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The OXALYS prosthesis

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Introduction:

Prosthetic arthroplasty of the thumb TMC joint is an area in which all the solutions to the requirements for long-term reliable arthroplasty have yet to be found. This can be seen in the vast number of techniques and prostheses available today, which suggest that we are all looking for the best compromise in terms of good performance, long-term stability, low wear, few complications, and good long-term clinical results.

We have designed and developed a new modular prosthesis combining the reliability of a tapered hydroxyapatite coated titanium stem with a silicone head and a titanium base that can be centred in the axis of the 1st metacarpal or tilted 15° in all directions to achieve the best possible biomechanics in relation to the distal pole of the scaphoid.

This implant makes it possible to respect the various centres of rotation of the trapeziometacarpal joint while maintaining an innovative flexible interface between the prosthesis and the scaphoid.

The first implants were performed in October 2008, and this report concerns the preliminary results of 17 patients.

Concept behind the OXALYS prosthesis: centring and tilt:

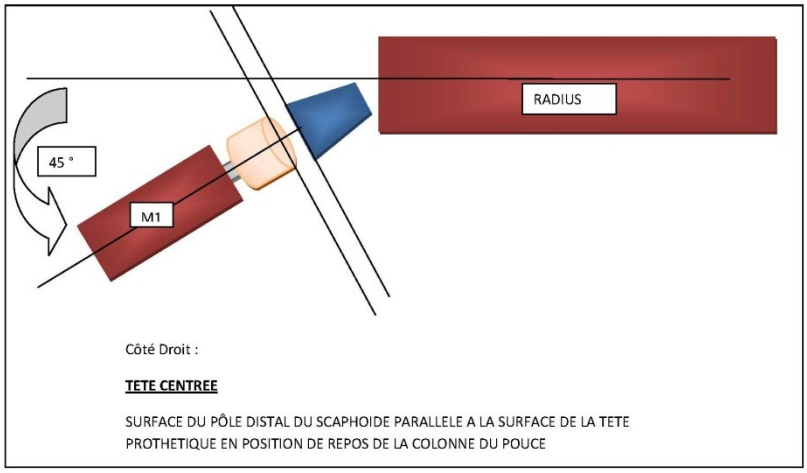
The OXALYS prosthesis is the fruit of a collaborative effort between OSD, a company located in Avignon, France and the authors of this article. OSD has NF EN ISO 9001, 2000, and NF EN ISO 13485, 2003 certification, and its products are compliant with the EC 93/42 Medical Devices Directive.

The philosophy behind this new arthroplasty involving a complete trapeziectomy resides in the possible adaptation of the prosthesis to the distal pole of the scaphoid, the orientation of which is extremely variable, due to personal factors, but also because of modifications stemming from peritrapezial arthrosis (5).

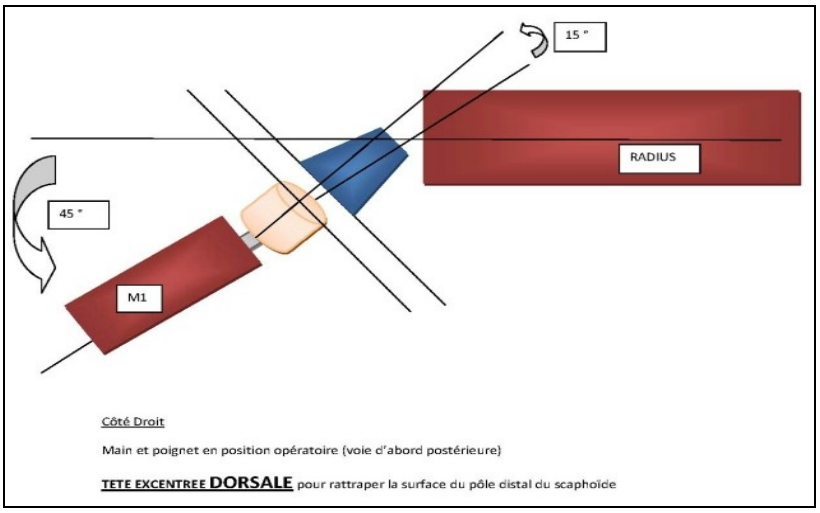
In our opinion, a fundamental issue is to be able to orient the head of the prosthesis as required by the position of the scaphoid while maintaining the various centres of rotation of the anatomical trapeziometacarpal joint, which constrained prostheses cannot do because they establish a normal single or inverted centre of rotation.

Our solution avoids the constraints linked to a single centre of rotation on the trapezium, which is by definition greatly solicited. All the anatomical components of the base of the thumb are reconstructed with our prosthesis, and there must be a solid capsular suture to ensure good stability.

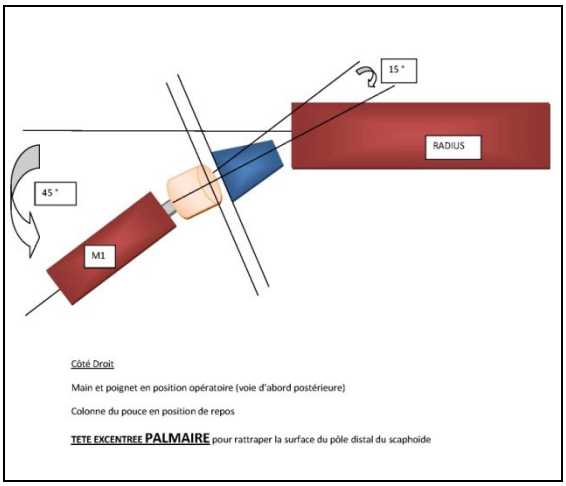
Schema of the different positioning of the prosthesis:



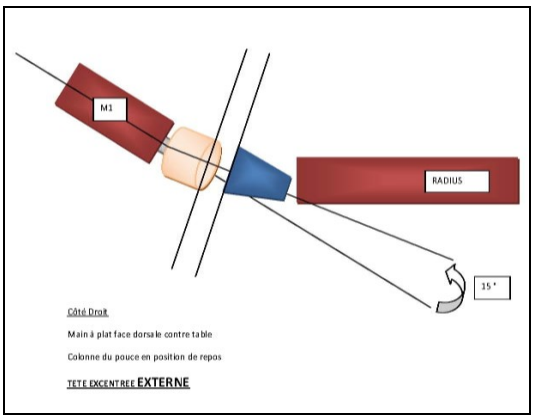
Right side : **straight head :** surface of the distal pole of the scaphoid parallel to the surface of the prothesis head with the thumb column in a resting position.



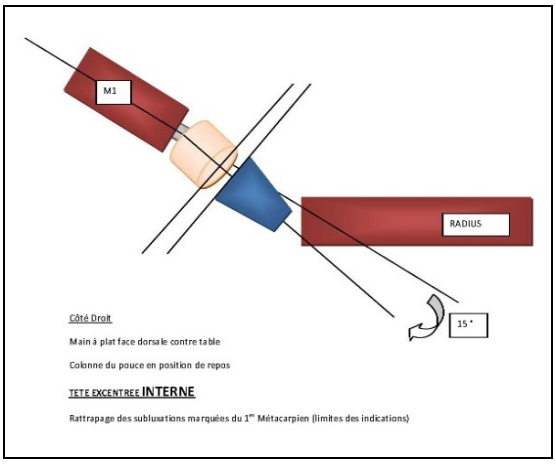
Right side : hand and wrist in active position (posterior approach) **Head tilted dorsally** to fit correctly with the surface of the distal pole of the schapoid



Right side : Hand and wrist in active position (posterior approach) Thumb column in resting position
Palmar tilt of the head so distal pole of schapoid is in the right position



Right side: Hand flat, backside against table. Thumb column in resting position.
Head is tilted externally



Right side: Hand flat, backside against table. Thumb column in resting position.
Head is tilted internally.
Compensation for significant sublaxations of the first metacarpal (border line indication)

Methods and Materials:

We set up a non-randomized prospective study with regular patient follow-up. This study reports on the first 17 patients corresponding to the following inclusion criteria: painful rhizarthrosis or peritrapezial arthrosis, which has not reacted favourably to medical treatment or orthotic treatment with a nocturnal brace for more than 2 years.

Case mix: There were 12 women and 5 men. Median age was 64.3 (52 to 74). The operation was performed 8 times on the dominant side, and 9 times on the non-dominant side.

According to DELL's classification, patients were predominantly in an advanced stage (9 stage III, and 2 stage IV, compared to 2 stage I, and 3 stage II). 1 case was not ranked because it corresponded to a repeat operation after a failed trapeziectomy.

Patients presenting with a dorsal subluxation of the base of the first metacarpal greater than 50% with respect to the trapezial axis were excluded, because they do not correspond to the indications for this arthroplasty. The average subluxation measured was 25% (0 to 40%).

Likewise, an uncorrected metacarpal-phalangeal hyperextension greater than 60° is not an indication for this arthroplasty. The average hyper-extension measured was 20° (0 to 60°).

An evaluation questionnaire on the methodology used to implant the prosthesis was filled in by each surgeon, which made it possible to analyse the operating procedure precisely.

Surgical technique: 15 posteroexternal approaches and 2 Gedda-Möberg anterior approaches were performed. The incision is made between the Abductor pollicis longus and Extensor pollicis brevis tendons for the posterior approach. A T incision is made in the periosteum and capsule, and it is absolutely necessary to place the horizontal branch of the T on the trapezial bone to preserve a solid scaphoidal capsular flap that can be used to cover the head of the prosthesis.

The trapeziectomy was always performed by sectioning, often after weakening the bone with one or two cuts with an oscillating saw. The Flexor carpi radialis tendon remained intact in 16 cases and was damaged in 1 case.

Resection of a small part of the trapezoid must be performed to completely uncover the distal pole of the scaphoid, and eliminate any risk of internal cam effect.

The section excised from the base of the first metacarpal is generally from 1 to 3 mm. The specific drill enables mechanised milling (slow speed) of the first metacarpal with a conic reamer with stops to gauge the depth (Figure 1). This reaming was considered to be easy and effective in 14/17 cases, and made it possible to successfully implant the appropriate stem (Figure 2).

In 5 cases, principally due to the hardness of the spongy bone, additional reaming was necessary with a burr of the next largest size.

Of the 3 sizes of rods used, 9 of the largest (size 20) were implanted, 6 size 18, and 2 size 16.

Fitting the trial heads into place was considered to be easy 11 times out of 17, and difficult 6 time out of 17. This difficulty is linked to the very concept behind this prosthesis, because it offers many modular possibilities. We believe the following two items must be taken into account:

- Touching the distal pole of the scaphoid, and the best possible congruency
- A balancing of the protraction/retraction and adduction/abduction movements (glide) while maintaining all the rotational possibilities and lateral displacements.

Tests were performed with the trial heads, 6 of which were placed in a centred position, 6 with palmar tilt and 5 with internal tilt. Most of the implanted heads were size 2 (12 patients). (Figure 3)

The prosthesis' stability was considered to be good or very good in 16/17 cases, which was also true of the quality of the capsular suture in 14 /17 cases.

All patients were immobilised with an orthesis or flexible brace for 4 to 6 weeks. Only 9 patients required physiotherapy.

Results:

Initial results were evaluated at 5 weeks, and then at 4 months on the basis of a pre/post-operative clinical comparison of the x-rays. Pain was assessed with a Visual Analogue Scale. A Dash questionnaire must be sent to the patient in the 6th month, and their results will be reported at the next congress.

Healing was good at two weeks. No infections or inflammatory phenomena were observed. There were no neuroalgodystrophic reactions in the series.

In the immediate post-operative control x-rays made, 15 prostheses are perfectly centred on the scaphoid with no overlapping of the axis of the first metacarpal in the profile, and 2 prostheses are slightly pushed towards the trapezoid. Therefore, the learning curve is short for using this prosthesis, which is easy to implant. (Figures 4 and 5) (Figures 6 and 7)

15/17 patients underwent post-operative immobilisation. 8 patients already enjoyed functional mobility of the column of the thumb at 5 weeks and had no need for physiotherapy.

All patients reported decreased pain, which was on average 1.25/10 on a visual analogue scale (0 to 3).

At 4 months, the patient presenting with the greatest metacarpal-phalangeal hyperextension (60°) was experiencing moderate posterior instability (20%), with no significantly painful symptoms. All other patients had a correctly centred prosthesis.

The average M1-M2 angle was 38° with functional opening of the first commissure. All patients had a score of 10 on the Kapandji index.

70% of the patients had a pinch force (measured with a pinch test) greater than in their pre-operative condition. This result is interesting because it shows that the absence of pain combined with the conservation of the length of the thumb column results in rapid functional recovery.

We will report on the results at 1 year for this series, with a greater number of cases, during our presentation.

Discussion:

Our clinical experience shows us that a pure trapeziectomy with or without ligamentoplasty or interposition often results in a collapse of the thumb column accompanied by a loss of force. This collapse of the thumb column can become clearly detrimental if the base of the first metacarpal ends up touching the distal pole of the scaphoid. Nevertheless, all trapeziectomy procedures, with or without ligamentoplasty, and with or without temporary pins (12) are good procedures to be used for patients less than 55 years old.

Artificial materials (Théole or Ligastic polyester) have been used for some time now to attempt to offset the collapse of the thumb column by reconstructing a mechanical base for the first metacarpal. However, reactions to foreign bodies (13) combined with close-up geodic images have resulted in a decrease in the use of these techniques, considered to be too likely to release particles (in 10 to 15% of the cases). Nonetheless, patients who experience no inflammatory reactions to these materials have a satisfactory long-term result, which suggests that it is fundamental to conserve a normal length for the thumb column. More recently, a degradable polyurethane-urea implant (Artelon) was proposed (16); however, the inappropriate nature of the technique leaves us dubious. It would appear that the same reactions to foreign bodies occur (4), which we have already observed twice. We are waiting to get more perspective and more information on this spacer implant.

The interposition of autologous material (a costochondral graft) may be a promising alternative, and the experience in Besançon (18) has much to teach us. However, other authors consider this technique should only be used for a salvage procedure (11).

Partial arthroplasties using silicone (14,17) have been abandoned because of an implant failure rate higher than 40%. Other partial arthroplasties with a chrome-cobalt implant give better results (7) with more historical perspective.

Spheric interposition arthroplasties have not been satisfactory (2), and this is why we will not express a firm opinion on the interest of pyrocarbon spacers, because they have not been used long enough for trapeziometacarpal joint surgery.

For several years, our preference went to the Sutter and Swanson silastic prostheses for indications of peritrapezial arthrosis in patients over 65 years old. They enabled us to achieve a good compromise between conservation of thumb column length and unconstrained, flexible arthroplasty, respecting the normal trapeziometacarpal joint's multiple centres of rotation. These prostheses gave us the best long term results (more than 10 years), whereas some faulted their potential instabilities, which were more due to a technical defect that to a material defect or the basic history of rhizarthrosis.

In our opinion, the debate on "silicone synovities" must be re-opened. The material known as "silicone", which groups together a wide variety of products, has continuously evolved over the past 40 years. Its material composition has become purer and purer, more and more wear resistant,

dense, and free of additive products such as polyethylene that could have been responsible for geodic reactions (8).

MED 4765 silicone elastomer manufactured by NUSIL TECHNOLOGY is a very high tear strength elastomer. Contrary to previous medical grade silicones, the catalysis process used for MED 4765 is a "polyaddition" process (and no longer peroxide polycondensation), which does not generate any peroxide residues in the material, or volatile by-products. Since this type of process eliminates the need for any additional cleaning using chemical procedures, it guarantees greater purity. The importance of mechanical properties is mentioned in the literature: Yoshihide Fukahori (10) has shown that improved mechanical properties, in particular firmness, decreases the number of phenomena linked to the abrasion of the silicone elastomer. MED 4765 is one of the firmest silicones available (19).

There were weak zones in the "100% silicone" prostheses, principally due to the shearing effect at the head-stem junction, resulting in an obligatory weakening of this zone with a possible release of particles. The irregular wear of the head, which is in contact with the distal pole of the scaphoid is also due to a defect in the prosthesis' density and its high wear coefficient. The rubbing of the stem in the base of the first metacarpal also results in wear, and for the Sutter prosthesis had led to wrapping the stem with a polyester mesh to be anchored in the spongy bone. Therefore, these prostheses were not perfect, either from a mechanical point of view, or in terms of their fabrication; however, they provided pain relief and mobility to many patients.

When these Sutter prostheses are stable, which depends on the first 3 months, the clinical results remain positive over time with more than 10 years of follow-up, and with no silicone synovities in our experience. Some authors have confirmed our results, with a long follow-up period (3), whereas others have disconfirmed them (23).

The problem with these unconstrained prostheses is their instability, which can lead to repeat surgery. This instability is often multi-factorial, with problems generally appearing in the following chronological order:

- Incorrect orientation of the prosthesis head (a bad choice in the direction of the tilt)
- A defective capsular suture or one that is not solid enough
- Post-operative immobilisation is too short or not respected by the patient

It also seems possible that a wrong surgical indication, in particular, for a kind of very off-centred rhizarthrosis with a very adducted thumb and hyper-extension of the metacarpo-phalangeal joint results in this posterior subluxation of the prosthesis. In such cases, it ends up being positioned where the natural evolution of rhizarthrosis displaces the base of the first metacarpal bone (21).

Whereas the prosthesis should provide comfort and mobility, it cannot modify the way in which the patient uses his or her thumb and the remaining sublaxation constraints on the base of the first metacarpal bone, which explain the see-sawing of the trapezium cupula as well as the prostheses' instability.

Based on these observations, we have designed and developed a prosthesis with the following specifications:

- A tapered hydroxyapatite coated titanium stem: it is not necessary to have an anatomical stem in a rather unconstrained prosthesis and we have chosen a proven secondary spongy HAP coated fixation.
- The prosthetic stem is completely level with the excised part of the base of the first metacarpal bone to simply the situation if a repeat procedure is needed (no part of the stem is placed in an intra-articular position)
- Fixation of the head with a Morse cone: 12 possible positions.
- Silicone heads with a titanium base: this is a new technology, which makes it possible to eliminate shearing effects at the head/stem junction.
- 3 sizes of straight heads and 3 sizes of tilted heads: our concept is based on finding the distal pole of the scaphoid whose position has been modified by peritrapezial arthrosis. This approach restores correct biomechanic relations while maintaining thumb column length.
- A balance between protraction/retraction and adduction/abduction movements (glide), and axial rotations

Our new approach cannot be compared to the old way used by many teams who have worked on total head/cupula arthroplasties, and whose results are well-known (1,9,15,20,22). These prostheses changed the way of treating rhizarthrosis; however, they did not respect the normal biomechanics of the trapeziometacarpal joint, which was transformed into a hip-type joint with a single centre of rotation. Physiologically, the double saddle displaces the centres of rotation (6), which explains why we feel it is preferable in our approach to restore the multiple natural gliding movements in relation to the scaphoid. This physiology explains the see-sawing movements, loosening, migration of trapezial elements, and the failures of these old style prostheses.

Similarly, anatomical prostheses such as Avanta and Camargue, which are by definition unstable, can only work with normal peri-articular ligaments; however, this is no longer true in cases of advanced arthritis, which explains the great amount of post-operative instability observed.

The experience acquired with all of these prostheses is vital. To develop a new device, we must base our efforts on what already exists, observe the good and bad concepts, and humbly attempt to innovate by combining theory, practical experience, new materials, and surgical techniques.

Time alone will judge our efforts.

Conclusion:

The OXALYS modular prosthesis proposes a new concept of arthroplasty for rhizarthrosis and peri-trapezial arthrosis. The prosthesis stem features primary and secondary fixations with hydroxyapatite coating. The head-stem interface offers 12 possible orientations. The silicone head is coupled with a titanium base, which prevents any shearing effects and provides a soft interface with the scaphoid.

The perfect orientation of the prosthesis head with respect to the distal pole of the scaphoid guarantees a biomechanical structure that can restore an adequate function to the thumb column.

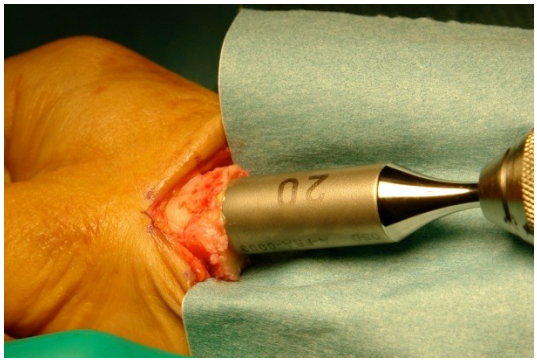


Figure 1. Power drill with a 20mm drill gauge

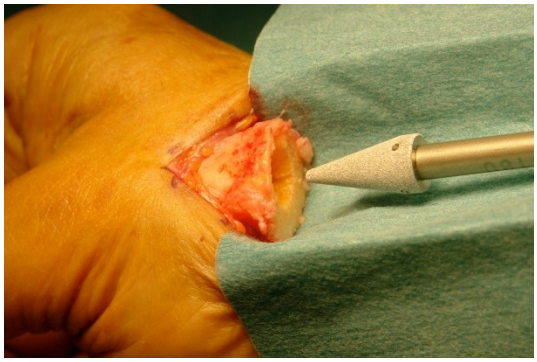


Figure 2. Definitive implanting of tapered hydroxyapatite-coated stem

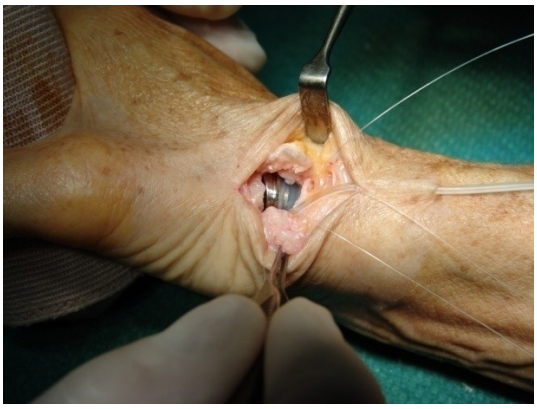


Figure 3. Patient 1 Definitive prosthesis implanted: Palmar tilt; Suture threaded through scaphoidal capsular flap

Figure 4. Patient 1 Peritrapezial arthrosis (Dell stage III)

Figure 5. Patient 1 Post- operative x-ray of OXALYS with palmar tilt

Figure 6. Patient 2 Rhizarthrosis (Dell stage III)

Figure 7. Patient 2 OXALYS prosthesis with a straight head

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