A new screw and technique for the treatment of ruptured multiaxial joint ligaments. A preliminary study on the Scapholunate dissociation of the wrist

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Abstract

A wide range of techniques on ligament reconstruction have been proposed, summarized in three main categories: The direct suturing or indirect reconstruction of the ligament using adjuvant devices, the "biological ligament " substitution with the use of autografts or allograft and the "artificial ligament substitution", with polyester fibers. We propose a new orthopedic screw, the Flexy Screw (FS) and the FS technique for repairing unstable joints due to ligament damage. The tools used for the FS insertion and removal, is all included in the overall flexyscrew system (FSS).

In this work we have particularly developed the FS technique for the scapholunate ligament rupture (SLR). The value 18.03N/mm (SD9.6) for the linear elastic mean stiffness for the SLIL, and 14.4N/mm for the FS, furthermore the FS max load 138N at 10mm, in comparison with the average elastic limit of 47N at 3mm for the SLIL are considered satisfactory.

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Furthermore, the FS technique is aiming to be applied in a wide spectrum of unstable joints needing “ligament substitution”, because, as a mechanical orthopedic device can be adapted in order to simulate more closely the physiological mechanical properties of the ligaments.

Keywords: Scapholunate, FLEXYSCREW, orthopedic, ligament, instability, treatment, device, spring, joint.

Introduction

The fallen in the outstretched hand especially in extension, ulnar deviation, and intercarpal supination, produces a spectrum of carpal injuries-carpal or perilunate instability. Five distinct stages have been described [1,2]: **stage I**: scapholunate dissociation (SLD). Characterized by, rotatory subluxation of the scaphoid, disruption of the scapholunate ligament (SLIL) and scaphoid rotation due to rupture of the radioscaphoid and scapholunate ligaments, **stage II**: perilunate dislocation. Characterized by, disruption of the capitolunate joint and lunate projection through the Space of Poirier. Normally the lunate remains aligned to the distal radius and the remaining carpal bones are dislocated (almost always dorsally), **stage III**: midcarpal dislocation. Characterized by, triquetrolunate interosseous ligament disruption or triquetral fracture where neither the capitate nor the lunate are aligned with the distal radius, **stage IV**: lunate dislocation (the end stage of progressive perilunate dislocation) where the dorsal radiolunate ligament (dRL) has been injured and the lunate has been dislocated in the palmar direction.

It is obvious from the above stages that the damage of the wrist is a complex phenomenon and involves a large number of interconnected system of joints and ligaments with various rotational and translational spectrum of dislocations. Therefore, stage I, which is of main interest of the study, is further classified by Kuo and Wolfe[3] in five (sub)stages[4] trying to describe a broad spectrum in the SL lesion, with the proposed treatment: **stage Ia**: Occult-partial, Scapholunate Ligament Rupture (SLR) treated with pinning or capsulodesis, **stage Ib**: Dynamic-incompetent or complete SLIL, where partial, volar extrinsic ligaments ruptured, and are treated with ligament repair with capsulodesis**, stage Ic**: SL dissociation, complete SLIL, where volar or dorsal extrinsic ligaments are ruptured (SL gap>3mm), and is treated with capsulodesis vs triligament reconstruction, **stage Id**: refers to the dorsal intercalated segment instability (DISI) lesion, where complete SLIL, volar extrinsic ligaments, there are also, secondary changes in radiolunate joint, SchaphoTrapeziumTrapezoid (STT) ligament rupture, dorsal ligaments rupture, SL angle>60^0, SL gap >3mm, RadioLunate-(RL) angle>15^o treated with triligament reconstruction or fusion, **stage Ie**: scapholunate advanced collapse (SLAC), where the ligaments as in stage Id, is treated with proximal row carpectomy (PRC) or fusion. Other

authors[5-8] give alternatively four distinct classification stages, for the SL injury and the results of the reconstruction are related to the technique used in each stage.
Especially, Garcia Elias et al.[9] described six stages of SL injuries and the technique as follows: Stage I: Partial SL injury. No dynamic or static gap is presented.
Stage IIa: Complete SL injury with repairable dorsal SL ligament (Acute). No dynamic or static gap is presented.
Stage IIb: Perilunate dislocation with repairable dorsal SL ligament (Acute). Dislocation of the lunate, complete SL disruption. The radioscaphocapitate ligament (RSC) ruptured. The d-SL is repairable.
Stage IIc: Complete SL disruption with d-SL repairable and reducible rotator Scaphoid subluxation. Dynamic and/or static gapping present.
Stage III: Complete non repairable SL injury with normally aligned scaphoid. No static gapping present.
Stage IV: Complete non repairable SL injury with reducible rotatory scaphoid subluxation. Complete SL disruption and disruption of the secondary stabilized ligaments e.g. dorsal inercarpal lig. (DIC), radioscapholunate lig. (RSL), STT, scaphocapitate (SC) ligaments. Dynamic and/or static gapping may be present. The scaphoid may be displaced dorsally during motion.
Stage V: Complete non repairable SL injury with irreducible rotatory misalignment but normal cartilage. As the previous stage mentioned with static gapping.
Stage VI: Complete non repairable SL injury with irreducible rotatory misalignment but with cartilage decay (SLAC). As the previous stage, with static and/or dynamic gapping may be present. Radioscaphoid (RSc) angle greater than 45^o and the lunate is extended in DISI.
Also according to arthroscopic findings of the injury there are four grades of ligament SL injury [10,11].
The grade of ligament injury can unveil treatment, however, a better guide is considered to be the period since injury occurred, which is best defined as follows: acute-less than 4 weeks since injury, sub-acute-4-24 weeks since injury, chronic-more than 6 months. The earlier the ligament repair takes place, the easier it is to perform a direct repair[12].
For the stages Ib, Ic, and Id of Kuo and Wolfe classification system, alternatively, for the II, III, IV, and V of Garcia Elias classification system, the reconstruction techniques of the Scapholunate Ligament Rupture (SLR) [13-16] have been proved insufficient with many complications[17] depending on the method used. From the anatomic point of view the SLIL consists of a system of individual ligaments, the dorsal (d-SL), intermediate (i-SL), and the palmar portion (p-SL) [18]. Most techniques in the SLR, reconstruct only the dorsal portion of the ligament, leaving the palmar portion unrepaired, and as it has been discussed this kind of repair mechanically falls short[19].
The purpose of this work is to present a new orthopedic flexible screw, the FlexyScrew (FS) with the tools for insertion/removal and the overall technique (FS technique) for a more efficient treatment of the above mentioned stages of injury, via a “mechanical substitution” of the torn SLIL, with the FS. Also, the FS technique for the SLD, provides a preliminary study which further aims the awareness of reconstructing the unstable joints, oughting to ligament

insufficiency, with a “mechanical device” so that, the proposed technique could be also extended in the treatment of various other unstable joints. The rationale behind the insertion of the FS into the unstable joints, is to simplify and improve the effectiveness of the current surgical techniques.

The FS is designed to simulate the biomechanical behavior of the specific torn ligament so as to be able to replace the function of the ligament.

Although the ligament force-displacement is not linear [20] its behavior can be approximated by the use of a simple spring which is designed to have an average modulus, between the low and high moduli of the ligament. This device, is a new type of orthopedic screw which is flexible in the middle section with the use of a spring. The tools used for the FS insertion and removal, is all included in the overall flexyscrew system (FSS) [21-23]. The FS Fig.1, has the ability to allow bending, rotation and extension in three dimensions, as a real ligament acts, and also has the advantage of minimal invasive insertion technique.

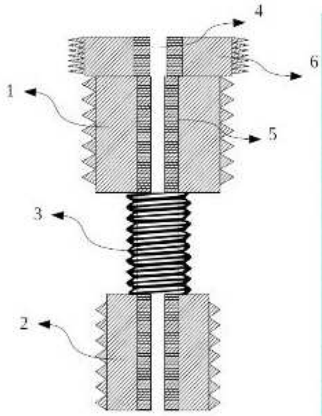


Fig 1a.Schematic presentation of FS. The middle part 3 is the spring-flexible part simulating the biomechanical properties of the SLIL

Fig 1b. The FS prototype. Notice the spring in the middle

Fig 1c. Cross-section of the cannulated hexagonal shape

Material & Methods

1. Cadaveric SLIL specimens

Biomechanical data, in uniaxial tension Fig 2a from 7 fresh frozen cadaveric SLIL was used in order to determine the spring parameters of the FS. The extracted values [24,25] were 18.03N/mm (SD9.6) for the linear elastic mean stiffness, 147N (SD54) for the ultimate load and 8.01mm for the ultimate displacement to rupture.

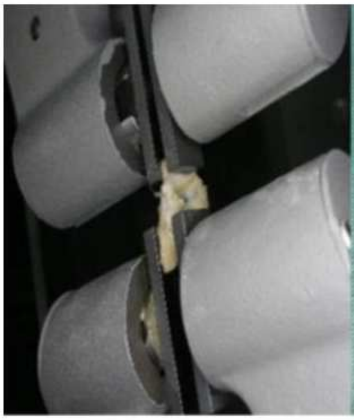


Fig 2a.Uniaxial tension of SLIL

Fig 2b.FS in bending and rotating. A k-wire inserted through the cannula.

Also, two out of seven specimens were tested to successive small increments of strain in cyclic loading (Fig 6a,b), in order to determine the transition point from the elastic to the plastic/damage range. High hysteresis levels indicate the point of plastic/damage initiation. The estimated average values for the maximum load and the maximum displacement in the elastic region, were 47N and 3mm respectively. These biomechanical parameters indicate the working elastic limit of the spring

2. Description of FSS

The FS Fig1a, consists of two screw ends (1), (2) made from suitable stainless steel alloy 316 Fig.1b or titanium or other compatible orthopedic material and can have various diameters, lengths Table 1, and pitches allowing controlled pulling of the two bones.

Table 1. The dimensions of the FS

Overall Length (mm)	External diameter (mm)	Core (mm)	Spring length (mm)
30	8	4	3

The two screw ends, are connected with a flexible part-spring (3) shown in Fig 1a,b, which approximates biomechanically the SL. The screw Fig.1a,c is cannulated (4), for the insertion of the two types of K-wires with two different diameters.

The cannula Fig.1a has internally hexagonal shape (5), in order to fit to the hexagonal screwdriver. In this way both ends of the FS are rotated simultaneously with the help of the screwdriver. The FS Fig.2b spring constant is determined from the existing tension-extension data for the SL. The distal end of one of the guide wires (the one with the small diameter) is specially marked with numbered notches (visible in fluoroscopy) to decipher the lengths of the threaded ends, the spring and the overall screw.

The screw driver Fig 3a,b is also cannulated and can accept the two k-wires of the different diameters.

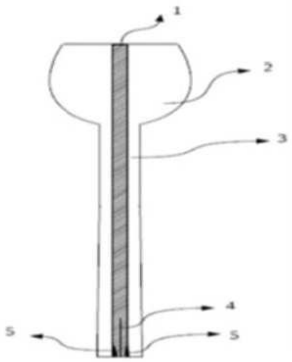


Fig 3a. Schematic presentation of the screwdriver for the insertion and removal of the FS. Notice the special notch 5 at the orifice

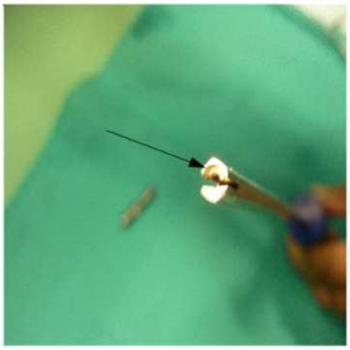


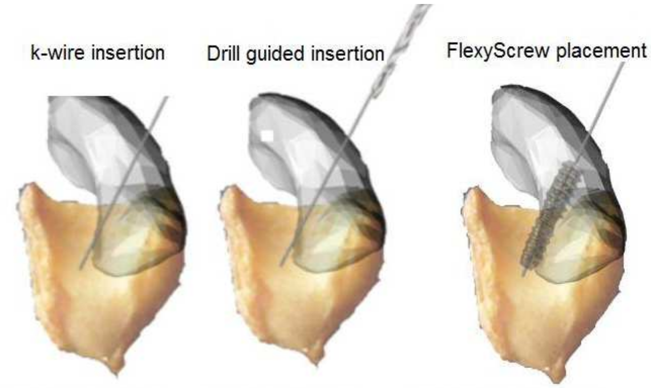
Fig 3b. Detail of the end of the screwdriver. Notice the slot and the wedge configuration of the end (arrow)

The thinner k-wire, is used as a guide for the insertion of the screw in the appropriate position and the thicker “securing K-wire”, is used for the removal of the FS. The “securing k-wire” acts as a wedge, so that it opens the lower slot of the distal end of the screwdriver Fig2b. In this way a firm friction contact is secured, between the screwdriver and the distal end of the FS. Wedge interlocking of the distal threaded part of the FS, secures the steady axial gripping and the pulling back of the screw while unscrewing for removal, when needed.

3. Method of insertion and removal of FS

The FS is inserted and anchored with the two screw ends on both bone sides of the SL joint using the Minimal Invasive Surgery (MIS) method. The flexible section of the FS, Fig 2b is surgically inserted in the joint space of the SL connecting the two bones, Scaphoid (Sc) and Lunate (L).

The proposed technique Fig 4 for insertion has 3 stages:



Stage 1. Minimal invasive insertion of the guide wire

Stage 2.Drilling through the guide wire

Stage 3.Insertion of the FS with the middle portion in the joint space

Fig 4. Schematic representation. MIS for insertion of the FS

Stage 1. Reduction and Insertion of the guide k-wire. The reduction can be performed, after traction of the wrist, using either open or closed method. It is important before the insertion of the FS to restore the normal bony anatomy and repair the soft-tissue damage. The lunate must be pinned with a 0.062 in. K-wire in order to manipulate it as a joy stick trying to neutralize and align the RL joint. Using another k-wire, the pinning of the lunate to the radius offers sometimes an additional help for securing the reduction. The scaphoid also with pinning must be reduced to the scaphoid fossa of the radius. The lunotriquetal ligament (LT) must not be violated. The reduction can maintained with a Kocher clamp. Possible reduction of the SL disassociation can be performed also by external methods (e.g. manipulation of the wrist) with simultaneous traction. If the closed reduction fails we must proceed to open reduction using the dorsal approach. After the reduction of the Sc and L bones the position of the guide wire under image intensifier (c-arm) has to be inserted through the bony masses. The insertion of the guide wires accomplished with a standard technique [26-28]. The markers of the guide wire define the overall length of the FS which bridges the two bones and the appropriate length of the spring which must be laid in the SL joint space. Stage 2. Insertion of the FS which can be self drilling and self-tapping. Otherwise drilling is needed. A radial styloidectomy can be performed in order to facilitate the placement of the FS screw. The insertion point of the FS is proximal to the site that would be used for fixation of scaphoid fractures. The average length of FS is 22-28 mm. An awl maybe used to create a pilot starting point for anchoring the FS. The position of the screw should be as central as possible in both the scaphoid and the lunate, following the RASL procedure[29]. Stage 3. The flexible portion of the FS is centralized in the joint space, and the position is checked under image intensifier.

The proposed technique for removal has 3 stages:
Stage 1: Insertion of the thin guide wire through the proximal and the distal end of the FS.
Stage 2: Insertion of the screwdriver through the guide wire. Stage 3: Removal of the thin guide wire and insertion of the securing K-wire. Locking the distal threaded portion of the FS,

facilitates the axial pulling out, as it prohibits any “idle” rotation of the screw into the bone mass, during unscrewing.

4. Experimental results

Testing of the FS was performed in quasi-static uniaxial tensile loading. The test was performed on a computerized electromechanical testing machine (model 1121; Instron, USA), Fig.5 with 1000 N Load Cell, equipped with wedge mechanical grips. Load and displacement for the FS were recorded with a data acquisition system.

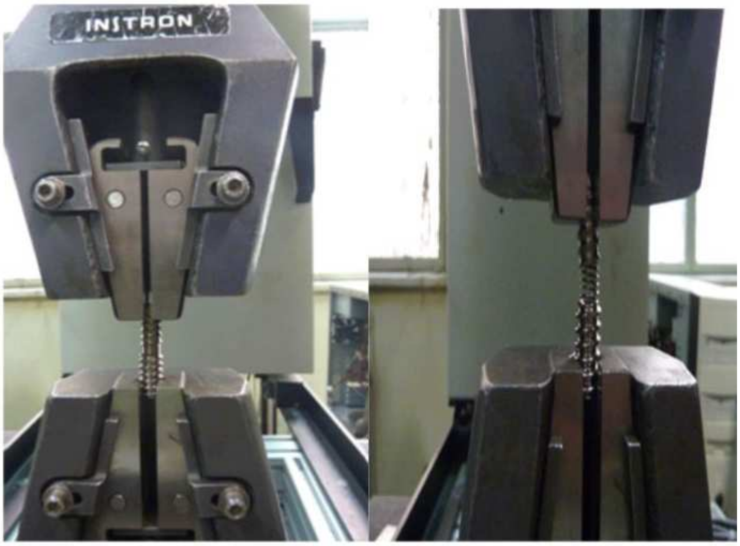


Fig 5. The FS testing in uniaxial extension. Left: In compression Right: In tension

The grip speed was constant at 5 mm/min. Loading was performed in the linear elastic region of the Flexy Screw-spring, in the plastic region (cycles 2 and 3) Fig. 6c and up to final failure. The maximum elastic load was found to be approximately 45N at 3mm displacement. The stiffness in the elastic region was found to be 14.4N/mm. In the plastic region there is a drop of the stiffness with hardening up to fracture at 600N.

Also for the SLIL specimens ko5 and ko6 in cycling loading, it is observed that the elastic/plastic transition occurs at about 3-4mm and further extension results in damage of the collagen fibres which is depicted in the plastic-like response of the curves Fig.6a,b without return to the initial elastic position.

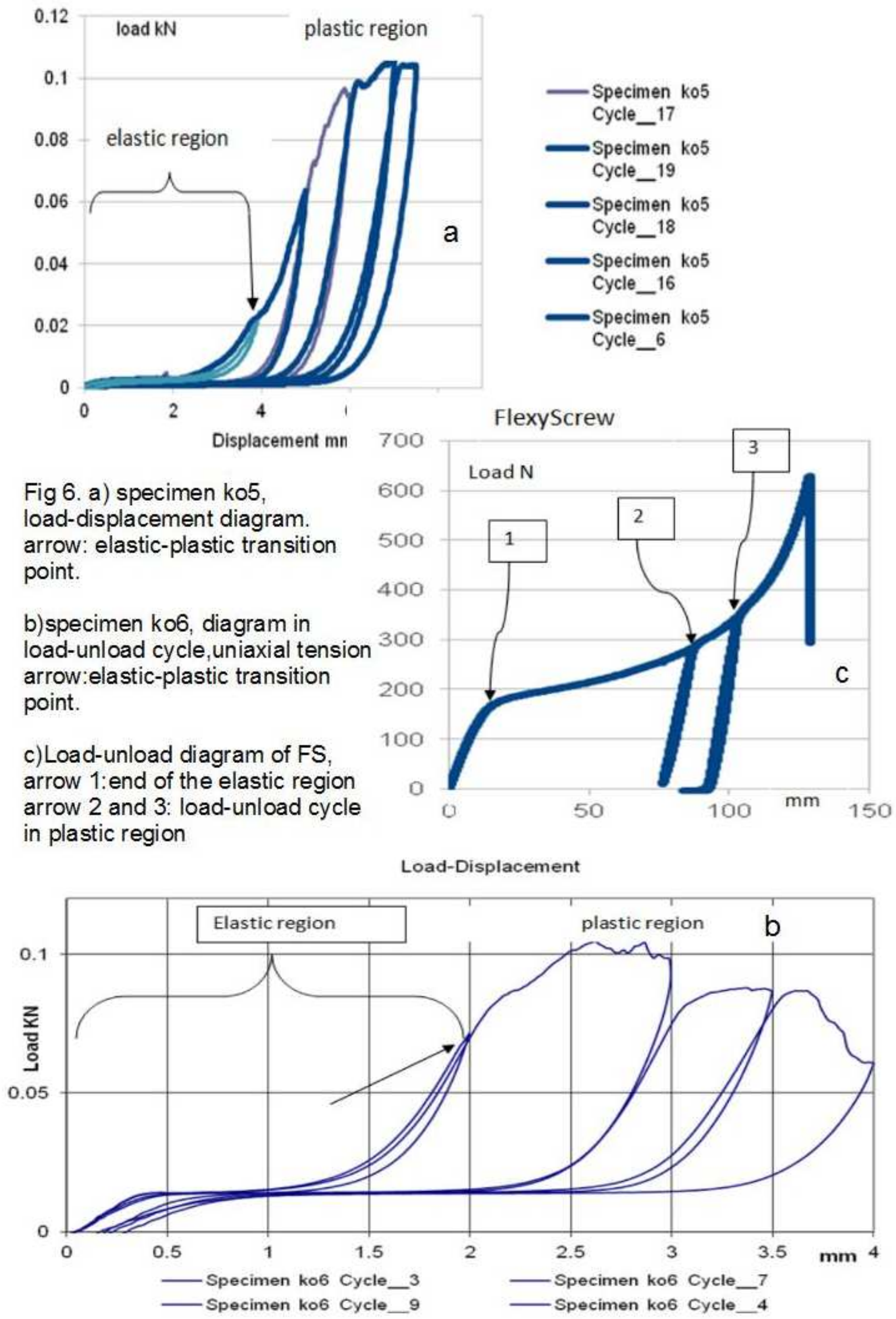


Fig 6. a) specimen ko5, load-displacement diagram. arrow: elastic-plastic transition point.

b)specimen ko6, diagram in load-unload cycle,uniaxial tension arrow:elastic-plastic transition point.

c)Load-unload diagram of FS, arrow 1:end of the elastic region arrow 2 and 3: load-unload cycle in plastic region

For this reason the FS is designed to approach this elastic response of the ligament having a max load higher than the SLIL max load.

Discussion

The proposed new orthopedic screw, the FS, is designed and constructed in order to improve and assist current techniques being state of the art for the SLIL reconstruction. In particular, concerning the SLIL reconstruction with the Reduction and Association of the SLIL (RASL) [30] technique, the SL joint is stabilized using the Herbert screw. The non threaded part of the screw has to be laid in the SL joint space, keeping it fixed. On the other hand, the FS, allows the micromotion of the SL joint, and makes the reconstruction kinematically more functional, permitting the relative micromotion of the articular surfaces of the SL joint during the various wrist positions[31].

Brunelli [32] and Blatt [8] procedures use autografts and reconstruct the joint with the use of flexor carpi radialis (FCR) tendon and the dorsal capsular flap (Dorsal Capsoulodesis). According to the Brunelli technique the FCR tendon is split longitudinally and a 7 cm tendon slip is prepared, preserving its distal attachment to the base of the second metacarpal. The tendon slip is passed through a 2.5 mm diameter tunnel drilled in the distal pole of the scaphoid and anchored on the dorsoulnar edge of the radius. A pitfall of this technique is that the tendon graft does not have the same material properties as the SL ligament and the tendon may stretch, leading to loss of reduction with resulting instability and pain. The Blatt procedure is used for acute or chronic, static or dynamic SL instability. A dorsal proximally based capsular flap 10-15 mm, is mobilized with the distal margin at the STT joint. A trough on the dorsal aspect of distal pole of scaphoid is created and the capsule is sutured, in the trough using anchors, after the reduction of the SL joint with the usual manner. A difficulty in this technique is to estimate the width of the capsular flap, which should be as wide as the distal pole of the scaphoid.

Patients with symptomatic dynamic dissociation, without arthritis at the RSC and STT joints can be treated with bone-graft-bone autograft reconstruction. [33, 34]. These methods do not appear to do well due to the tension on the graft as a result of the significant soft tissue and bony changes that occurred in long standing SLD. Studies indicate that this kind of autograft from the distal radius, maybe significantly weaker and less stiff than the SL ligament. Cadaveric studies show that caprometacarpal and navicular-first cuneiform are closer to the biomechanical properties of the SL ligament. On the other hand, FS can be manufactured in such a way, as to have exactly the same or even higher moduli and strength than the actual SL ligament.

The FS, can be used as an autonomous mechanical device implanted in the approximate centre of gyration of the joint, defined from the adjacent cartilage surfaces of the Sc and L bones as described in stage 2 of the technique or can be used as an adjuvant device at non satisfactory direct ligament repair suturing. For example in cases with partial rupture of the SLIL (e.g p-SL intact with un-repairable d-SL).

There are also other proposals [35], in the literature, for assisting the reconstruction of the SLIL, as for example the use of the SL Intercarpal (SLIC Screw) System [14], which consists of a cannulated cylinder-in-cylinder screw design which allows some degree of rotation and flexion. However the SLIC screw is inextensible without the trend of returning to the equilibrium position and cannot be used as permanent reconstruction thus must be removed after the healing of the ligament.

The kinematics of the SL joint has been extensively studied with various methods of experimental measurement, cadaveric or in vivo. Two basic methods of kinematic description are used, the absolute intraosseous 3D motion of the scaphoid[36] and the relative 3D motion of the Sc to L bone[37,38]. Relative scapholunate rotation was found to be 14.7° ± 6.7° in 60° wrist flexion-extension and ±3mm translation from the neutral position [39]. This relative 3D motion of the SL joint, is reproduced by the FS, which comprises of a mechanical coupling with the spring mid section part, and provides: a) tension-compression, b) rotation and bending with mechanical assisted return" to the equilibrium position, as in the case of the natural properties of the ligament.

In general the flexible elastic part (spring) of the FS offers all possible 3D degrees of freedom. The physical motion of the spring has been extensively studied and covers all the above 3D micromotions i.e tension-extension, bending and rotation.[40]. Especially, the spring has been manufactured having a stiffness constant equal to that of the SL ligament-joint. This stiffness is experimentally acquired from uniaxial tension of the cadaveric SLIL, reproducing the typical model of capitate intrusion injury [24].

It is evident that there are similarities as well as differences Fig.6 between FS and SLIL. The stiffness for the SLIL and the FS at average 18N/mm and 14.4N/mm respectively , are considered satisfactory. This difference can be further improved and adjusted as desired, with the appropriate choice of the alloy and the geometry of the spring. Furthermore the FS max load at 138N and displacement at 10mm, in the elastic region, is considered satisfactory, in comparison with the average elastic limit of 47N at 3mm of the SLIL, since the screw is allowed to work at a higher elastic range.

A limitation for the FS could be considered the linear elastic behavior contrary to the non linear elasticity Fig 6 of the ligament [41]. In other words only the average stiffness of the SLIL can be simulated by FS and this could be considered a limitation of the technique.

Future work should aim to the implementation of the FS into the cadaveric SL joint specimens, for a more detailed biomechanical study, in order to optimize the stiffness, geometry and materials for the device.

A major advantage of the FS technique is the use of Minimal Invasive Surgery (MIS) accompanied by non autograft use, lead to limited surgical iatrogenic damage. It should be noted that all the above techniques including the FS, reveal a major difficulty, which is the appropriate reduction of the SL joint. The posteroanterior x-ray with an apparent SL diastasis and a lateral radiograph with a normal or not RL angle (i.e. lunate that is not dorsiflexed) has to be checked and corrected if needed. Another advantage of the FS technique is that, it can be used as a general method of repair rupture ligaments and can be applied to other joints like the knee or coracoacromial joint etc. For each type of ligament new design parameters (dimensions, spring stiffness and strength, threads, material) will be applied. For instance, we have different properties for the anterior cruciate ligament of the knee and for the coracoacromial ligament. A predominant technique today, for the knee cruciate knee ligament reconstruction is the Ligament Augmentation Reinforcement System (LARS), with or without the use of autografts. The extensibility of this material is rather limited, compared to the natural ligament, resulting in impulsive forces which may lead to unavoidable early failure.

Mathys Ltd Bettlach Co has developed a type of screw which is inserted into the tibia tunnel, consisting of a spring, so it can absorb the impulsive forces during flexion and extension of the knee[42]. However, this development does not concern small joint reconstruction as the carpal joints and basically is a structural composition of a uniaxial spring mechanism.

Conclusion

The FS technique is a new proposal for a mechanical reconstruction of the SLR providing a simultaneous micromotion in *bending, rotation and tension-compression, with self-return to the equilibrium position.* Thus, FS closely reproduces the physical kinematics of the joint. Therefore, the FS technique could possibly offer a simpler, easier and more advanced method of ligament substitution in trauma surgery.
Furthermore, the FS technique is aiming to be applied in a wide spectrum of unstable joints needing “ligament substitution”, because, as a mechanical orthopedic device can be adapted in order to simulate more closely the physiological mechanical properties of the ligaments.

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Figure Legends

Fig.1a. Schematic presentation of the FS. The middle part 3 is the spring- flexible part of the screw simulating the biomechanical properties of the SLIL.

Fig.1b.The FS prototype. Notice the spring in the middle part.

Fig.1c.Cross-section of the cannulated hexagonal FS

Fig 2a. Uniaxial tension of SLIL.
Fig 2b. FS in bending, and rotating. A k-wire inserted through the cannula.

Fig 3a. Schematic presentation of the screwdriver for the insertion and removal of the FS. Notice the special notch 5 at the orifice.

Fig.3b. Detail of the end of the screwdriver. Notice the slot and the wedge configuration of the end (arrow).

Fig 4. Schematic presentation. MIS for insertion of the FS

Fig 5. The FS testing in uniaxial extension.
Left: In compression. Right:In tension.

Fig 6a. specimen ko5, load-displacement diagram, arrow: elastic-plastic transition point.

Fig 6b. specimen ko6, diagram in load-unload cycle, uniaxial tension, arrow: elastic-plastic transition point.

Fig 6c. Load-unload diagram of FS, arrows: 1. end of the elastic region, arrow: 2 and 3 load-unload cycle in plastic region.

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