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New method for medical devices design and manufacture: Case study—scapholunate implant

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Abstract

The scapholunate interosseous ligament is located between the scaphoid and lunate bones and if it torns causes instability, leading to weakness in the hand, chronic pain, and lack of motion. While many treatment options are available, based on the type of instability, all of them present side effects including stiffness in the wrist, long recovery times, and widespread scarring. As such, wrist prostheses have been introduced as an alternative treatment. As suitable scapholunate prostheses implanted using arthroscopy are a promising option in reducing complications associated with conservative treatments, this work proposes a new implant designed to replace the scapholunate ligament. The implant is a completely new design, which was manufactured to determine its workability. Medical experts and engineers approved and validated the new design process, and the prototype obtained will be used to evaluate performance and to propose possible future improvements.

Keywords

Scapholunate ligament, scapholunate instability, wrist prosthesis, arthroscopic surgery, prosthesis design

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Introduction

Thanks to its complex anatomy of 15 bones and more than 20 articulations, the wrist is one of the most frequently injured human joints. Carpal motion is based on joint surface configuration, static stabilizers (ligaments), passive forces, and loads, which control kinematics between carpal bones.[1] After falling on an outstretched pronated hand, carpal bones may lose their normal alignment, resulting in the disruption of normal motion known as carpal instability. In a normal situation, the angle between the scaphoid and lunate carpal bones ranges from 30° to 60°. However, when the scaphoid flexes and the lunate extends, this angle may increase by more than 70° or 80°, thus inducing instability. Based on the Mayo Classification, there are four major carpal instabilities: (1) Carpal Instability Dissociative (CID)—instability within a row of carpal bones, (2) Carpal Instability Non-Dissociative (CIND)—instability between rows of carpal bones, (3) Carpal Instability Complex (CIC)—instability within and between rows, and (4) Adaptive Carpus—secondary malposition of the carpus.[2]

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CID leads to the most common type of scapholunate instability.[3] CID results in severe swelling, deep pain, and a lack of motion due to the breakage of one or more intercarpal ligaments.[4,5] The scapholunate interosseous ligament (SLIL) works as the wrist's primary stabilizer by binding the scaphoid and lunate bones together. Usually, SLIL is the intercarpal ligament most affected, and sometimes, SLIL tears are known to produce intercarpal instability, degeneration of the secondary stabilizers of the carpus, and alterations in the kinematic loads, which in turn causes the dissociation and rotation of the scaphoid and lunate bones.[6]

It is important to detect an SLIL tear in its early stages because this not only saves the patient from severe pain, but more importantly it ensures successful and proper recovery in patients. When SLIL remains untreated, continued scapholunate instability may lead to degenerative arthritis, which then tends toward scapholunate advanced collapse (SLAC) of the wrist as well.[4,7] The majority of carpal instabilities can be diagnosed through palpation during a detailed physical examination. Radiographic evaluation and imaging (computed tomography (CT), magnetic resonance imaging (MRI), and arthrograms) can also form part of the diagnosis. However, arthroscopy remains the gold standard for evaluating carpal instabilities. Arthroscopy permits direct extrinsic and intrinsic carpal ligament observation under dynamic and static instability conditions, and furthermore, it is a minimally invasive technique routinely utilized to detect and diagnose accurate carpal ligament tears.

When diagnosis and treatment occur within the first 6 weeks after injury, good results can be achieved.[8] On the other hand, optimum treatment for irreparable SLIL lesions is still unclear. Nowadays, several surgical techniques can be used as treatment options such as scaphocapitate fusion, scapho-trapezoidal fusion, ligament repair with dorsal capsulodesis, capsulodesis alone, bone–ligament–bone reconstruction, and tenodesis.[9–12] Although most of these techniques makes lower levels of pain and improve strength, none of them restore the SLIL alignment, and as a result, there is a considerable deterioration in wrist motion.

Moreover, physicians tend to favor open techniques for SLIL reconstruction, which means stiffness in the wrist joint, widespread scarring, and long recovery times, all of which are highly uncomfortable for patients.[13] Furthermore, arthroscopy allows to repair for other mainly pre-dynamic and dynamic scapholunate instabilities, such as debridement, radiofrequency thermal collagen shrinkage, and transarticular pinning (wire placement), to be managed. As a result, arthroscopy had been gaining popularity worldwide. However, many contraindications have been associated with these techniques,[14] and while no perfect surgical approach for scapholunate instabilities is available yet, the goal of this study is to develop an innovative implant for scapholunate ligament replacement without losing sight of SLIL functionality. This work contributes with new scapholunate implant to restore ligament tore by defining new geometry and materials. In addition, the work applies design methodology in totally different field as usual. Normally, design methodologies are applied between technicians, who more or less agreed in technical words and understanding, while it is difficult to know the progress and good results when these methods are applied in mixed field as technicians and physicians are involved. This research demonstrates the combination of design methodologies which are useful in this scenario.

State of the art

A thorough state-of-the-art review spanning benchmarking and scientific research was conducted, and patent analysis was first conducted to understand the challenging problem scapholunate instability poses.

Benchmarking

Different types of wrist implants are available in the market all around the world. Some market solutions focus on replacing the wrist completely, while others focus on replacing only the carpal bones. Some examples are described as follows:

- RE-MOTION™ is a total wrist system restoration designed to minimize resection of the distal radius and carpal bones.
- Maestro™ is a total wrist system based on the treatment of the SLAC and other functional disabilities on scapholunate ligament joints. Biax™ is a total wrist system utilized in rheumatoid arthritis cases. This system mainly replaces wrist joints disabled by arthritis.
- Herbert™ Bone Screw and 2.4/3.0 mm Headless Compression Screw are used for partial wrist restoration. Both screws are designed to fix or repair very small bone parts. However, although both systems solve scaphoid bone fractures, they cause some reduction in wrist motion.

Scientific research

Numerous biomechanical studies have been performed in an effort to determine normal wrist kinematics. The main movements of a wrist are flexion/extension and radial/ulnar deviation,[15] and the normal range for these movements is 76° for flexion, 75° for extension, 22° for radial deviation, and 36° for ulnar deviation.[4] Moreover, Palmer et al.[16] found there has to be a small

amount of rotation, from 2° to 12°, between carpal bones and distal radius. Studies of dynamic in vitro carpal kinematics, such as the ones performed by Foumani et al.,[17] provide biomechanical data useful for understanding carpal motion. When measuring tendon loadings, Foumani also showed a statistically significant effect of flexion–extension movements on carpal kinematics and radio-ulnar deviation. Gislason et al.[18] analyzed wrist reactions when loads were applied during grip and showed a region of high stress in the radial zone. Very often, the normal motion of the wrist is altered due to injuries or pathologies. SLIL lesions often involve the rupture of both the palmar and dorsal portions of the ligament, and so, the biomechanical contribution of the ligament plays a very important role in determining the most appropriate treatment option. Scapholunate ligaments are made of three parts (palmar, dorsal, and intermediate), which were studied by Nikolopoulos et al.[19] largely to characterize their biomedical properties. Results showed that both the palmar and dorsal parts contribute about 50% of the tensile force and as such must be taken into account during surgery and recovery.

Specific treatment for scapholunate instability is based on the degree of the injury. For partial SLIL tears, a splint can be used. When this treatment is unsuccessful, arthroscopic debridement and K-wire fixation through open surgery are the most commonly used options.[20] Arthroscopic union between bones has also been reported. For instance, Rosenwasser et al.[15] developed an arthroscopic union between the scaphoid and lunate bones using a cannulated Herbert-type screw. If the ligament is not repairable, then a reconstructive procedure is required. Blatt[21] describes dorsal capsulodesis, which uses a ligament flap to fix the distal pole of the scaphoid. Other authors have since modified this procedure.[4,22] Tendons and grafts, instead of ligaments, may be used to hold the scaphoid and lunate bones together when the SLIL is not directly repairable, but dissociation is reducible.[23,24] When SLAC is present, arthrodesis (fusion of some carpal bones or the entire wrist) is the best option.[25,26] Nowadays, available surgical treatments are not completely effective, and all of them exhibit significant side effects such as wrist stiffness and long recovery times due to open surgery. The use of a prosthesis has been reported as a substitute to arthrodesis for wrist injuries; for example, Ramakrishna et al.[27] studied a silicone rubber implant solution and proposed to rapidly substitute the carpal lunate bone when the pain from Kienböck's disease was revealed, while Menon[28] analyzed the effect of a total wrist implant in patients suffering from arthritis. Both Ramakrishna et al.[27] and Menon[28] were pioneers in this approach. Recently, Gupta[29] and Reigstad et al.[30] have continued working in this direction with more novel concepts of total wrist implants. Filan and Herbert[31] studied a further solution using a Herbert screw, which is normally used to repair scaphoid bone fractures. There are many different screw designs used for bone fracture restoration, some of which are analyzed by Assari et al.[32] With regard to new designs, a new pyrocarbon implant (Amandys® implant) for the wrist is introduced by Bellemère et al,[33] while Rahimtoola and Hubach[34] designed a total modular wrist implant, which differs from that of Shepherd and Johnstone[35] who proposed a new design concept for wrist arthroplasty by paying special attention to forces and motions to assemble plate, radial, carpal, and flexible parts.

Description of wrist implant patents

A number of patents related to wrist instabilities and restoration have been issued. Nevertheless, only three of them were found to be closely related to scapholunate ligament repair or replacement:

- US0306480A1—This patent proposes a rotatable rod connecting two plates, but it is difficult to use in arthroscopy surgery.
- US0177291A1—This patent presents a cylindrical prosthesis for connecting the scaphoid and lunate, which will still allow movement between them. It can be introduced using arthroscopy surgery.
- US0076504A1—This patent is for an implant based on a cylindrical part used to align elements. The cylindrical part connects the bones, thus allowing displacements and movements among them. This implant can be utilized with arthroscopic surgery.

Methodology

The methodology in this study includes both the design and the manufacturing processes. During the design process, the steps carried out in the systematic design methodology[36] were applied (Figure 1) in order to reach the main design concepts. These steps included identifying customer needs (CNs), detailed benchmarking, state of the art of the research, functional analysis of the product, formalizing functional requirements (FRs) and constraints (Cs), and developing the morphological matrix. Final geometry and design selection was refined after the concepts had been carefully and systematically evaluated by highly experienced physicians. Once the shape and geometry had been refined and selected, a preliminary combination of materials, along with the manufacturing process, was then evaluated. The final design phase, known as detail design, results in complete drawings. Throughout this final phase, the manufacturing processes were begun to

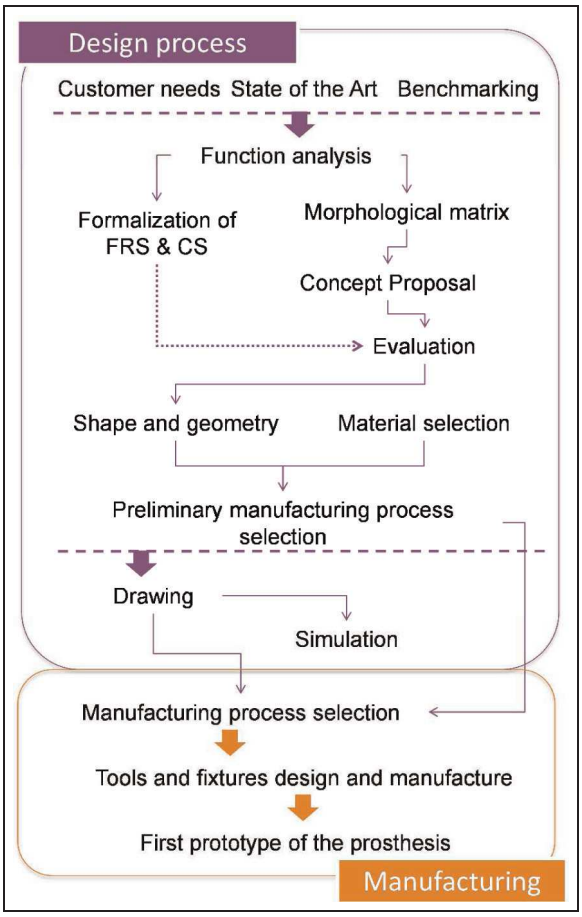

Figure 1. Design and manufacturing activities.

determine what manufacturing technology would be selected. Once the manufacturing process had been chosen, once again tool and fixture design had to be refined before the wrist prototype was finally produced.

New implant design method

Final design success is achieved when the CNs are completely satisfied.[36,37] Furthermore, gathering information from patients and expert physicians was required in this case study. Likewise, product functional analysis was essential to discern, in detail, the range of functions that the product had to satisfy. In this case study, three levels of functions were identified (Table 1).

Based on design domain structures utilized by axiomatic design principles, CNs and functions compiled in the Customer Domain have to be transformed into FRs and Cs in the Functional Domain. FR is what the product should do independent of any other possible solution considered[36] and has to be written down in order to be ranked, traced, measured, verified, and validated.[37] FR is defined by function and qualifiers[37]

Table 1. Functional analysis.

F0_To replace the scapholunate intermediate ligament
F1_To keep the scaphoid and lunate separated
F12_To maintain the relative angle between bones
F11_To keep the distance between bones
F2_To support the loads
F21_To support axial load
F22_To support flexion
F23_To support torsion
F24_To support fatigue
F3_To allow bone movements
F41_To allow flexion
F42_To allow extension
F43_To allow radial movement
F44_To allow cubital movement
F45_To allow pronation
F46_To allow supination
F4_Assure the bone integration

(Table 2). Function means what role(s) the product should satisfy and is defined by an active verb and object.[36,37] Qualifiers mean those Cs linked to function which limit possible design variants and solutions. There are two kinds of Cs:[37] design and functional (Table 2). Functional Cs directly limit function either before the action is executed or after applying the action, both cases are noted by verb. Design Cs are restrictions linked directly to the physical definition components, such as Cs2, Cs6, and Cs7 (Table 2), or to restrictions resulting from the environmental conditions where the action has to be carried out, that is, Cs1, Cs4, or Cs5 (Table 2). At least one functional constraint should be defined for each FR, and each FR could be limited by more than one design constraint.[37] Different sources allow information useful in quantifying FRs and Cs to be obtained. For example, the quantifiers linked to movements and loads, such as FR21 and FR31, were obtained from the scientific literature, while those linked to surgery or to anatomical processes (e.g. FR11, FR12, Cs2, Cs6, or Cs7) came from doctors' expertise (Table 2). For those cases where a quantitative value is not available, the FRs can neither be measured nor validated, and for this reason, it is very difficult to know whether the FR has been fulfilled or not.

The morphological matrix captured close-to physical solutions that could satisfy each function from the functional analysis. In other words, possible "hows" were proposed for each function from the first and second levels of the functional analysis. Results of this analysis are given in Table 3.

When combining these ideas, two main design concepts were proposed: a compact system (Concept 1) and a ball–socket system (Concept 2; Figure 2). Two rigid parts at the ends are joined by a flexible one to form a compact system. In the ball–socket–ball system,

Table 2. Formalization of functional requirements (FRs) and design constraints (Cs) for the implant design device.

Functional requirements		
Code	Function	Functional constraint
FR11	To keep the scaphoid and lunate bones separated at distance *d*	1 mm$\leqslant d \leqslant$5 mm
FR12	To allow relative motion between the scaphoid and lunate bones	Flexion, extension, deviation
FR21	To support axial loads	28 ± 8, 6 N[38]
FR31	To allow flexion movement	76°[39]
FR35	To allow supination movement	15°[39]
Design constraint		
Code	Description	Quantifier
Cs1	Biocompatible materials for implant	List
Cs2	Maximum dimensions of implant	Diameter: 4 mm Length: 25 mm
Cs4	Easy to insert	Time to be inserted less than 8 min
Cs5	Easy to remove	Subjective
Cs6	Internal hole diameter	Bigger than 1 mm
Cs7	Self-rotating thread	Pitch (mm)

Table 3. Result of the morphological matrix.

Function	Physical solution				
FR 0	Open surgery		Arthroscopy surgery		
FR 1	Fixed distance	Variable distance	Fixed position	Variable position	
FR 2	Circular	Variable	Plain	Braided	Stent
FR 3	Rigid	Flexible		Elastic	
FR 4	Thread	Press fit	Self-rotating		Rounded

all the parts are rigid as one is threaded and the other is a press-fit system joined by a ball–socket–ball system. Both designs can be used by arthroscopy surgery, but when implemented the solutions are somewhat different. The compact system design is defined by a cylindrical shape and composed of elastic material. This shape and material composition enable the distance between the scaphoid and lunate bones to be changed. With this solution, bone integration is easily achieved with the implant using a rounded system. The ball–socket–ball system design only permits the implant position to be changed, but the distance between bones remains the same. The shape of the implant is variable and integrating it into bone is achieved with a press-fit system.

Expert doctors had three principal reasons (see below) for selecting the compact system design over the ball–socket–ball system design:

1. The compact system design reduces the number of movements required in surgery due to the elasticity of the material.
2. The compact system design is easier to insert and/or remove from the patient if required.
3. The compact system design is considered a very novel idea for solving a SLIL tear.

Additionally, and from an engineering point of view, the compact system design contains fewer parts than the ball–socket–ball system design, thus making manufacturing more feasible.

Several design proposals were developed which were then refined during meetings between engineer designers and expert doctors until the final one was achieved (Figure 3):

- Design 1: Starting with Concept 1 (Figure 2) as the design basis, the mid-joint was moved to the end of the device to avoid problems. Subsequently, the implant was inserted between the scaphoid and lunate bones and analyzed by expert doctors, provoking some interesting discussion. The team, made up of engineer designers and expert doctors, decided that bones could be damaged by this kind of union, thus the rigid implant ends were changed to a cylindrical shape with conic shape degree. To improve the insertion of these implant ends, threads were added to make bone fixation and integration easier. The union between the elastic and rigid parts was rectangular-shaped slots to ensure they remained fixed. A hole with a hexagonal cross-

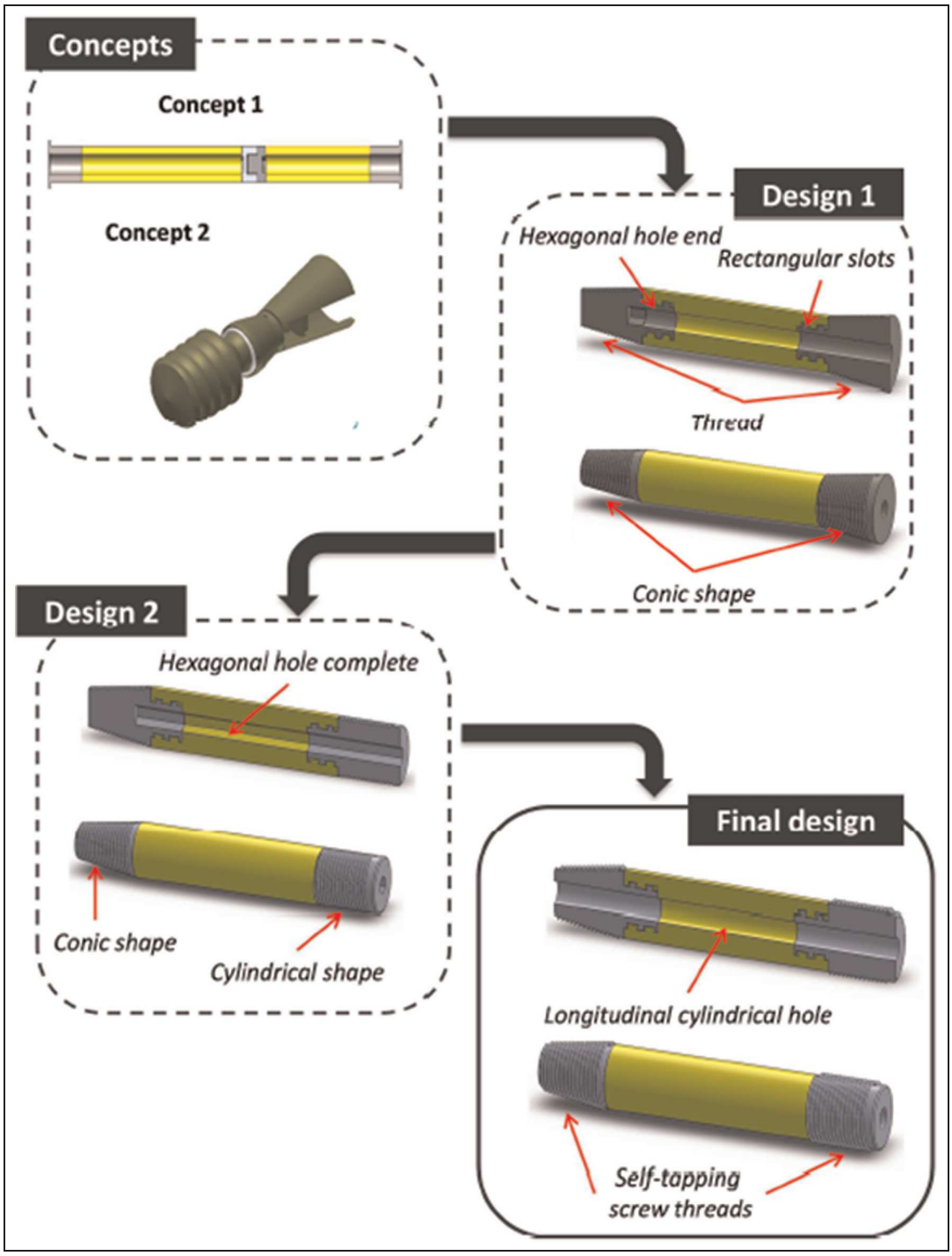

Figure 2. Design process result.

sectional shape inside the implant was made to transmit rotational movement during the implant insertion into the scaphoid and lunate bones.

- Design 2 (Figure 2): The conical shape from the scaphoid part was removed and changed to a cylindrical shape. The cylindrical shape is enough to assure insertion and fixation into the bone. In this design, the internal hole is hexagonal to help with torque transmission, while the prosthesis is inserted during surgery.
- Design 3 (Figure 2): This was the final design selected after several meetings and a number of discussions. A teamwork session with engineer designers and expert doctors led to the final shape, geometry, and materials being decided on. Both rigid end parts, such as the scaphoid

and lunate parts, were exchanged for self-tapping threads similar to those used for other standard implants and prosthesis. The internal hole of the prosthesis was changed to a circular cross-sectional shape because this is easy to manufacture and to use with a 1 mm in diameter Kirschner needle (NB: a Kirschner needle is a popular system used to guide devices during surgery). Final implant length and diameter were matched to standard dimensions in a final modification to increase fittings in patients.

The compact system design is made up of three different parts, that is, the scaphoid (rigid material), the lunate (rigid material), and the middle part (elastic). The final design was adjusted to obtain a final match with all the materials, dimensions, shapes, surface roughness, and tolerances. With this information, the implant could then be manufactured. Since the diameter of the prosthesis is 3 mm and its length is less than 20 mm, this implant can be considered as a micro part, not because of its dimensions but rather because of its geometrical shape. Biocompatible titanium was selected for the rigid parts and biocompatible rubber platinum was selected for the elastic part.

As a final step, to assess the final design it was carried out the implant insertion simulating real situation using virtual images tool from a CT scan. Figure 3 shows the prosthesis inserted in the scaphoid and lunate bones. The final geometrical solution selected allows physicians to fulfill two main Cs since others analyzed in the literature and patents' review were not. The implant is designed to be used in an arthroscopy surgery scenario, which means to decrease pain and recovery time avoiding open surgery, and it allows all required movements at mechanical level once the surgery is done.

Prototype manufacturing

The proposed device design was manufactured by pouring silicone into a mold where the metallic parts with the appropriate shape had already been placed. Figure 4 depicts the prototype device, and a summary of some of the steps taken to produce it is as follows:

1. An Okuma lathe was used to fabricate the metal parts (the scaphoid and lunate) once the optimum shape, process parameters, materials, and tools had been evaluated, and a set of screening experiments were designed to obtain sufficient accuracy and quality for the metal parts.
2. Two different geometrical (rectangular and cylindrical) mold solutions were proposed, and advantages and disadvantages between the rectangular and cylindrical molds were considered. Although the rectangular shape seemed to be the optimal shape for the pouring process, eventually the cylindrical shape was chosen because the mold and parts had to be manufactured using the available facilities. (NB: While outsourcing the manufacturing of the mold and metallic parts was considered, it was discarded because it would increase manufacturing time and costs.)
3. Finally, molding took place. The silicon was poured, a Kirschner needle was introduced into the mold, and after closing the mold, it was cured in an oven. Once curing had finished, the mold was extracted from the oven taking care not to damage the prototype prosthesis in the process.

The prototype prosthesis was manufactured in our facilities without considering industrialization of the product. Thus, the prototype was built to a mesoscale to check its fit, form, and function. It means at this step, the size is still big to be installed in an arthroscopy surgery. In the future, some adjustments will be made to improve the final quality of the prosthesis. Production concerns are the manufacturing process at micro-scale level and materials. Manufacturing process and materials usually need to be studied at the same time, while materials depend on manufacturing process and manufacturing process set-up is related to materials. Implant manufacturing process is partially addressed by combining micro-machining lathe process for metal implant parts and ultrasonic micro-molding for flexible parts. Screening tests were carried out with good results. Those screening experiments were made with titanium medical grade for metallic parts and bioimplantable silicon material for flexible parts.

Conclusion

Repairing the instability of the SLIL through arthroscopy surgery means that it can be used designed prosthesis. Thus, by taking into account medical knowledge and feedback from the specialized doctors, a novel device was developed during this research project, whose main advantages are as follows:

- A reasonably simple and compact design, working as a simple part, avoiding joints during surgery and resulting in reduced surgery time as it can easily be implanted into the scaphoid and the lunate bones is proposed.
- The combination of elastic and rigid materials allows position and relative distance between scaphoid and lunate bones to be varied, resulting in better functionality and reduced limitation to wrist movement.

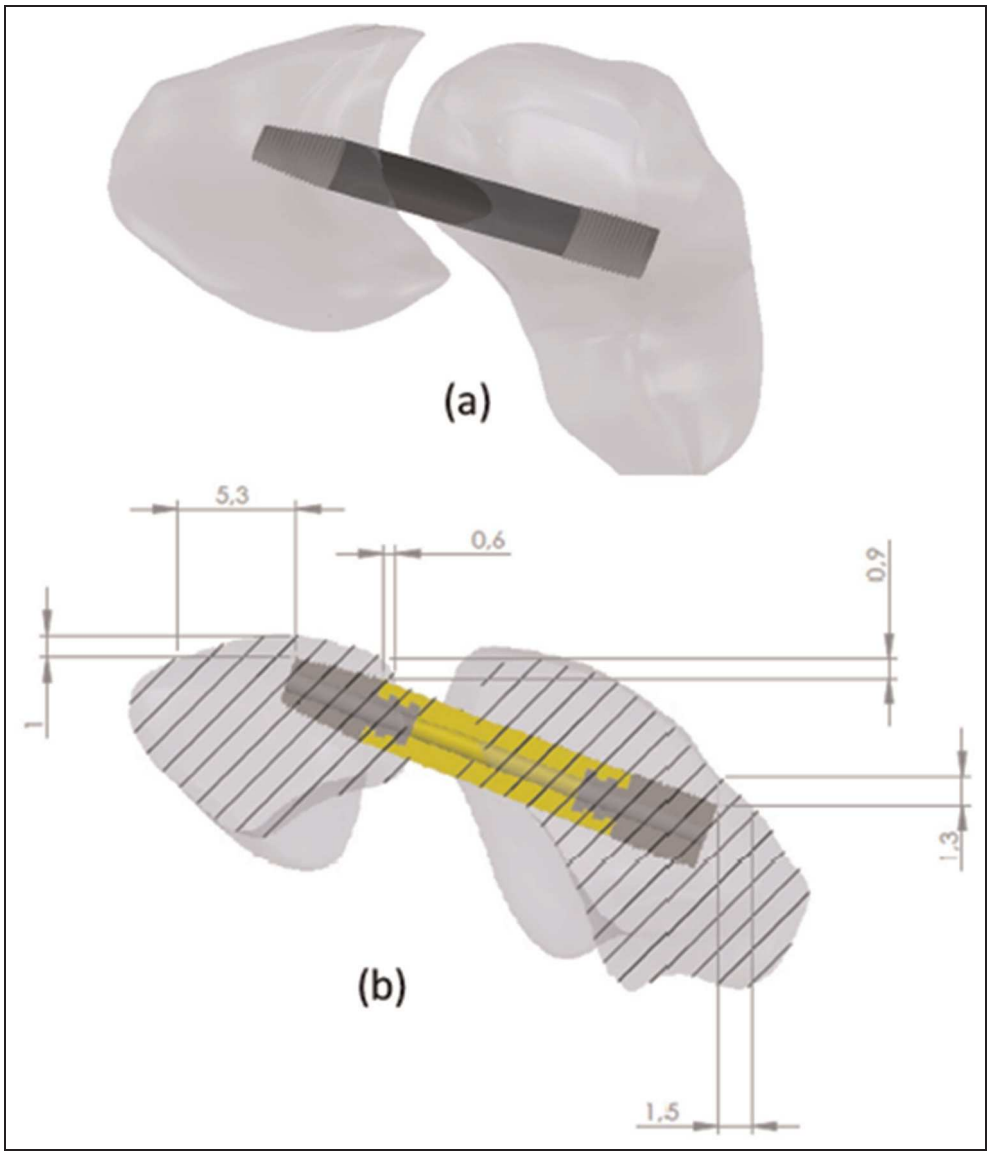

Figure 3. Final scapholunate prosthesis inserted in the bones.

- Patient personalization was possible as a result of the short variance in length and diameter.
- Injury caused by surgery was dramatically reduced as it only requires a 2.5-mm-diameter × 25-mm-long hole to be drilled.
- Design flexibility as it can be easily modified to take into account the anatomy of individuals, different biocompatible materials, and implant geometry to assure that wrist motion does not hinder hand performance.

All these concepts remark the benefits of this new implant solution compared with solutions explained in section "State of the art." In fact, solution at patent level can fulfill several requirements at the same time, but physicians required at the same time all mechanical movement between two bones and less invasive surgery to easy and fast recovery. This new implant mainly reaches these two Cs at the same time which is the advantage over other implants developed before.

Despite the panel of expert doctors' assurance that this design approach could be a good solution, some issues still need to be addressed:

- According to the doctors, in this case, the type of silicon used for the elastic part is unsuitable.
- From a technological standpoint, the fact that union between the elastic and rigid parts cannot be guaranteed should be considered.

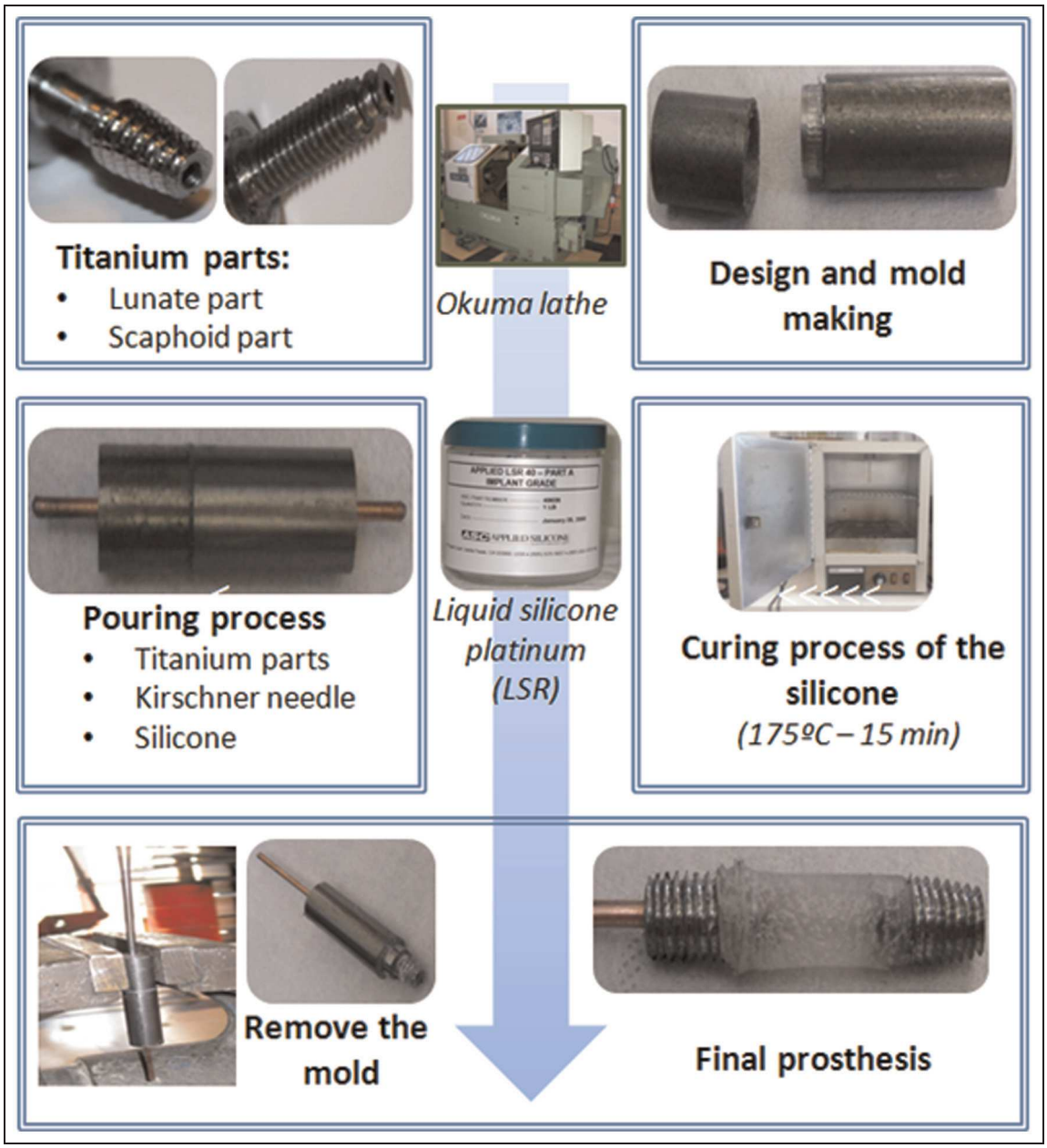

Figure 4. Manufacturing steps.

- In terms of manufacturing, more suitable manufacturing processes should be used and new technologies, such as ultrasonic molding, could be tested.

Further adjustments could be made in the future. First, considering the knowledge and information that has been acquired and characterized in this initial study, it could apply the systematic design methodology to other designs. If this methodology is applied, the user could propose and develop new solutions to ensure the satisfaction of customers' needs. Second, further tests of the prosthesis from a mechanical point of view, such as load, tensile, and deformation, could be carried out to confirm this implant design. Finally, computational prototype models with the finite element method (FEM) could be used to check and test prosthesis behavior when taking wrist movements into consideration and applying external loads in the hand. Besides further studies on mechanical properties, new implant design features should also be studied and analyzed. Next steps about implant will focus on tests. However, there is no animal model similar to human for this specific ligament case study due to bone configuration. For this reason, tests will be carried out on cadavers to check its installation; its movements and

forces are also tested. Since no special instrument is required, test will be conducted once the micro implant was manufactured.

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