

the lumbosacral region is the new ilio-sacral method with fusion (ISaF) (Fig. 1). The implant, thanks to its two-element, threaded structure, fulfills a stabilizing and corrective function, ensures the correction of the articular space through the possibility of controlled compression. The Ti-3D-Truss spatial structure (matrix) filling the implant, adapted for collection, transport, and self-formation of the bone flange from autogenous bone, performs the function of growth accelerator.

So far, multicenter data on the practical application of the ISaF method in surgical treatment allowed for the grouping of patients qualified for fusions in the area of the I-S joint and sacrum (Fig. 2) and for the selection of problems qualifying for ISaF stabilization.

ISaF stabilization in clinical practice

For the treatment of a single joint, it is recommended to use 3 ISaF implants following the non-linear positioning rule thus immobilizing the joint (the so-called triad of support). In cases of atypical morphometry: sacral dysmorphia (present in 30 to 40% adults) [3-5], joint asymmetry and other anatomical conditions revealed with x-ray diagnostics, replacement of one of the implants with corresponding one-piece I-S implant of a smaller diameter is possible. In exceptional situations, insertion of only two implants can be considered, however, it is associated with loss of biomechanical stability.



Fig.3. ISaF: Ilio Sacral autogenous Fusion in treatment of ilio, sacral and lumbar regions ...

In a case of confirmed bone calcification in the patient (according to experts, present in 10% of all cases), the intraoperative procedure should include preparation of a wider excision area in the iliac region or even in the sacrum cortex. On the one hand, it will facilitate the implantation, on the other, it may involve less bone being transported into the intra-articular space. Difficulties arise in the classification and surgical procedure of excessively obese patients. In this group, it may be necessary to expand the area of surgical access, wherein standard procedure is realized on an incision approximately 4 cm long.

Surgeons performing surgery on the skeletal system of patients with osteopenia and osteoporosis struggle with many unknowns. In such cases, the ISaF technique makes it possible to implement procedures according to alternative surgical scenarios (ISaF+).

ISaF Stabilization - statistics

According to collected data, the percentage share in currently used individual sizes of ISaF implants in surgeries (2018-2020) is as follows: L35 – 9%, L40 – 36%, L45 – 38%, L50 – 11%, and L55 – 6%. Women (W) were treated more often – 62%. The average age of the treated women (W) was 51,3 years, where in men (M) was 62,5 years. The most frequently treated group were patients aged 40 ÷ 50 years and 60 ÷ 70 years.

Summary

The idea behind ISaF (Ilio-Sacral autogenous Fusion) stabilization [6] was to provide the surgeon with means of unique functionality for the treatment of the sacroiliac region, where the main element in a form of an implant will favor effective stabilization (fixation) of the joint and will lead to accelerated fusion (“4a” principle).

Good clinical results are confirmed by the surgeons applying stabilization in clinical practice. Also, assumed accelerated bone growth in the I-S region is achieved. Previous clinical data also point to an expanded group of indications of surgical support of the patient with problems in the ilio-sacro-lumbar region using the ISaF/ISaF+ system.

Literature

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ISaF: Ilio Sacral autogenous Fusion - Scope of applications of the ISaF method in clinical practice

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key words: ISaF, autogenous fusion, sacroiliac joint, indication groups, ISaF development

Abstract

In the correct qualification of patients with pelvic girdle pain or/and low back pain, conscious and extensive diagnostic indicating the area and cause of dysfunction are important. The assessment of the patient might be difficult due to the complexity of this area of the body. Based on the experience in the surgical treatment of the I-S joint using IfC's ISaF (Ilio Sacral autogenous Fusion) method, the data was pre-collected and the patients were classified to form the groups of indications for I-S joint surgery. Clinical examples were given for the groups, but other needs and possibilities of using the ISaF method were also indicated, including the directions of its development.

Introduction

Factors disrupting the functioning of the I-S joint are degenerative and inflammatory joint processes, pathological changes in joint anatomy, hypermobility caused by dysfunction of the ligaments and periarticular tissues. As well as, traumas, pregnancy, and associated hormonal changes affecting the relaxation of the connective tissue and other, rarely recognizable.

Problems of the I-S joint may also have a biomechanical basis, related to posture abnormalities or previous mechanical stabilizations in adjacent areas, such as hip/knee prosthesis or fixation of the lumbar/lumbosacral region of the spine. After the surgery, a risk of the so-called Failed Back Surgery Syndrome (FBSS) exists. The imbalance in one of the regions of the musculoskeletal system can result in decompensation of other structures located in distant anatomical regions. In spondyloimplantology, it is called the Adjacent Segment Disease (ASD) [1-2].

The causes of I-S joint problems in patients are of various origins and are often difficult to identify. Overlapping clinical symptoms can lead to misdiagnosis. Due to these reasons, a set

of questions arise: what is the right way to diagnose a patient, how to localize the source of pain? When and on what basis to make a decision to perform a surgery with the use of an implant? Which surgical approach, method, and measures to choose? What order of the treatment to adopt in case of multi-level or widespread dysfunctions?

Methods of the ilio-sacral stabilization

The main indication for the surgical treatment of the I-S joint is the lack of effectiveness of conservative treatment. Surgical treatment is primarily expected to relieve the patient of pain by immobilization and fusion of the joint, preferably with accelerated osseointegration. An effective and controlled surgical technique with an implant, as well as, intraoperative accurate use of a morphologically and biomechanically strong bone region are key elements of the treatment.

Known forms of sacroiliac stabilizers usually have a form of “nails”, with polygonal cross-section or one-piece screws that fix ilium with the sacrum. Installation of the polygonal pins leads to damage in a form of fracture of tougher cortical bone in the joint, which weakens the bio-system and delays desired bone fusion. The use of simple screws does not fix the joint sufficiently. Both designs do not provide sufficient joint control in terms of its compression, or if required distraction. They do not provide the possibility of correcting the arrangement of the bone elements, especially with bilateral stabilization. This results in extended treatment time and diminished effectiveness.

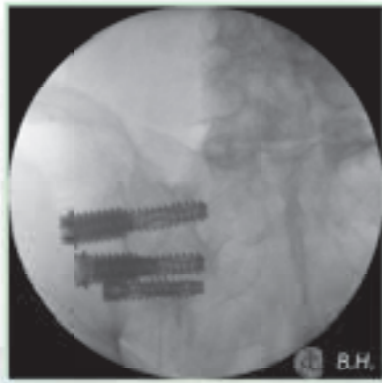
An alternative and complementary method of treating



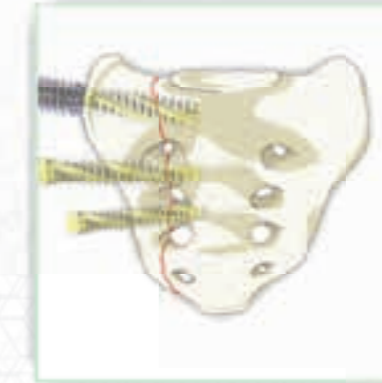
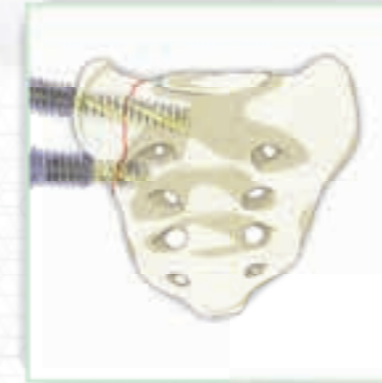
Fig.1. Ilio-sacral stabilization surgery using the ISaF system (A); ISaF as the new stabilizing and compressing method for fusion with two-piece mesh implant „3D-Truss-Ti” (B)



... at IlioSacral joint disorders



... B1 to C1 sacral fractures according to AOSpine Classification

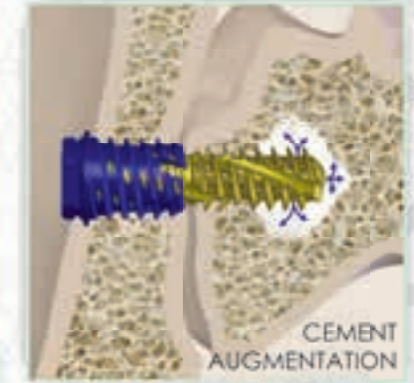
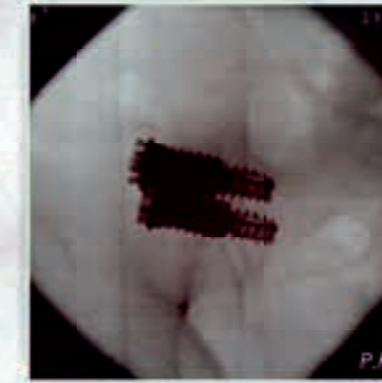


SCOPE of APPLICATIONS

... multi bilateral stabilizations



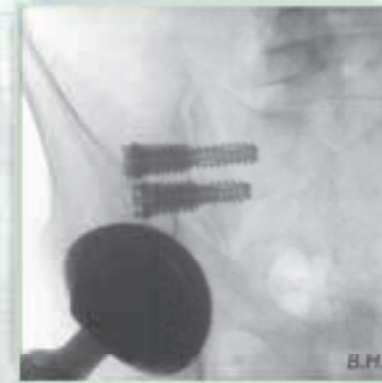
... Ilio-Sacral osteopenic/osteoporotic disorders



ISaF[®] IlioSacral autogenous Fusion

clinical practice

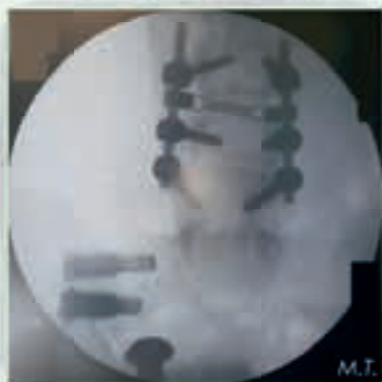
... after hip alloplasty



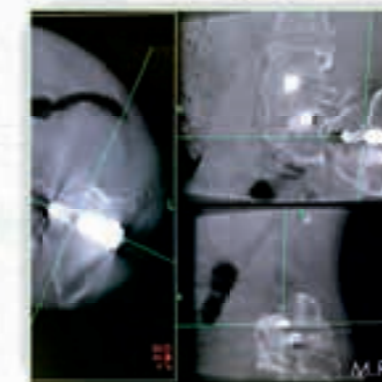
... treatment of post-pregnancy pain



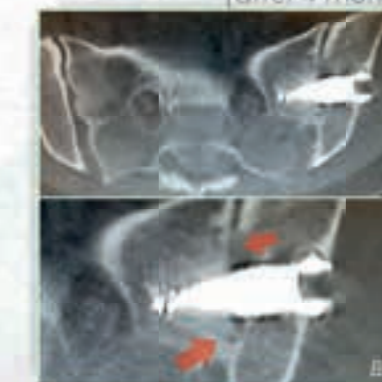
... after spinal surgeries



... with navigation



... accelerated fusion
(after 4 month)



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Fig.2. Development and scope of applications of the ISaF method in clinical practice