 5, 10] have encouraged us to test the applicability of SR-PLA for the type of osteosynthesis described above. We performed a finite element analysis of SR-PLA osteosynthesis by simulating the postoperative loading of two transcondylar fractures, a stable and an unstable one, fixed with SR-PLA screws and a Kirschner wire.

The modeling of the humerus and implants

We used transverse-section images of a CT scan to create the 3D CAD model of the distal humerus. The model takes into account the different mechanical and biological properties of the two types of bone that make up the distal humerus, according to its structure: an outer shell of compact bone for epiphysis, metaphysis and diaphysis and a core of cancellous bone only for epiphysis and metaphysis (the epiphysis and metaphysis are composed of an outer layer of compact bone and a core of cancellous bone, while the diaphysis has only compact bone surrounding a central cavity. The bone marrow contained in this cavity was not modeled due to its insignificant mechanical resistance – fig. 3). The implants (the two screws and the Kirschner wire) were added to the model and embedded into the bone by creating cavities allowing for perfect matching. Two types of fractures were then created, a stable and an unstable one. The latter was achieved by subtracting a thin slice from the humerus, so that the proximal and distal fragments had no contact. Two solid models resulted: a stable and an unstable transcondylar fracture fixed with the same implant (model A and B respectively).

Next the models were imported into Ansys 14.0 for static finite element analysis (FEA). The element used for meshing was SOLID 187, suited for both brittle and ductile materials. In order to minimize the computation errors, small elements were used, with variable size and slow transition, according to conformational details and contact areas between bone and implants.

Test set-up

Each model has seven components: four osseous components and three SR-PLA components. The fracture line is situated approximately between epiphysis and metaphysis, so each bone fragment has two components. The three SR-PLA components are the two screws and the locking wire. While there was little uncertainty regarding the mechanical properties of compact bone, a tougher call had to be made for the cancellous bone and the SR-PLA. There is wide variation for both their yield strengths, with values ranging between 0.6-23 MPa for cancellous bone [6, 7, 14, 18, 25] and between 120-789 MPa for SR-PLA [2, 8, 9, 24]. The yield strength of cancellous bone is a function of its density [6, 25]. We chose the mechanical characteristics of a moderately demineralized bone with an apparent density of approximately 0.4 g/cm^3 (table 1). Both the compact and cancellous bone are considered isotropic, frequent practice for this type of study due to the complexity of dealing with anisotropic materials. The mechanical properties of SR-PLA depend upon the manufacturing process [2, 8, 9, 24]. Based on our previous experience [15], we used a high Young modulus for this material, in order to unload the metaphyseal cancellous bone adjacent to the screws.

The boundary conditions were defined according to the real connections between the components. The type of connection between the bone components and between implants and bone fragments allows no sliding or separation between faces or edges and is widely used in similar studies [12, 13, 20, 23]. Concerning the bone-implant

Table 1
MECHANICAL PROPERTIES OF THE MATERIALS USED IN THE ANALYSIS

	Young's modulus (MPa)	Poisson's ratio	Tensile yield stress (MPa)	Compressive yield stress (MPa)	Tensile ultimate strength (MPa)	Compressive ultimate strength (MPa)
SR-PLA	10000	0.3	240	300	-	-
Compact bone	13000	0.3	100	120	110	140
Cancellous bone	300	0.2	6	6.5	-	-

interface, this is justified by the solid anchorage of the screws in the proximal bone fragment and the distal "H" armature provided by the implant. For model B (unstable fracture) there is no contact between the two bone fragments. This configuration is currently used in FEA biomechanical studies. In case of model A the static analysis took into account the friction between the two bone fragments. There are very few studies regarding the bone to bone friction coefficient. Moreover, we have not found any study defining the friction coefficient between two fragments of cancellous bone. Instead, we followed the procedure used by Zhang et al. [26]. The values ranged between 0.9 up to 1.4 for a smooth interface. Considering that the friction coefficient is rather a system property than a material property, much higher values would be expected for a usual ragged fracture line. We considered a friction coefficient value of 1, conservatively, in order not to underestimate the sliding risk of an atypical regular fracture line. For compact bone-compact bone interface the friction coefficient value used in the analysis was 0.5.

The loading conditions were simulated according to the actual forces acting on the joint surfaces during postoperative rehabilitation. The humerus was anchored at its cranial end, about 10 cm cranial to the joint line. The forces acting in the sagittal plane (during active flexion and extension) were then applied. These are the most important forces and are often the only taken into account in biomechanical studies [17, 20, 21]. Their magnitude and orientation were drawn from the 1980 key study of Amis et al. [1]. There are distinct values and orientations for trochlear and capitellar reaction forces. These forces are a function of elbow position and instant of movement. In our static analysis we considered elbow reaction forces corresponding to a 10 N load applied at the hand for four elbow positions, each taking flexion and extension into consideration; the magnitude and orientation of the forces

Fig. 5. The forces acting on capitulum and trochlea in extension from 0^0; anteromedial view of model A

acting on the distal fragment are depicted in the table 2. The values are similar to those mentioned in previous studies [1, 3, 16].

Results and discussions

Usually, the aim of biomechanical tests (either in vitro or by FEA) is the assessment of bone-implant assembly stability. This is accomplished by detecting the displacements, implant breakage or bone fragments refracturing [17, 20-22]. The finite element analyses usually test the stability by measuring the bone and implant stress values [12, 13, 20, 23]. In the present study we evaluated the interfragmentary displacements, equivalent stress (von Mises) in implants and maximum principal normal stress values in bone fragments (maximum principal normal stress being more suitable than equivalent stress for brittle materials like bone). For a better assessment of implant and bone loading, we used safety factor maps. The safety factor is defined as the ratio between the tensile yield value and the stress value at a given node (von Mises stress for implant and maximum principal normal stress in bone). The results are shown in table 3, figures 6 and 7.

The displacements between the two fracture fragments are negligible for both models in all eight loading cases, less than 0.1 mm. These are too small to preclude the fracture healing in vivo.

The maximum equivalent stresses in implants are well below the elastic limit of the material in model A (minimum recorded Sf=13.2), unsurprisingly given the high yield strength of SR-PLA, comparable to that of austenitic alloys. In model B the von Mises stresses are higher, but again below the yield strength of SR-PLA (minimum Sf=1.8). These values render an in vivo implant failure very improbable in the given loading conditions. As expected, the highest von Mises stress values were located in the screws, adjacent to the fracture line.

The maximum principal stress in bone is well below its yield strength in model A (Sf=2.71). In model B the maximum principal stress exceeds significantly the yield strength in several cases (minimum Sf=0.36 - fig. 7). For both models, the highest maximum principal stresses occur in the cancellous bone of the proximal fragment, next to the screws. The high maximum principal normal stress values occurring in model B makes probable in vivo cancellous bone compaction and subsequent osteosynthesis failure. With respect to these results, it is wise to restrict the osteosynthesis with SR-PLA screws to stable

Table 2

MAGNITUDE (in N) AND ORIENTATION OF THE REACTION FORCES IN THE SAGITTAL PLANE; THE SECOND VALUES INDICATE THE ANGLE BETWEEN THE DIRECTION OF THE FORCE AND HUMERAL CAUDOCRANIAL AXIS; A NEGATIVE ANGLE INDICATES AN ANTERIOR DIRECTION

Position	Flexion		Extension	
	Trochlea	Capitulum	Trochlea	Capitulum
0^0	$114/-20^0$	$-8/-8^0$	$122/-13^0$	$86/0^0$
30^0	$102/4^0$	$135/19^0$	$122/-13^0$	$86/28^0$
90^0	$55/30^0$	$80/75^0$	$172/5^0$	$86/83^0$
120^0	$55/30^0$	$66/105^0$	$206/33^0$	$86/111^0$

Table 3

VON MISES STRESS FOR IMPLANTS

	Flexion from 0^0	Flexion from 30^0	Flexion from 90^0	Flexion from 120^0	Extension from 120^0	Extension from 90^0	Extension from 30^0	Extension from 0^0
Von Mises (MPa) Model A	18.15	7.88	6.96	9.53	12.25	5.31	10.57	13.65
Von Mises (MPa) Model B	132.92	93.8	12	20.95	18.75	45.4	86.93	106.2

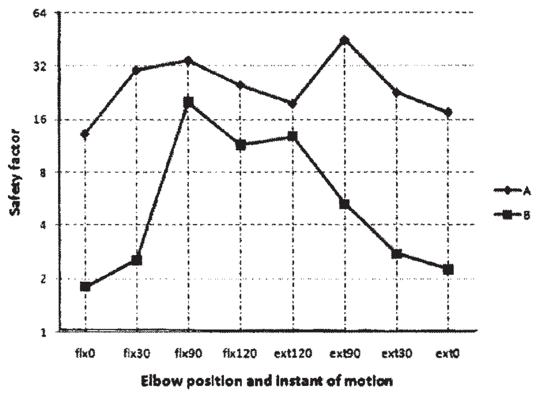

Fig. 6. Minimum Safety factor recorded in implants

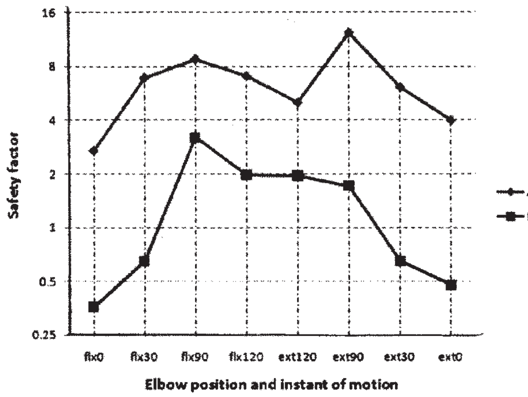

Fig. 7. Minimum Safety factor recorded in bone

Fig. 8 Inferior view of the proximal fragment and implants (model B), after removing the distal fragment. Safety criterion during flexion from 0^0

Fig. 9 Anterior view of the implants in model A illustrating the loading of the screws (after bone removal). Equivalent stress during extension from 0^0

transcondylar fractures, at least in case of demineralized bone.

Results from other studies are not available, since this novel implant has not been tested for SR-PLA manufacturing, making any comparison impossible. The same holds for studies using FEA to test the elbow osteosyntheses in conditions similar to in vivo loading. The results remain to be confirmed by future biomechanical studies.

For both models, the highest stress values are recorded during flexion and extension from 0^0 and 30^0 (fig. 8, 9) This is a secondary finding of the analysis and reflects the results of previous biomechanical studies [1, 3, 16].

The test limitations are mainly those specific to a FEA study. One of the most important ones derives from the structural and mechanical properties of the bone tissue. We considered the bone homogenous and isotropic since this is customary in FEA studies [12, 13, 20, 23].

Secondly, the bone-implant contact areas were bonded, assuming that no sliding exists. This approximation does not appear excessive when considering the tight anchoring of the screws in compact bone.

Another source of error is the magnitude of the friction between the bone fragments, for which we considered a rather low value. The test set-up considered neither an irregular fracture line nor the favorable fracture compression achieved by the implants. In vivo, both of these factors would decrease the fracture slippage risk and unload the assembly.

Conclusions

The SR-PLA appears a suitable material for this kind of implants considered in this study. The screws were found suitable to withstand even the high loads imposed by an unstable osteosynthesis, due to the improved stiffness compared to the previous generations of bioresorbable polymers. However, the implant should be avoided in the unstable transcondylar fractures of demineralized bone, as the risk of metaphyseal refracturing is high during 0^0-30^0 active movements. For stable fractures, the bone-implant assembly behaved well in all given loading conditions, with a low risk of failure. The small displacements, principal and equivalent stresses in the stable osteosynthesis make us confident that these favorable results will be replicated in the forthcoming in vitro and clinical studies.

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