Personalized Resurfacing for Osteochondral Lesions of the Talus

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KEYWORDS

• Osteochondral lesion • Talus lesion • Metal inlay • Epic surf • Talus resurfacing

KEY POINTS

- Symptomatic osteochondral lesions (OLTs) of the talus are challenging to treat. Each of the available biological surgical treatment options has its indications and contraindications.
- Prefabricated metal inlay as a treatment option for osteochondral lesions of the talus has unpredictable surgical outcome.
- Patient-specific instruments have shown to improve surgical accuracy and results.
- Customized patient-specific metal inlay is a viable treatment option for OLTs and can serve as a bridge between biologics and conventional joint arthroplasty.

INTRODUCTION

Osteochondral lesions of the talus (OLTs) are the most common cause of chronic deep ankle pain.[1–3] They are characterized by damage to the cartilaginous and subchondral bone of the talar dome. Up to 75% to 100% of the OLTs are associated with underlying trauma.[1,4] These lesions can be a significant traumatic event or recurrent microtrauma.[3,5] In recent years, advancements in imaging modalities, arthroscopic techniques, and biological-based treatment have extended the surgical indication for OLTs.[5,6] For lesions up to 107 mm^2, microfracture and bone marrow stimulation (BMS) are the treatment of choice.[7] However, the clinical results of biological treatments in more extensive lesions and the results of microfracture for secondary

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surgeries are less predictable.[7,8] Osteochondral autologous transfer surgery (OATS) has been used for such lesions, but donor site morbidity is a big drawback for such a procedure.[9–11] For that reason, a focal metallic inlay was developed as a bridge between biologics and conventional joint arthroplasty.[12] Despite promising initial results, prefabricated implants are associated with unpredictable results. This article describes a novel customized patient-specific metal inlay as a treatment option for OLTs.

Etiology

The most common etiology for osteochondral defect of the talus is trauma by an ankle sprain or ankle fracture. Some lesions are non-traumatic and find their origin in ischemia, necrosis, genetics, and other idiopathic etiologies.

Raiken and colleagues used a 9-quadrant grid as a reference point to locate the OLTs; in their cohort, the medial side lesions were more predominant than the central and lateral lesions, with most medial OLT injuries located near the equation of the talar joint. The lateral injuries were found at the anterior quadrant of the talar dome (Fig. 1).[13,14]

The anterolateral defects are usually oval-shaped and shallow and are usually caused by an ankle sprain. The ankle rotates inside the mortise, causing a sheer force that separates the chondral, subchondral, or osteochondral layers. In contrast, the medial defects are usually deep and cup-shaped and are caused by torsional force and axial loading. The fragments can remain partially or wholly attached, while others can be displaced and become loose bodies in the joint.

Both anatomic and mechanical reasons contribute to the talus predisposition for OLTs development. The talar bone is covered with over 60% of its surface with cartilage tissue. Therefore, it has a relatively low blood supply and many watershed areas.

The ankle morphology has 2 important biomechanical characteristics that contribute to the tendency for OLTs in the face of trauma: the ankle congruency and the relatively small load-bearing area-to-forces conducted ratio. The talar dome's average cartilage thickness is 1.2 mm. In contrast, the average thickness of the hip and knee is 1.6 mm and 2.2 mm, respectively, making the ankle cartilage the thinnest with respect to the other joints in the lower limb. Shepherd and Seedhom hypothesized that the compressive loads are spread evenly across the articular surfaces in congruent joint surfaces. Therefore, the need for thick cartilage that can withstand deformities diminishes.

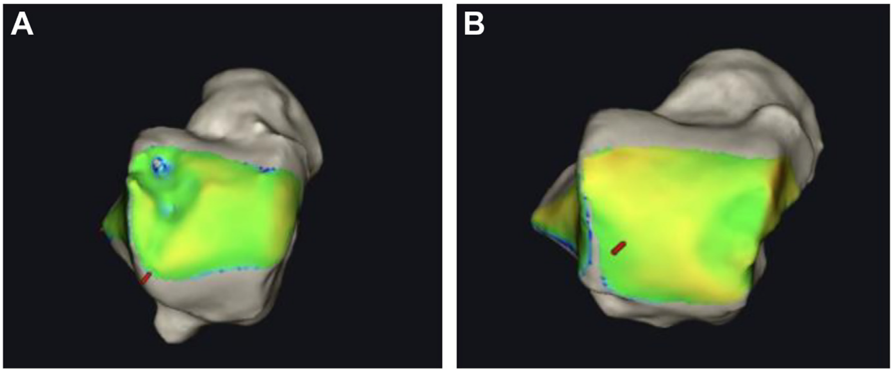

Fig. 1. (*A*) Distance map of the talar dome demonstrates an anterolateral lesion. (*B*) Distance map of the talar dome demonstrates a center medial lesion.

In contrast, incongruent joint cartilage requires withstanding deformities and is consequently covered by a thicker cartilage layer. It is hypothesized that thin cartilage has inferior shock-absorbing capabilities and reduced elasticity, rendering it susceptible to lesions.[2,3]

An important factor is the ankle's relatively low articular surface-to-force conducted ratio. Two main components are responsible for ankle shock-absorbing capabilities, the cartilage and the underlying bone. When the total cartilaginous surface diminishes due to local cartilage defect, it is associated with a load redistributing to the remaining cartilage, requiring adaptation of the joint.

Ankle trauma can affect different parts of the cartilage. A crack or fracture in the subchondral bone plate can create a gateway for joint fluid to the underlying chondral and subchondral layers. During the walking cycle, an intermittent fluid flow is pushed through this crack, reducing or inhibiting the healing of the lesions. In some cases, the remaining cartilage could act as a valve that allows liquids to flow to the subchondral layer and prevents its return. In those cases, the intraosseous pressure increases causing bone absorption and potentially cyst formation. In addition, a decrease in congruency, joint displacement, or malalignment further increases the contact pressure per cartilage area, accelerating the damage progression even further.

The clinical presentation of osteochondritis dissecans (OCD) varies between acute and chronic injury. In the acute setting, the associated injuries mask the acute cartilage injuries. The patient usually presents with swelling, limited range of motion, and pain. The injury could be associated with ankle locking if cartilage fragments displacement exists. These symptoms usually subside after 4 to 6 weeks. Chronic OLTs injuries usually manifest with deep ankle pain with a full ankle range of motion and are usually deprived of ankle swelling. Several factors play a role in pain in OLT injury: increased intraosseous pressure secondary to bone marrow edema or growing cyst volume, increased intraarticular hydrostatic pressure, and interosseous nerve-ending involvement.

Treatment

In the last decades, advancements in imaging modalities and surgical techniques have notably improved the surgical outcome for OLTs treatment. Consequently, conservative treatment for progressive and symptomatic OLTs is no longer recommended. If fragment fixation is impossible, most surgical treatments for primary OLTs are joint preserving and rely on biological treatment. Biological treatment for chondral lesions can be divided into 3 groups, bone-stimulating surgeries, osteochondral grafting, and cell-based technique.

The consensus is that for primary lesions up to 107 mm^2, microfracture and bone marrow stimulation (BMS) are the treatment of choice. However, the consensus between surgeons needs to improve regarding the optimal treatment for more extensive lesions and revision surgeries.

Guelfi and colleagues[15] evaluated the treatment algorithm for OLT of the talus across 1804 foot and ankle surgeons from different nationalities. They found a large variety of OLT management protocols across the responders. More than half of the surgeons advocated 3 months of conservative treatment, including activity restriction and physiotherapy (ranging from 4 weeks to 6 months), before proceeding to a surgical solution. The type of treatment was determined mainly by the patient's activity and demand, lesion size, presence of loose bodies, patient's age, and concomitant ankle instabilities. A total of 92% of the surgeons advocated addressing the lesion and the concomitated injuries contemporaneously, not only the lesion. Regarding the lesion size, most surgeons agree that a lesion under 15 mm should be treated only with

BMS (78%) or with additional procedures such as a scaffold or intra-articular injections (11%). In contrast, non–specific surgical tendencies were found among the participants for more extensive and deeper OLTs, reaffirming the considerable disagreement regarding the optimal biological treatments.

The second treatment option for OLTs is partial or total joint-sacrificing surgeries, such as metal resurfacing, total ankle resurfacing, and arthrodesis. These surgeries are mostly preserved for second-line treatment in middle-aged patients with extensive OLTs.

Biologic Treatments

Bone marrow–stimulating techniques

BMS surgical techniques are based on the violation of the subchondral layer. They require a debriding of the OCD, after which additional micro-fracturing or antegrade drilling can be performed. The microfracture establishes subchondral bone openings. Additionally, it disrupts intraosseous vessels. The damage to the bone and blood vessels introduces blood and bone marrow cells into the OLTs and allows a clot of scar tissue to form.[5] They are followed by fibrocartilaginous tissue replacement of the defect. BMS surgical techniques are relatively non-demanding. Recent studies indicate that BMSs are highly effective in lesions with diameters inferior to 10 mm if patients are younger than 40 years old.[16–18] However, in larger lesion diameters, older patients, and revision surgeries, BMS surgical outcome is related to less favorable results.

Some authors suggest using BMS surgery with the autologous matrix-induced chondrogenesis (AMIC) technique. During this procedure, after the standard BMSs steps, the surgeon covers the lesion site with a collagen I/III membrane that lodges the clot in place and allows for better fibrocartilage formation.[8,19,20] A meta-analysis by Walther and colleagues that included 492 patients found a statistically significant improvement in patient-reported outcomes at the 5-year follow-up. In 2015, Usuelli and colleagues[21,22] introduced an all-arthroscopic AMIC surgical technique that has reduced the need for malleolar osteotomy. AMIC is effective in lesions larger than 1 mm; however, a negative correlation between age and surgical outcome was observed. In addition, patients with a high body mass index (BMI) had less favorable outcomes.[20]

Therefore, BMS alone could be used in the minor lesion in a younger population; in a more extensive lesion, and in age-appropriate patients, BMS in conjunction with AMIC could be used. However, alternative surgical treatment should be considered in revision surgery, OLTs with a significant bone defect or bone cyst, and middle-aged patients.

Osteochondral Grafting (OG)

Osteochondral grafting is a viable treatment option for large OLTs. Currently, 2 main types of OG exist, autograft (osteochondral autologous transfer surgery [OATS] and mosaicplasty)[11,23] or fresh allograft.

Several studies have demonstrated the possible use of autologous allograft for large OLT lesions; in a meta-analysis by Feeney[11] that included 797 patients with an autologous allograft for large OLT, they found a significant improvement in both Visual Analog Scale (VAS) and American Orthopedic Foot and Ankle Score (AOFAS) scores with a mean follow-up of 47.7 months. A meta-analysis by Seow and colleagues[24] evaluated 205 ankles of athletic patients treated with autograft. They found that 86.3% of the patients returned to play, and 81.8% reported returning to preinjury status. A significant side effect is donor site morbidity. For knee-to-ankle transplants, the average donor-side morbidity is 19.6%. And when considering centers that only do a limited number of these OATS procedures(less the 20 procedures), the donor side morbidity is even 37%[25]

Another grafting technique involves the use of fresh allograft. This surgical technique has a few advantages since it does not require graft harvesting from an asymptomatic surgical site and could be fitted precisely to a particular surgical site. A systemic review by Pereira and colleagues[26] evaluated 191 patients treated with fresh allograft for OLT of the talus. They found a significant improvement in AOFAS and VAS scores and an overall graft survivor rate of 86.6%.

The benefit of both techniques stems from the ability to provide hyaluronic cartilage and structural bone support. In contrast, BMS techniques do not provide structural bone support, producing fibrocartilage tissue with inferior qualities concerning hyaluronic cartilage. Jerkin and colleagues compared the clinical results between patients under and over 40 years old and found satisfactory results in the patient-reported outcome and graft survival in both age groups.[18] However, these techniques have limitations. The autograft technique is associated with 9% to 15% of donor site morbidity.[23,27] Whereas frozen allograft and fresh frozen allograft had an unacceptable failure rate; therefore, only the more expensive and less available option, fresh allografts, are used. In addition, this technique carries an increased risk of disease transmission.[26]

OG surgeries are often associated with graft failure, cyst development, and progressive osteoarthritis. Moreover, both techniques are time-consuming and require advanced surgical skills. Finally, achieving anatomic congruence, graft incorporation, and complete healing can be difficult.[27]

Cell-based therapy

BMS techniques rely on the induction of fibrocartilage regeneration. In contrast, the principle behind cell-based treatment approaches is the ability of transplanted chondrocytes to generate a hyaline-like repair tissue with biochemical and biomechanical properties closer to the native articular tissue. Autologous chondrocyte implantation (ACI)[5] is a 2-stage procedure in which chondrocytes are harvested during the initial procedure, expanded in culture, and then reimplanted to the defect in a second procedure. Matrix-associated chondrocyte implantation [5] involves culturing the harvested chondrocytes on collagen or hyaluronic acid–base matrices before implantation. Using this technique, a more even spread to the chondrocytes is obtained. In a large meta-analysis, Mu Hu et al[23] reported that 458 patients reported an 89% success rate and 86.3% improvement in patient-reported outcomes. A vital shortcoming of this technique is that it is not readily available since it requires an advanced lab to cultivate the cells. They do not provide structural support in cases of a significant bone defect.

Metal implants

The notion of using partial or total metal resurfacing has existed for a while. Sir Jhon Charnley introduced it to orthopedic surgery in the 1960s. Partial and complete resurfacing has been widely accepted in hip and shoulder surgery. However, only in recent years has joint resurfacing been reintroduced for knee and ankle surgery. The main goal of this surgical technique is to recreate the ankle anatomy based on intraoperative topographic mapping.

This technique also allows concomitant soft tissue and bony surgical procedures since the metal components do not increase joint volume. The additional benefit is that metal resurfacing is performed with limited surgical exposure, reduced surgical time, simple surgical technique, and scarce blood loss. The success of the resurfacing is based on the implant integration into the surrounding bone, the integrity of the surrounding cartilage, the adherence of the healthy cartilage of the implants, and a correct redistribution of the joint load on the surrounding cartilage.

The main indications are symptomatic middle-aged (35–60 years)[18] active patients with an osteochondral defect of greater than107 mm[27] with significant subchondral bone defects (subchondral cysts) and a history of failed first-line biological treatments. This method can be regarded as the final attempt at joint preservation surgery in a symptomatic young patient before continuing to the joint sacrificing procedure.

Over the last decade, Hemicap,[28–30] a prefabricated focal prosthetic inlay adapted from knee surgery, was introduced as a second-line salvage treatment for OLTs. The initial results were encouraging. Vuurberg et al[29] analyzed 38 patients treated with Hemicap. The study's mean follow-up time was 5.1 years. They reported improved patient-reported outcomes and good patient satisfaction with only 2 revision cases. Other case series demonstrate less favorable results. Ettinger and colleagues[31] reported a 50% revision rate and pointed out that patients with increased BMI treated with Hemicap have a poor prognosis. Maiorano et al[28], in a different study, reported unsatisfactory pain improvement. A few authors have raised concerns about the implant that could explain the outcome discrepancy. First, this implant had only 15 offset configurations, and since there is wide variability in talus morphology,[32] it is highly challenging to reconstruct the complex morphology of the talar dome. An additional limitation of this system is implanting positioning; a biomechanical study highlighted that metal resurfacing could recover more than 90% of the contact area. However, if the implant protrudes by 0.25 mm, peak contact stress increases by 220%. In case the implant recessed 0.25 mm, the peak values of implant-on-cartilage contact stress decreased, while there was an increase in peak values of the cartilage-on-cartilage contact area.[30] Therefore, the surgical results are influenced by the surgeon's ability to position the component in the correct location and depth.

Patient-specific instruments

During the last decade, a few groundbreaking technologies were introduced to foot and ankle surgery. This technology allows tailoring a patient-specific surgery that considers each patient's unique anatomy. Advanced imaging techniques currently enable surgeons to create individualized preoperative plans. Using this plan, surgeons can manufacture patient-specific "tool kits" with customized operative guides and implants. In ankle arthroplasties, weight-bearing computed tomography for preoperative plans and customized implants have been proven to improve surgical accuracy in many studies.[33] Premanufactured focal implants for osteochondral currently demonstrate limited ability and are technically demanding. In order not to compromise on implant location, size, and shape,novel patient-specific metallic inlay for OLTs and focal cartilage defect of the knee was proposed. The currently available literature is scarce. Stålman and colleagues [34] used customized femoral condyle implants for focal cartilage injuries. In a short-term study, they reported no implant migration and good subjective outcomes at the 12-month follow-up. Al-Bayati et al.[35] evaluated the surgical outcome of customized knee metal inlay at the 5-year follow-up. They reconfirmed that improvement persisted, there was no conversion to total knee replacement, and only 1 patient had progression in OA changes. Specifically, in OLTs treatment, a case report by Holtz et al[36] evaluated the result of a 33-year-old physically active patient with a history of large OLTs in the medial aspect of the talar dome. After a failed conservative and AOTS treatment, he was treated with patient-specific metallic inlay (Episealer Talus Implant, Episurf Medical, Stockholm, Sweden).

At the 5-year follow-up, he reported subjective improvement and a total return to a highly demanding sports activity. The promising results of patient-specific instruments metal inlay for a focal osteochondral lesion in the knee and talus are encouraging. Furthermore, it indicates that it could become a valuable bridging treatment.

Indication and Contraindications

Indication criteria

1. Focal medial or lateral OLTs of the talar dome.
2. Lesion osteochondral lesion of greater than or equal to 12 mm, (>107 mm^2).
3. Symptomatic OLTs causing deep ankle pain unresponsive to conventional conservative treatments.
4. Age between 18 and 65 years.
5. BMI less than35.
6. Absence of joint space narrowing in standard radiographs. (Osteophytes are not considered a contraindication).

Absolute contraindications

1. Non-focal defects demonstrated on an MRI scan.
2. Ongoing infection in the ankle joint.
3. Inflammatory arthritis or radiographic osteoarthritis in the ankle joint.
4. Sensitivity to cobalt–chrome alloys and materials typically used in prosthetic devices.
5. Inadequate bone stock where the Episealer is to be inserted.
6. Existing prosthesis in the area of treatment or opposing surface.
7. Severe lesion on the opposing tibial surface.

Relative contraindications include

1. Pain of unknown etiology
2. Demineralized bone
3. Instability or malalignment in the ankle joint (maximum 5° malalignment)
4. Other diseases or medications that may affect the bone anchoring of the Episealer
5. An uncooperative patient that is not willing to follow instructions.
6. Muscular insufficiency
7. Vascular insufficiency
8. Medical, hormonal, hematological, immunologic, or metabolic illnesses

Image analysis and implant design

Based on a preoperative MRI, a patient-specific virtual 3-dimensional (3D) model of the focal osteochondral lesion is created digitally and used to design an individualized metal implant and corresponding instruments before the surgery (Fig. 2). During the damage mapping (Damage Marking Report), the cartilage and bone structure of the talar dome and the tibial plafond are assessed. The assessment must confirm localized isolated cartilage damage in the talar dome without an opposing cartilage defect or other comorbidities. Based on the 3D joint model, an implant is designed to cover the entire defect of cartilage and underlying bone.

The metal implant is a cobalt–chrome alloy covered with titanium (undercoating) and hydroxyapatite (outer coating). Both joint-facing layers have a thickness of approximately 60 μm and are in the center of the implant. The implant has 1 or 2 centered pins to ensure immediate fixation. The Episealer is manufactured on a custom-made basis.

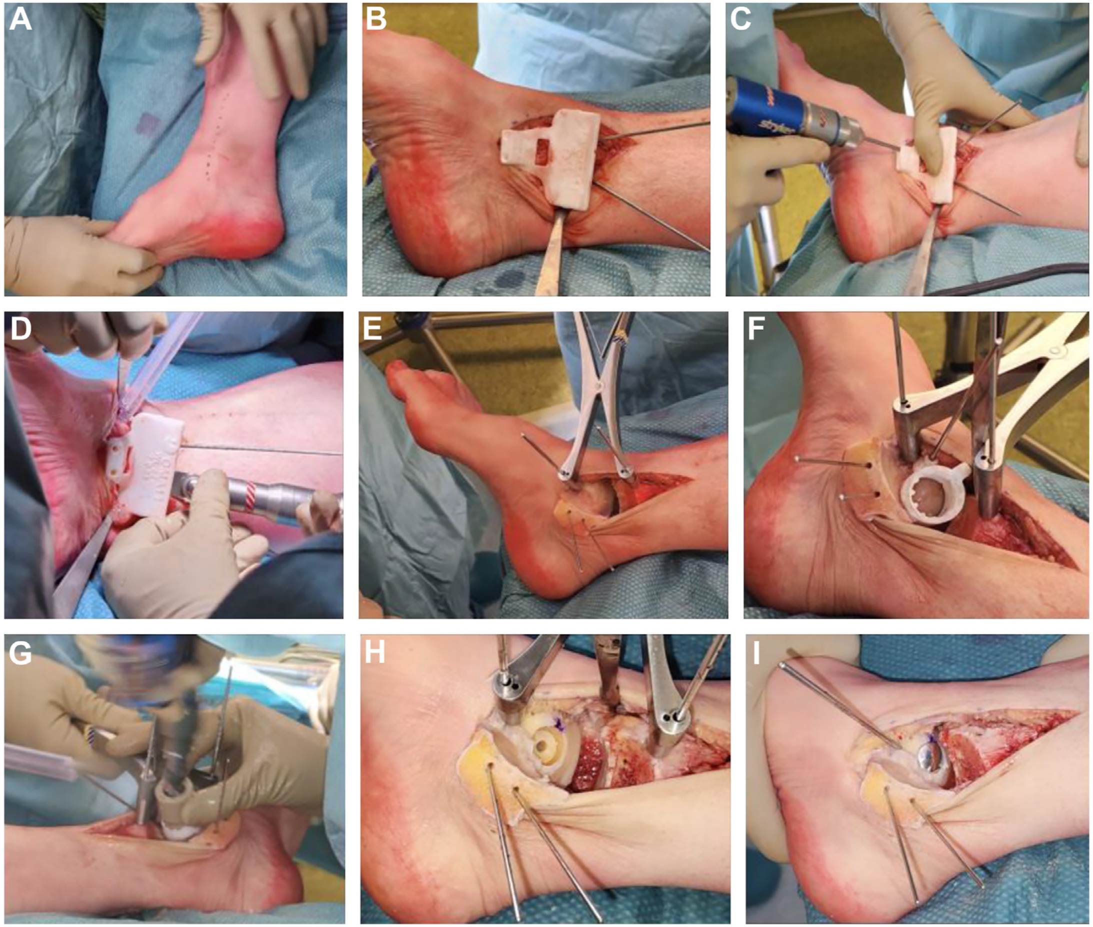

Fig. 2. Episurf surgical technique is performed using a medial approach to the ankle (*A*). A patient-specific osteotomy guide is placed over the medial malleolus and secured using 2 K-wire (*B*). Initially, 2 holes are drilled to prepare the malleolus for fixation at the end of the surgery (*C*). After that, an osteotomy is performed (*D*). The medial malleolus is removed, and the OLT is exposed (*E*). The guide is placed over the OLT (*F*). Through the epiguide, the talar dome is drilled (*G* and *H*), and the implant is inserted (*I*).

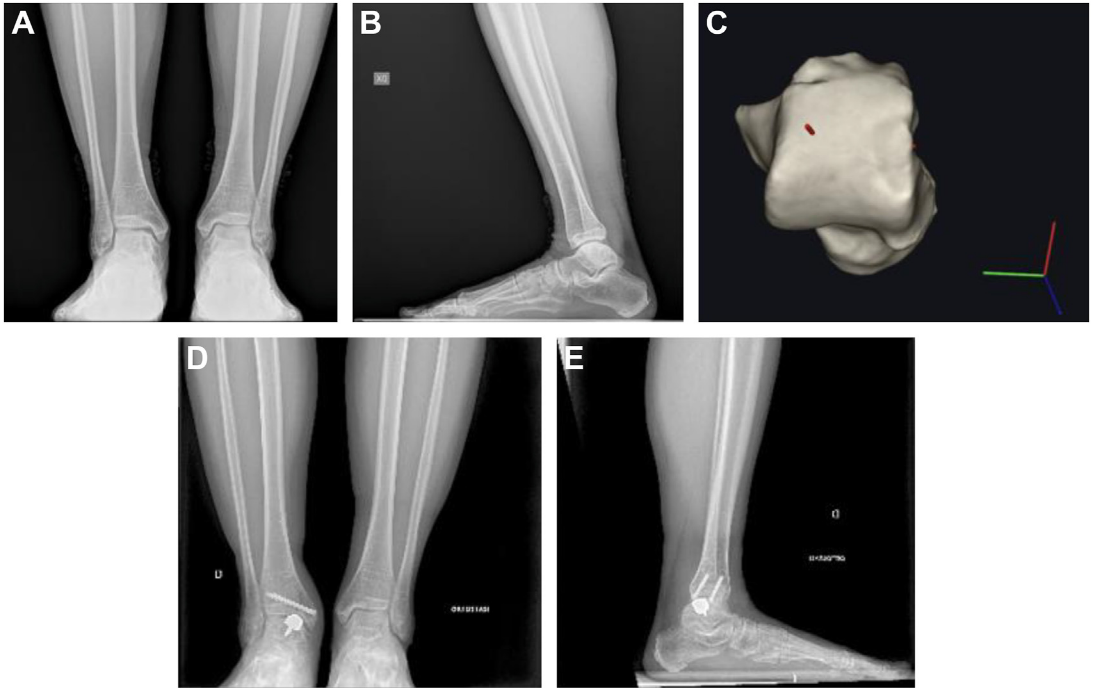

Fig. 3. (A) Preoperative weight-bearing X-rays in an anteroposterior (AP) view showing a medial side osteochondral lesion. (*B*) Preoperative weight-bearing X-rays in lateral view showing an osteochondral lesion. (*C*) Preoperative weight-bearing computed tomography (CT) showing medial osteochondral lesion. (*D*) Sixteen months postoperative weight-bearing X-ray in an AP view showing an Episurf metal implant. (*E*) Postoperative 16-month follow-up weight-bearing X rays in lateral view showing an Episurf implant.

Surgical Technique

In order to access the articular surface for a medial lesion, an osteotomy of the medial malleolus is required. The surgery is conducted in the supine position. A tourniquet usage is recommended. The surgery can be performed with general or spinal anesthesia. For the osteotomy, a patient-specific osteotomy guide is placed. This ensures the correct location and depth of the osteotomy. The guide also contains 2 drill holes for the screws used to fix the osteotomy at the end of the procedure. After the osteotomy and posterior capsular release, the malleolus is displaced. A bone spreader facilitates the placement of the Epiguide. This patient-specific drill polyamide guide (Epiguide) produced by a 3D printer is placed and secured with 2 K-wires on the bone surrounding the defect. Through the Epiguide, the defect is drilled. The drill has a deep stop to prevent over-reaming and can be adjusted by 0.2 mm steps. The implant is delivered with a 3D-printed dummy (Epidummy) that simulates the implant. The dummy ensures that the drilling is deep enough and that the Episealer is not protruding and implanted at the "save zone" 0.4 mm below the native cartilage surface. A dummy is positioned to check if the depth is correct. If the resection is deep enough, the implant can be inserted. Implanting the component 0.4 to 0.6 mm under the adjacent cartilage border is essential to avoid damage to the opposite tibial cartilage. The tibia-oriented surface of the implant (diameter 15 mm) is designed to mimic the talus's original curvature. After implantation, the osteotomized tibia is reduced and fixated with 2 screws. The capsular and subcutaneous tissue and the skin are closed after lavage. Postoperative care includes 6 weeks of partial weight bearing with crutches until the osteotomy consolidated.

THE AUTHOR'S OPINION

Treating symptomatic OLTs can be challenging, especially since the current literature lacks a clear consensus on how to treat extensive lesions, revision cases, and the older population. Emerging technologies offer an opportunity to enable tailor-made patient-specific treatment solutions. Introducing a new surgical technique or technology should follow a specific, stepwise validation process, including concept/theory formation, procedure development and exploration, procedure assessment, and long-term evidence-based studies.[37] The authors have a positive experience with custom-made metal inlays for OLTs (Fig. 3). However, long-term follow-up and larger cohorts are required. The authors believe that this technique is proven effective. The authors expect that the indications for metal inlays as a solution for focal osteochondral talar defect will broaden toward other indications, such as primary focal defects.

CLINICS CARE POINTS

- Preoperative evaluation should include careful assessment of the lower limb alignment and concomitant injuries.
- Any concomitant injuries should be addressed during the OLT surgeries.
- A preoperative evaluation must include an assessment of the OLT dimension, depth, and location.
- The surgeon should tailor a surgical treatment that fits the lesions' morphology.
- Symptomatic Lesions with a diameter inferior to 107 mm could be treated with microfracture. Microfracture shows a less predictable outcome and requires other surgical solutions.

- Preoperative planning using 3D modeling and patient-specific instruments improves surgical accuracy.
- Personalized resurfacing for osteochondral lesions of the talus could serve as a bridging treatment in OLT with significant bone defects and revision surgery.

CONFLICT OF INTEREST

F.G. Usuelli: consultant for ZimmerBiomeet, Episurf, Artrex, Paragon, Gelistlich, planmed. International editor for Foot and Ankle international. N. Van Dijk: consultant for Episurf and Editor ibn chief for Journal of ISAKOS.

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