

Lima News



Indianapolis, IN, November 28, 2011

Lima USA Inc. is officially on!

Following the path of internationalization Lima Corporate has eventually found its way to make its "American Dream" real.

The incubation of the project USA has gone through different ideas, initially thinking about using preexisting partners, then moving to the more challenging and fascinating trail of creating Lima USA directly, reflecting Lima Corporate philosophy.

Therefore the organization has been defined basing Lima USA Inc. on a few solid pillars: the main logistic structure will be based in Dallas, TX and will care about receiving the products from Italy and sending them over the different US States where and when they will be needed.

On the field, instead of using mere stock distributors, Lima has decided to put its face on the market, fostering branding and awareness, and has been looking after sales agents who will, in fact, become authentic partners.

The sale strategy will be supported by a net of agents spread upon the different territories, covering from the beginning some determined areas, like for instance the South-East, Texas, California and Nevada. They will not be left on their own, since they will be able to count on the backup from the main Headquarters in Italy, in terms of products information, updates and impulses to keep the momentum.

In order to boost the penetration in the States, Lima will push its most innovative and renowned products: the SMR Shoulder System and the DiPHOS H plate.

The European claim of SMR speaks by itself, it is said to be "always the best option": in fact it is possible to adapt the system to any different pathology having to deal with. Thanks to its total modularity, SMR allows the surgeon to change scenario also during the operation, permitting him to pursue a step-by-step flexible procedure.

This system is "reversible" too; it is by occurrence feasible to evolve the system following the evolution of the patient's pathology without performing a revision. For example the surgeon can convert a total shoulder prosthesis to a reverse one keeping in place the humeral stem and the glenoid metal back component, just swapping the humeral body and adding a glenosphere. Introducing the SMR System in the States, Lima would like to replicate the model applied to other countries, as it is been done in Australia and New Zealand, where SMR has become market leader. DiPHOS H, the proximal humeral plate for fracture, is the natural complementary product that Lima wants to launch along with the SMR System.

After testing the biocompatibility of the materials, even if already used in Orthopedics, Lima designed and introduced DiPHOS H, which is the first application of PEEK in Trauma. PEEK has excellent mechanical resistance properties and it is inert, its purpose in Trauma is to avoid galvanic corrosion phenomenon, allowing an easy removal. The screws are poliaxial locked self tapping the plate, providing angular stability. In addition PEEK is translucent, making possible to easily check the fracture healing. Lima Corporate, in order to support the US strategy, has developed a rich Professional Education program dedicated to American Surgeons and Sales Representatives.

During 2012 there will take place different activities, like for instance Cadaver Labs and specific SMR Trainings. During the years there have been created the so called Visitation Centers, a way of introducing the American Surgeons to Lima's most influential Key Opinion Leaders, including Live Surgeries and a factory tour. This instrument is very valuable in order to transmit Lima's true spirit and share the commitment to the product development.

Nonetheless, in order to support the American Surgeons who would like to approach to Lima's world, there will be also organized several visits "on demand" and there will be reserved several places at the Reverse Shoulder Arthroplasty Course held in Europe.

Lima Corporate has taken on this new stars and stripes challenge, a new demanding market where sales will be

Focus on

Lima USA Inc. is officially on!



pursued by American sales agents, while production and design will remain "made in Italy".

The official event that will launch Lima in USA will be the AAOS, February 2012, San Francisco, where all the people will see that SMR in the US is all the opposite than a mirage. The pride, the high expectations and the awareness of its means will drive Lima to export once again its vision,

becoming the best choice for the patient and the surgeon, and with ambition and broad minded view Lima may also dare to moon the giants. ✕

M. Piovani

Business Development Director
Lima Corporate

And a warm welcome to **Peter Fabok**, Director Central and Eastern Europe and **Patrik Volentier**, Subsidiary Manager



The Czech Republic, Slovakia and Ukraine are just three of the countries in the area we call Central and Eastern Europe. Our company is proud of its experience and presence across a sizable swath of this geography, always in the forefront of orthopaedic surgery and traumatology.

In several regions, politics and economic developments have impacted market trends, preventing them from experiencing the same growth rate as other EU countries. However, the situation is fast changing. New regulations are being enforced in public and private health insurance systems, and are helping most of the countries in the area to quickly catch up. Considerable increases have been reported in the number of prosthetic implants and the demand for service and groundbreaking materials is burgeoning.

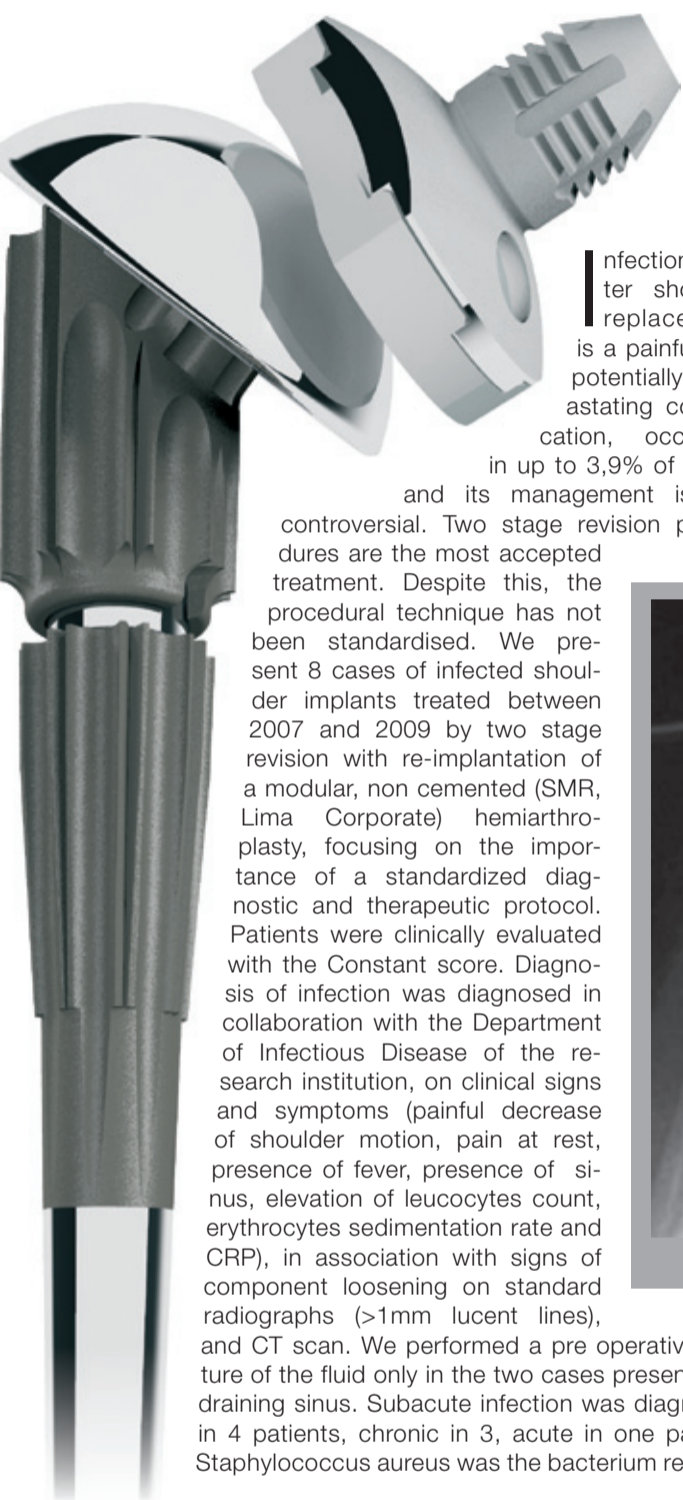
It is against this backdrop that Peter Fabok was given the position of Director Central and Eastern Europe on 1 September. Peter has been put in charge of managing the existing Lima Corporate branches in the area, and he will be striving to develop areas where Lima's presence is still marginal, as well as to break into new areas. The country that represents perhaps the most ambitious challenge of all is Russia: its sheer size and unique market conditions will require the utmost effort. Peter Fabok's experience includes spearheading the launch of Lima SK in Slovakia, where he put together a rock solid organization that is generating a great deal of satisfaction for Lima and the people working in the Slovakian branch.

Patrik Volentier, for years one of Peter's people in Slovakia, is the new branch manager. We are confident that Lima Corporate's ongoing growth will generate many more opportunities like this, enabling our most experienced people to take on exciting new positions. ✕

I. Volpi Lisjak

Director of Sales - Europe
Lima Corporate

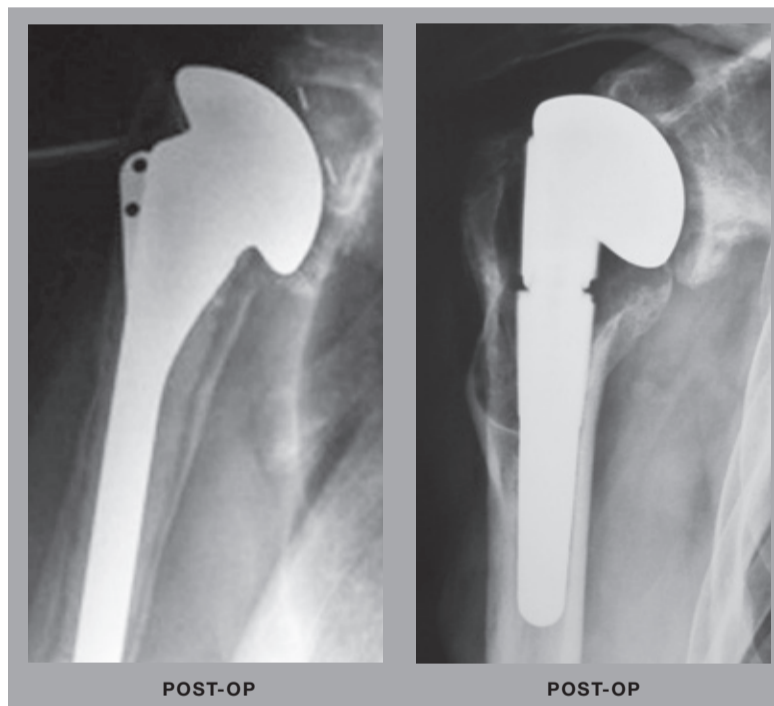
Two-Stage Revision for infected **Shoulder Arthroplasty**



Infection after shoulder replacement is a painful and potentially devastating complication, occurring in up to 3,9% of cases and its management is still controversial. Two stage revision procedures are the most accepted treatment. Despite this, the procedural technique has not been standardised. We present 8 cases of infected shoulder implants treated between 2007 and 2009 by two stage revision with re-implantation of a modular, non cemented (SMR, Lima Corporate) hemiarthroplasty, focusing on the importance of a standardized diagnostic and therapeutic protocol. Patients were clinically evaluated with the Constant score. Diagnosis of infection was diagnosed in collaboration with the Department of Infectious Disease of the research institution, on clinical signs and symptoms (painful decrease of shoulder motion, pain at rest, presence of fever, presence of sinus, elevation of leucocytes count, erythrocytes sedimentation rate and CRP), in association with signs of component loosening on standard radiographs (>1mm lucent lines), and CT scan. We performed a pre operative culture of the fluid only in the two cases presenting a draining sinus. Subacute infection was diagnosed in 4 patients, chronic in 3, acute in one patient. Staphylococcus aureus was the bacterium respon-

sible of the infection in four cases (50%) and Propionibacterium acnes in 2 cases (25%). In two cases (25%) no bacteria were isolated from the cultures. Any broad spectrum antibiotic treatment was suspended at least two weeks before surgery. Intra-operatively, prior to administration of antibiotic prophylaxis, at least 3 biopsies for culture and hysto-pathological study were taken from the bone and soft tissue around the prosthesis, and joint fluid aspiration was performed for culturing. Previous implants were removed, and an antibiotic-loaded cement spacer was inserted.

Patients received broad spectrum antibiotic therapy until obtaining the results of the cultures. In the cases of presence of the bacterium patients received a specific treatment for six weeks minimum. Otherwise they continued the same broad spectrum antibiotic treatment. Values of leucocytes count, erythrocytes sedimentation rate and CRP were checked every 3 weeks. In two consecutive cases normal results were seen, treatment was suspended and a three-phase bone isotope



scanning was performed. Patients were re-operated, with a mean interval of 7.5 months (5-14) between surgeries. Intra operative biopsies and joint fluid were taken for culture. The cement spacer was removed, and a modular non cemented hemiarthroplasty (SMR,

SMR

ALWAYS THE BEST OPTION

Lima Corporate) was implanted, in order to restore biomechanics and deal with bone loss. In 6 cases (75%) a simple hemiarthroplasty was implanted and in two cases a CTA hemiarthroplasty. In the last two cases, the quality of the cuff was

very poor and the subacromial space was significantly reduced. After surgery, all patients followed a similar rehabilitation programme of between 10 and 14 weeks.

The mean clinical and radiological follow up was 20 months (14-39). In all cases infection was eradicated, as biopsies and fluid cultures were negative. No major complications were observed. Medium value of the Constant Score improved from a pre operative value of 21 (7-30) points to a value of 43 (40-48) at follow up. Radiological evaluation did not show pathologic changes of the implants. No case required revision surgery.

The correct management of infected shoulder prostheses is not standardised. A proper diagnostic work up, as a multidisciplinary approach can lead to eradication of the infection and satisfactory results. The use of a modular CTA (SMR, Lima Corporate) prosthetic system at re-implantation time can optimally deal with the possible situation of compromised biomechanics and bone loss. ✗

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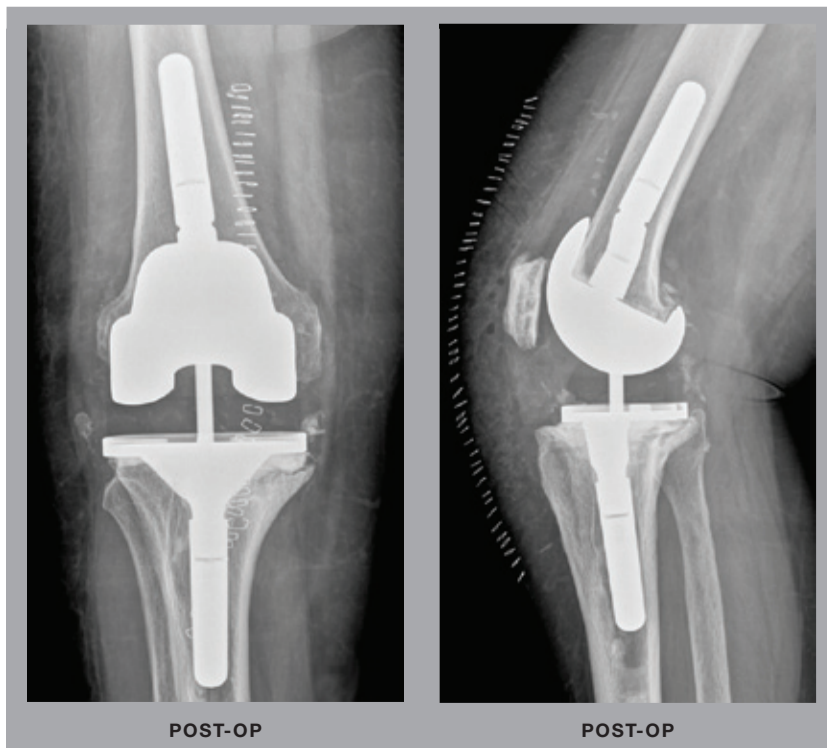
"Federico II" Orthopaedic Clinic, University of Naples, Naples (Italy)

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MULTIGEN⁺

THE TOTAL KNEE SYSTEM



Multigen Plus CCK Revision Knee

Knee balancing, joint line restoration and bone stock preservation are the main key issues in knee revision arthroplasties.

CLINICAL CASE: 57 – years old female

The patient, affected by medial osteoarthritis and internal post-meniscectomy, underwent unicompartimental knee replacement in 2003.

In 2004, due to persistent pain and loosening of the tibial component, the unicompartimental knee was replaced with a cemented tricompartmental knee. With the total knee prosthesis the patient had further complications such as algodystrophy and sepsis, treated in 2006. Four years on, the tibial component was in varus and she was still in severe pain.

In 2010 we decided to perform total knee revision surgery. The preoperative x-rays showed how complicated this case was, due to tibial and femoral misalignment. The patient required both tibial and femoral stems and management of excessive bone loss.

The chosen revision implant was CCK, belonging to the Multigen Plus Total Knee System (Lima Corporate).

The modularity of the Multigen Plus CCK system and the precise instrumentation enabled us to check the components' correct alignment and, thanks to the 17mm liner, to restore the correct knee joint line.

Stem's offset of 6mm was used to achieve the best tibial's cortical bone coverage and, stem's offset of 3mm was used to align the femoral component to the femoral canal.

Thanks to the Multigen Plus CCK system the patient is pain free, the postoperative ROM is of 0° - 100° therefore we can conclude that we have an excellent result for such a difficult case. ✗

P. H. Charon, MD

Clinique des Franciscaines
Nimes (France)

The Lima Delta Revision System

Since the introduction of the Lima Delta Revision system to our department it has become the revision component of choice in Paprosky Type 2c up to 3b situations. In the author's opinion the biggest advantages of this system are as follows:

1. All components having intimate bone contact are built of Trabecular Titanium (TT), a titanium structure built up by electron beam melting. The friction coefficient of this material is higher than tantalum and the elastic modulus is very close to natural bone.
2. The system allows for intraoperative customization: The trabecular titanium shell is equipped with a hook to be placed in the foramen obturatum, furthermore screw fixation is done by dome screws placed in the direction of the resulting hip force and fins to be fixed by screws to the iliac bone. After proper implantation of the shell special augments can be used to obtain optimal inclination and anteversion angles. If bone voids are apparent they can be filled by specially designed hemispheric modules matching to the implanted diameter of the shell. After having chosen the most suitable inner augment the surgeon can choose between various liner options up to 36mm diameter Delta ceramic inlays or dual mobility liners for maximum stability.

By the end of 2011 the author personally has implanted 45 Lima DELTA-REVISION Systems, by now none of these implants had to be revised for aseptic loosening. In 22 cases a hemispheric module to fill bone voids had to be implanted (all Paprosky type 3 defect situations). In 18 cases an angled inner augment was implanted to enhance orientation as far as inclination and anteversion is concerned. ✕

D. Neumann, MD
Salzburg County Hospital
Salzburg (Austria)



Clinical Case

This female patient (77 years old) received a total hip arthroplasty more than 25 years ago. Before the revision we performed a CT scan which revealed massive osteolysis in the area of the cup not to be anticipated on the plain X-Ray.

After removal of the cup the defect had to be classified as a Paprosky type 3b defect situation. As a solution a Lima DELTA-REVISION System was used consisting of the TT shell fixed with dome screws and lateral screws placed in the os ilium, a hemispherical module to fill the bone void in the iliac bone and a 10 degrees angled augment to correct anteversion and inclination together with a 36 mm Delta ceramic inlay.



Fig. 1
Plain anteroposterior of the patient presenting with polyethylene osteolysis.



Fig. 2
CT scan depicting osteolysis at the teardrop.



Fig. 3
Direct postoperative result.

First Multigen Plus H Knee implants



PRE-OP



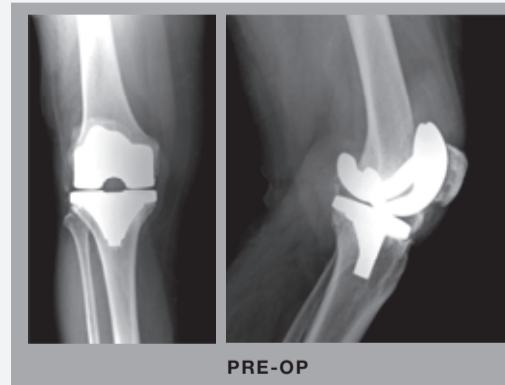
POST-OP

GENDER: female
AGE: 82 years old

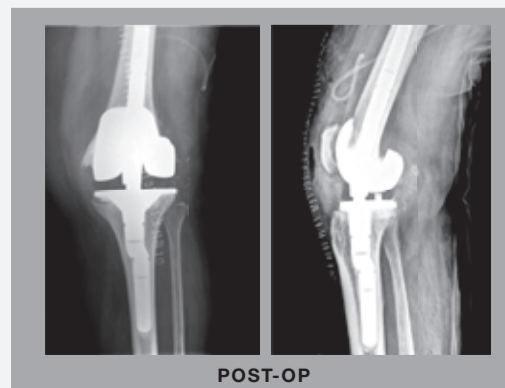
Walking with crutches for 100 m, with pain and insecurity.
Osteoporosis.

- Pre-op right knee:
- Fixed, not reducible, valgus above 15°
 - Anterior tibial subluxation
 - Hypoplasia of lateral condyle

10/1/2012
S. Ourcival, MD
Clinique la Parisière
Bourg De Peage (France)



PRE-OP



POST-OP

GENDER: female
AGE: 76 years old

TKA LT 6 years ago.
TKA RT 5 years ago.

Asymptomatic up to one year ago. In the last 6 months increased pain and instability of the left knee during gait.

- Pre-op left knee:
- Joint effusion
 - ROM -5°/110°
 - Lateral instability
 - Progressive deformity in varus
 - X-Ray: sinking of the femoral component

19/1/2012
E. Balcells, MD
P. Martínez, MD
Hospital de Mollet
Barcelona (Spain)



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Lima Corporate | TRAUMA
Orthopaedic **motion**

Diphos Nail: a new system for IM fixation of proximal humeral epiphyseal fractures

Fractures of the proximal end of the humerus are relatively common and account for 4-5% of all fractures. Over time, various fixation systems have been developed, including angular stable plates, external fixation devices and intramedullary nails; achieving the most anatomical reduction, stable fixation, ensuring faster mobilisation and the complete functional recovery of the shoulder. Our elective choice for proximal humeral fractures treatment, up to 3 or 4 fragments, is IM nailing. Therefore, we focused our efforts on various issues associated with the method in conjunction with Lima Corporate | Trauma and ultimately developed a new proximal humeral IM nail called the Diphos Nail, whose unique design allows for the proximal screws to be placed in two different configurations for simpler and more stable fixation of the humeral tubercles, as compared to similar commercially available nails.

Moreover, we believe that, the problem of proximal screws pulling out/migrating, especially in elderly patients, can be solved by inserting a new polymer (Polyether ether ketone) combined with 30% Carbon fibres, into the proximal part

DIPHOS | Nail
SEE WHAT YOU ARE DOING

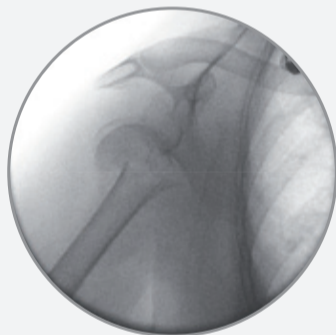
of the nail. Technologically, this new concept enhances the angular stability of the proximal screws and actually prevents them from mobilising. Our preliminary experience with the Diphos Nail has been extremely positive. We found the configuration with the proximo-distal/postero-anterior blocking screw to be particularly useful and innovative, especially for 3-fragment fractures with separation of the greater tubercle. None of the cases treated with the Diphos Nail displayed pull-out/migration of the proximal screws, and the fractures consolidated within the expected time frame. ✕

Clinical Case

PATIENT

GENDER: Female

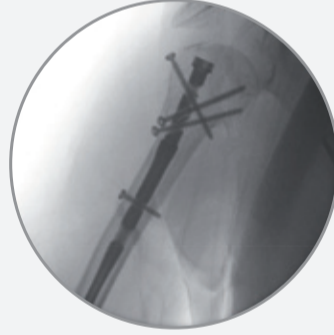
AGE: 66 years old patient



PRE-OPERATIVE



INTRA-OPERATIVE



POST-OPERATIVE

Upcoming Events

❖ February 7-11, 2012

A.A.O.S Annual Meeting
Moscone Center, San Francisco, CA

❖ February 8-10, 2012

IMUKA (Int'l Meeting Unicompartmental Knee Arthritis)
Maastricht, NL

❖ February 24-25, 2012

The 42° JSRA (Annual Meeting of the Japanese Society for Replacement Arthroplasty)
Okinawa - Japan

❖ March 19-21, 2012

16° Congr. Naz. C.I.O. "Le protesi su frattura e le fratture su protesi"
Bolzano - Italy

❖ March 22-23, 2012

CFCOT 9ième Cours de l'Epaule (Shoulder Course)
Paris - France

❖ March 23-24, 2012

SMR Cadaver Workshop
Adelaide, S.A. - Australia

❖ May 17-20, 2012

The 85° JOA (Annual Meeting of the Japanese Orthopaedic Association)
Kyoto - Japan



Christmas Party 2011

Klinika za Ortopediju
Šalata (Croatia)

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Early results in osteosynthesis of fractures of the proximal Humerus with a radiolucent plate of PEEK

INTRODUCTION

The treatment of the fractures of the proximal humerus is controversial and there is a poor consensus especially for the three and four-part fractures. The poor consensus concerns also the materials of fixation. We report the short-term follow-up of this kind of fractures treated by angular stable plate of PEEK (Polyether ether ketone) fixed by titanium screws (Ti6Al4V).

MATERIALS AND METHODS

This non-randomized prospective study includes 10 patients with fractures of the proximal humerus and was started in December 2009. The average age was 70 years (range, 64-78). Of these, seven had 3-part fractures and three had 4-part fractures. Surgery was performed in the beach chair position using a delto-pectoral approach without detachment of the deltoid and an angular stable plate of PEEK (DiPhos). Patient re-evaluation was performed following the constant score.

RESULTS

The mean follow-up was of 10 months (range, 7-16). The mean constant score was 68 and the maximum was 84. The average front elevation was 98 degrees and the average external rotation was 28 degrees. There were no infections, malunions or loss of reduction in any of the patients. Union occurred in all patients at an average of seven to nine weeks postoperatively.

DISCUSSION

Early results in osteosynthesis of fractures of the proximal humerus with plates of PEEK are encouraging. The ease of implantation and the percentage of union have been similar to those obtained with titanium plates. Also the functional outcomes have been similar to those obtained with osteosynthesis using the traditional angular stable plate of titanium. We also had the advantages provided by the new material. The hole in the fixed-angle plate in fact is not threaded, but the titanium screw taps the plate hole, thus it can be inserted in the desired direction. Furthermore, PEEK

DIPHOS
SEE WHAT YOU ARE DOING

is an inert material and so the galvanic corrosion between the plate and the screw head is absent: the removal of the implant is easier.

Finally, the radiolucency of the plate is useful in controlling intraoperative reduction of the fracture and at follow-up of the healing process.

CONCLUSIONS

PEEK seems to be a very interesting material in osteosynthesis. However, due to the short follow-up and the small number of patients, the proceedings and the results must be considered provisional. ✕

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