Knee Surgery, Sports Traumatology, Arthroscopy
https://doi.org/10.1007/s00167-023-07450-8

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High degree of consensus amongst an expert panel regarding focal resurfacing of chondral and osteochondral lesions of the femur with mini-implants

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Received: 6 November 2022 / Accepted: 2 May 2023

Abstract

Introduction The rationale for the use of mini-implants for partial resurfacing in the treatment of femoral chondral and osteochondral lesions is still under debate. The evidence supporting best practise guidelines is based on studies with low-level evidence. A consensus group of experts was convened to collaboratively advance towards consensus opinions regarding the best available evidence. The purpose of this article is to report the resulting consensus statements.

Methods Twenty-five experts participated in a process based on the Delphi method of achieving consensus. Questions and statements were drafted via an online survey of two rounds, for initial agreement and comments on the proposed statements. An in-person meeting between the panellists was organised during the 2022 ESSKA congress to further discuss and debate each of the statements. A final agreement was made via a final online survey a few days later. The strength of consensus was characterised as: consensus, 51–74% agreement; strong consensus, 75–99% agreement; unanimous, 100% agreement.

Results Statements were developed in the fields of patient assessment and indications, surgical considerations and postoperative care. Between the 25 statements that were discussed by this working group, 18 achieved unanimous, whilst 7 strong consensus.

Conclusion The consensus statements, derived from experts in the field, represent guidelines to assist clinicians in decision-making for the appropriate use of mini-implants for partial resurfacing in the treatment of femoral chondral and osteochondral lesions.

Level of evidence Level V.

Keywords Consensus · Mini-implants · Resurfacing · Knee · Chondral · Osteochondral · Defect

Introduction

A variety of treatment modalities have been proposed for the management of knee chondral and osteochondral lesions. Biological repair concepts aim to fill a symptomatic lesion with a durable repair tissue providing patients with pain relief and functional recovery. These concepts could be either procedures that only address cartilage repair, or osteochondral procedures that treat both cartilage and subchondral bone [7]. However, patients after failed biological cartilage procedures, residual symptomatic lesions or negatively influencing factors—such as increasing age, mechanical axis deviation or meniscal deficiency—still represent a therapeutic challenge.

Focal femoral resurfacing of these lesions with mini-implants has been shown to be a valid alternative. Whilst conventional joint arthroplasty is usually reserved for patients with bone on bone disease, the use of mini-implants has been mainly advocated as a bridging interim procedure between biological treatments and conventional arthroplasty [4, 6, 10, 28]. In the published literature, these mini-implants

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Published online: 12 May 2023

are represented by the HemiCAP® and UniCAP® (Anika Therapeutics, Bedford, MA, USA), the Episealer® (Episealer, Episurf AB, Stockholm, Sweden) and the BioPoly® (BioPoly, Fort Wayne, IN, USA).

The rationale for using these implants as a primary or secondary treatment option for chondral and osteochondral lesions of the knee is still under debate, with some authors supporting delay of varus deformity [8] and others that osteoarthritis progression is not completely avoided with this technique [21]. Some clinical studies, and data from the Australian Knee Arthroplasty Registry, report a relatively high revision rate [1, 6, 18, 21]. Conversely, acceptable longer term results are postulated in various case series and the Danish Knee Arthroplasty Registry [4, 6, 10, 11, 18, 22]. However, all the available evidence to date comes from level IV studies [31] or registry data; many of which have short-term follow-up.

As such, the literature supporting the appropriate use of mini-implants is not well defined. It consists of low level of evidence studies with often conflicting information. Hence, the German Knee Society (Deutsche Kniegesellschaft, DKG) in cooperation with the European Knee Associates (ESSKA-EKA) designed a consensus meeting, aiming to develop expert-based consensus statements to guide clinicians in decision-making during the perioperative period for the appropriate use of partial resurfacing mini-implants in the treatment of chondral and osteochondral femoral lesions.

Materials and methods

A consensus process using the modified Delphi method was implemented. Delphi is a systematic procedure that aims to develop consensus when empirical evidence is lacking. A panel of 25 international experts was selected to participate in this project, taking into consideration their known expertise on mini-implants and their scientific publications on the subject. All of the experts were contacted via email and agreed to participate in the study.

Initially, the primary authors (CB, PDM) proposed a series of consensus questions based on an extensive literature review. The questions had the purpose to clarify state-of-the-art diagnostics and treatment as well as any areas of controversy. These questions were sent to the experts' panel via a web-based survey, with an open answer format. The respondents were also asked to add any further questions or comments to be considered for discussion. Subsequently, their answers and additional input were categorised and 25 questions were designed and sent back to them. This second web-based survey round had a multiple-choice format that was created based on the panelists' answers.

Amongst the 25 participants, 69% had experience with the HemiCAP® and UniCAP® implants, 58% with the Episealer®, and 23% with the Biopoly® (some of them were familiar with more than one implant). The HemiCAP® and UniCAP® comprise a contoured articular prosthetic consisting of two components. A rounded cobalt-chromium cap-like top is fastened to a titanium screw. The articular component of the HemiCAP® comes in diameters of 15 mm and 20 mm, being available in various offset sizes to match the contour of the patient's cartilage surface. The UniCAP® has an oblong-shaped top that follows the same principle with HemiCAP®, but is designed for defects sizes of maximum 20 mm × 35 mm. The Episealer® is a customised prosthesis that is manufactured via a computer-aided process using data from magnetic resonance imaging (MRI). The BioPoly® is a microcomposite of ultra-high molecular weight polyethylene and hyaluronic acid that is overmolded onto a grit-blasted titanium-alloy stem. Three sizes (15- and 20-mm diameter round-shaped, and 15 × 24-mm oblong-shaped) are available.

The Mini-Implant Consensus Meeting was held in-person during the 2022 ESSKA congress in Paris. The experts' panel discussed further the results of the second round and debated on each of the questions. They finally voted with hand raise and 25 statements were formed. During the following days, a final agreement on these statements was made via a final web-based survey. The consensus statements strength was set as follows: consensus, 51–74% agreement; strong consensus, 75–99% agreement; unanimous, 100% agreement.

Results

Amongst the 25 statements discussed by this working group, 18 achieved unanimous consensus and 7 achieved strong agreement. The first statement was created during the in-person meeting of the experts at the 2022 ESSKA congress in Paris and applies for any of the following 24 statements (Table 1). The experts' panel unanimously agreed (100%) that the use of focal mini-implants needs to take note of the specific manufacturers indications such as implant maximum depth and size options available. Similar to biological treatment options, adequate patient selection is vital, whilst influencing factors such as alignment, stability, meniscus status, underlying bone condition, grade of osteoarthritis, etc., need to be taken into account during the decision-making process. The following 24 statements can be categorised in 3 different areas; patient assessment and indications, surgical considerations and postoperative care (Table 1).

Patient assessment and indications

The experts agreed (100%) that the recommended imaging for preoperative assessment is magnetic resonance imaging

Table 1 Results of the 25 statements discussed by the expert panel

	Questions and agreed statements	Agreement (%)
1	What are general considerations when using a mini-implant in the treatment of knee chondral or osteochondral lesions? The use of focal mini-implants needs to take notes of the specific manufacturers indications such as implant maximum depth and size options available. As with any biological treatment of these lesions, patient selection is important, whilst influencing factors such as alignment, stability, meniscus status, underlying bone condition, grade of osteoarthritis, etc., need to be taken into account in the decision-making process	25/25—100%
	Patient assessment and indications	
2	What imaging modalities are needed for the preoperative assessment of a mini-implant? Recommended imaging for preoperative assessment consists of an MRI, AP + lateral weight-bearing radiographs and a long-leg standing radiograph. Other imaging options such as a Rosenberg view, a Merchant view or a CT scan may also be necessary in certain circumstances	25/25—100%
3	At what patient age range (if any) mini-implants can be considered? The suggested age range for mini-implant treatments should be between 40 and 60 years. However, patients younger than 40 years can be also considered in certain circumstances (e.g. failed prior regenerative biological treatment, bone necrosis etc.). Patients older than 60 years may also be considered in certain circumstances (e.g. focal lesion without generalised osteoarthritic changes)	24/25—96%
4	Should an increased BMI be considered as a contraindication? A BMI > 35 kg/m^2 represents a relative contraindication	24/25—96%
5	For which type of knee chondral or osteochondral lesions can the treatment with a mini-implant be considered? ICRS grade 3 and 4 chondral or osteochondral lesions (incl. OCD) could be considered for treatment with a mini-implant	25/25—100%
6	What is the maximum lesion size that can be treated with a mini-implant? The maximum lesion size that can be treated with a mini-implant depends on the size options of the available system(s). Risk of failure may increase in larger implant sizes	25/25—100%
7	Are there limitations in the use of mini-implants with respect to the opposing cartilage status? A mini-implant can be used with opposing cartilage damage not more than ICRS grade 1–2 in the respective compartment	25/25—100%
8	Are there limitations in the use of mini-implants with respect to the cartilage status of the other knee compartments? A mini-implant can be used if cartilage damage in the other knee compartments is not more than ICRS grade 1–2. Defects with ICRS grade higher than 2 may be also acceptable, provided that they are not symptomatic	25/25—100%
9	Are there limitations in the use of mini-implants with respect to the arthritic condition of the knee joint? A mini-implant can be used with radiographic OA changes no greater than 1–2 according to the Kellgren and Lawrence grade and no significant joint space narrowing in the respective compartment	24/25—96%
10	Are there limitations in the use of mini-implants with respect to the meniscal status in the same compartment? In general, mini-implants should be used in < 50% meniscal volume loss. This percentage can be higher, only if the meniscal rim and roots are intact and no extrusion is documented in the MRI and/or intraoperatively	25/25—100%
11	Are there limitations in the use of mini-implants with respect to the meniscal status in the contralateral compartment? A mini-implant can be used with meniscal deficiency in the contralateral compartment, provided that the respective compartment is not symptomatic	25/25—100%
12	What knee axis deviation could be accepted when using a mini-implant? In general, less than 3 degrees (varus/valgus) of HKA angle deviation should be accepted; as measured on long-leg standing X-rays. Axis deviation of 3–5 degrees (varus/valgus) may be also acceptable in certain circumstances	25/25—100%
13	Can the implantation of a mini-implant be considered with a concomitant osteotomy for correction of the axis deviation? A mini-implant can be used with a concomitant or prior osteotomy for correction of the axis	24/25 -96%
14	Should a ligamentous instability be considered as contraindication when using a mini-implant? A mini-implants should not be used in a clinically proven ligamentous instability. However, a mini-implant can be used with a concomitant or prior ligamentous stabilisation procedure	25/25—100%
15	Are there any other conditions or comorbidities that should be considered when using a mini-implant? There are no absolute contraindications considering patient comorbidities for the use of a mini-implant. Inflammatory arthritis (in general) and metal allergy may be relative contraindications. However, an individualised approach in terms of comorbidities may be necessary in the decision process	25/25—100%
	Surgical considerations	
16	How much time (if any) should be waited from conservative or surgical treatment (failed) until the consideration of a mini-implant? The time to wait from conservative or (failed) surgical treatment until the consideration of a mini-implant will vary from patient to patient and depends on patient individualised factors, such as pain intensity and lesion individualised factors, such as size and depth of the lesion and whether or not it is causing gross mechanical issues	25/25—100%
17	In which knee compartments can the use of a mini-implant be considered? A mini-implant can be used in the medial, lateral and patellofemoral compartments	25/25—100%

Table 1 (continued)

	Questions and agreed statements	Agreement (%)
18	Could the use of a mini-implant be considered in different compartments in the same knee? A mini-implant can be used in different knee compartments in the same knee if there are focal lesions without generalised osteoarthritic changes	25/25—100%
19	Is the use of round- and oblong-shaped mini-implants appropriate? Round- and oblong-shaped mini-implants can be used	25/25—100%
20	How should a mini-implant be positioned in relation to the adjacent cartilage? A mini-implant should be positioned slightly recessed in relation to the adjacent cartilage	25/25—100%
21	Are there any specific considerations to develop competence with the implantation of a mini-implant? The implantation of a mini-implant is a simple procedure for a surgeon experienced in knee regenerative procedures and/or knee arthroplasty	24/25—96%
	Postoperative care	
22	How should weight bearing be allowed after surgery? Personal preferences and specific considerations such as implant size, opposing cartilage defects, meniscal status, alignment and manufacturer guidelines could be taken into account in the decision process on the postoperative advice regarding weight bearing	25/25—100%
23	Should a brace be used after surgery? After implantation of a mini-implant, no postoperative brace is needed with no restriction of range of motion (if not required by any concomitant procedure)	24/25—96%
24	What kind of imaging and clinical follow-up is recommended after implantation of a mini-implant and at what time points? Clinical and radiographic follow-up should be performed postoperatively and at 6 weeks and 1-year follow-up	22/25—88%
25	What kind of activities/sports are allowed after the implantation of a mini-implant? All kinds of activities/sports are allowed depending on overall knee function	23/25—92%

(MRI), anteroposterior and lateral weight-bearing radiographs and a long-leg standing radiograph. Further imaging including a Rosenberg view, a Merchant view or a computer tomography (CT) scan may also be necessary in certain circumstances.

The suggested patient`s age range for mini-implants was agreed by most of the experts (96%) to be between 40 and 60 years. However, they agreed that patients younger than 40 years old can be also considered in certain circumstances (e.g. failed prior regenerative biological treatment, bone necrosis, etc.). Likewise, patients older than 60 years old may be mini-implant candidates in certain instances (e.g. focal lesions without generalised osteoarthritic changes). The majority of the respondents (96%) supported that BMI > 35 represents a relative contraindication.

The panel unanimously (100%) agreed that only ICRS grade 3 and 4 chondral (or osteochondral) lesions could be considered for treatment with a mini-implant, whilst the maximum defect size depends on the size options of the available system. They highlighted that the risk of failure increases in larger implant sizes. Additionally, they agreed (100%) that the opposing cartilage damage should not be more than ICRS grade 1–2. Considering the other knee compartments, ICRS grade 1–2 defects do not represent a limitation and grade 2 defects and higher may be still acceptable if not symptomatic (100%). In respect of osteoarthritic changes, the majority (96%) supported that mini-implants can be used if the Kellgren and Lawrence grade is not more than 2 and if no significant joint space narrowing is documented in the given knee compartment.

In general, the respondents agreed (100%) that mini-implants should be used when meniscal volume loss is < 50%. This percentage can be higher, only if the meniscal rim and roots are intact and no extrusion is documented on the MRI and/or seen intraoperatively. All of the panellists suggested (100%) that meniscal deficiency in the contralateral compartment does not represent a contraindication, provided that the respective compartment is not symptomatic.

In general, less than 3 degrees (varus/valgus) of hip-knee-ankle (HKA) angle deviation was accepted (100%), whilst axis deviation of 3–5 degrees was considered acceptable in certain circumstances. Furthermore, most of the experts (96%) postulated that a mini-implant can be used with a concomitant or prior knee axis correction osteotomy. They unanimously (100%) agreed that such implants should not be used where there is clinically proven ligamentous instability; however, they can be used with a concomitant or where there has been prior ligamentous stabilisation procedure.

There are no absolute contraindications considering patient comorbidities according the consensus panel (100%). Inflammatory arthritis and metal allergy may be relative contraindications; however, an individualised approach in terms of comorbidities is necessary during decision-making.

Surgical considerations

The overwhelming majority of experts (96%) stated that the time from conservative or failed surgical treatment until the consideration of a mini-implant varies. It depends on patient individualised factors, such as pain intensity and lesion individualised factors, such as lesion size and depth or gross mechanical issues.

They unanimously (100%) decided that mini-implants can be used in the medial, lateral and patellofemoral compartments. More than one can be used in the same knee, in different compartments, to address focal lesions without generalised osteoarthritic changes. It was also agreed (100%) that round- and oblong-shaped implants can be used depending on the defect configuration.

Considering the surgical technique, all of the experts (100%) postulated that mini-implant should be positioned slightly recessed in relation to the adjacent cartilage, whilst most of them (96%) stated that their implantation is a simple procedure for surgeons experienced in knee regenerative procedures and/or knee arthroplasty.

Postoperative care

The panel decided unanimously (100%) that personal preferences and specific considerations, such as implant size, opposing cartilage defects, meniscal status or alignment and manufacturer guidelines should be taken into account regarding postoperative weight bearing. Most of them (96%) supported that no postoperative brace is needed and no restriction of range of motion is required, unless required for another concomitant procedure. The majority of the experts (88%) suggested that clinical and radiographic follow-up should be performed postoperatively, at 6 weeks and at 1 year. All kinds of activities and sports are allowed, depending on the overall knee function, according to 92% of the panellists.

Discussion

The panel of the Mini-Implant Consensus Meeting suggested that these devices should mainly be considered in the setting of femoral chondral or osteochondral lesions, when conservative or other surgical treatment fails, in middle-aged patients between 40 and 60 years. Additionally, they agreed that these devices can be used in different knee compartments (even of the same knee) if they represent focal lesions, with no generalised osteoarthritic changes. Patients are not expected to have significant restrictions after surgery, unless specific considerations apply. High degree of agreement was achieved by the experts in all questions, creating strong guidelines for the appropriate use of these devices.

The first statement of this study supports that as with any of the biological treatments, patient selection is important, whilst influencing factors such as alignment, stability, meniscus status, underlying bone condition, or grade of osteoarthritis should be taken into account. The latter 24 statements provide important guidelines that should be consulted when the use of mini-implants is considered. Individual influencing factors must be always respected and included in the decision-making.

Only one prospective study is available for the BioPoly®, presenting 33 patients with a good clinical outcome at 2-year follow-up [24]. However, longer term results have not been published for this implant. Two clinical studies including a case series of ten patients with 5 years minimum follow-up [4] and a multicentric analysis of 75 patients at 2-year follow-up [17] are published for the Episealer®. A good subjective outcome was obtained in both studies with a low revision rate [4, 17]—one patient was revised to unicompartmental knee arthroplasty (UKA), and one was revised to bone grafting and a membrane [17]. The majority of the related literature focus on the HemiCAP® and UniCAP® implants, including four systematic reviews [5, 14, 15, 21] and data from two large registries [2, 10]. All these studies represent evidence level 4, whilst the reported revision rate ranges widely. In the Australian Arthroplasty Registry documenting 245 "partial knee resurfacing procedures", 49.5% were revised at 12 years [2]. Conversely, in a retrospective case series of 266 patients, a survival of 96.2% was reported using as endpoint implant revision or/and progression of osteoarthritis, with a cumulative hazard for any-reason reoperation of 12.0% [22]. Other authors reported 20% failure rate of the HemiCAP® in 9.4 years. They advocated that this is comparable and potentially more effective than other options, as autologous chondrocyte transplantation and mosaicplasty which have failure rates of 18% and 28% at 11.4 and 10.2 years, respectively [23]. UniCAP® implants are designed for larger lesions, and include the option for an additional polyethylene component on the opposing tibia. The latter show the highest revision rates (between 50 and 56%), in mid-long-term follow-up [10, 20] although good clinical outcomes are documented for the patients who were not revised [20]. Differences in patient selection might be a major factor for these significant differences, and the published papers do not report the state of the tibial corresponding surface when the tibial component was not used. Additionally, lesions requiring a bigger implant are more likely to represent an osteoarthritic pathology followed by extensive degenerative changes. Statements no. 2–20 (unanimous agreement in 14 of them), along with statement no.1 strive to provide clear guidelines to help the clinician regarding the use of mini-implants; hence, they are suggested to be consulted during the decision-making process. As supported in other reports, the panel agreed that patients between 40

and 60 years, with ICRS 3–4 cartilage lesions and no knee instability or significant axis deviation are good candidates for this procedure [8, 9, 18]; however in some instances, patients above or below this age range could benefit from this limited invasive procedure [19, 29].

There is strong agreement that the implantation of a mini-implant is a simple procedure for a surgeon experienced in knee regenerative procedures and/or knee arthroplasty. The permission of full weight-bearing may represent an advantage of this treatment against biological procedures that typically demand weight-bearing restrictions. However, there was unanimous agreement that personal preferences and specific considerations such as implant size, opposing cartilage defects, meniscal status, alignment and manufacturer guidelines should be taken into account regarding the postoperative weight-bearing recommendations. A mini-implant should be positioned slightly recessed in relation to the adjacent cartilage, whilst an axis deviation of more than 5° and ligamentous instability should be addressed with an axis-correcting osteotomy or ligament reconstruction.

The majority of questions in which no unanimous agreement (7 of 25 questions) was achieved, belong to the area therapy and rehabilitation. The statement that "all kinds of activities/sports are allowed depending on overall knee function" can be supported by studies that postulate that the activity level does not appear to affect the survivorship of UKA or TKA at mid-term follow-up [12, 13]. However, it should be noted that the published outcomes after surgery are quite conflicting and vary between case series and registries, with usually higher revision rates for younger patients in the registries data as compared to case series [16, 25, 26, 30]. However, taking into account the nature of the given procedure being specific resurfacing of the joint in a limited area, it is more comparable to the limited biological cartilage repairs than arthroplasty. In this regard, the reason of failure is usually not loosening but ongoing pain and OA progression [10, 22]. In this regard, mini-implants should probably not be compared with UKA and TKA. Between the biological repairs, the highest rates of return to sports are reported after treatment with the osteochondral transplantation (OAT) technique, which can be better compared with a resurfacing implant. In a systematic review and meta-analysis, the authors concluded that OAT should be considered for athletes seeking to benefit from sustained future involvement in sport [27]. However, since the evidence of physical activity after the implantation of a mini-implant is limited, clinicians should consider the first statement of this article when counselling the patient.

It has to be mentioned that consensus statements are level V data, as they represent a blend of experts' opinion and the best available evidence [31]. Even if this could be considered a limitation, the lack of high-quality clinical evidence in this field to date raises the demand of practise guidelines that can be only provided by leaders in the respective field. Further recommendations specifically for the use of mini-implants in the patellofemoral compartment of the knee and the ankle joint appear being fruitful as well.

Recently, a guidance about focal resurfacing implants to treat articular cartilage damage in the knee was published in UK by NICE (National Institute for Health and Care Excellence) [3]. It concurs with the positions of this paper and recommends to consider further research on patient selection, including the site and size of the cartilage damage and long-term outcomes, including the incidence of revision procedures and joint replacements. Furthermore, it was recommended that the implants should be followed up using a suitable registry.

Finally, given the lack of robust evidence, clinicians will be guided by these consensus statements in the appropriate treatment of femoral chondral and osteochondral lesions with mini-implants. The consensus will be updated in the event that further evidence for or against any of the current statements becomes available.

Conclusion

A strong consensus was reached by the expert's panel on all given statements of the Mini-Implant Consensus Meeting. They agreed that mini-implants for chondral or osteochondral lesions of the femoral condyles are easy to use and should be considered as a treatment option when conservative or other surgical treatment fails. Patients between 40 and 60 years with ICRS 3–4 cartilage lesions and no knee instability or significant axis deviation are good candidates. This method is acceptable in both knee compartments, as long as meniscus of the operative compartment is not deficient and there is no generalised osteoarthritis. Finally, the panel suggested that no significant restrictions are needed after surgery.

Funding No funding was received to assist with the preparation of this manuscript.

Data availability Not applicable.

Declarations

Conflict of interest Karl Eriksson, Clemens Kösters, Mats Brittberg, Johannes Holz, Tim Spalding and Peter Verdonk are members of the Consultant Advisory Board for Episurf AB, Stockholm, Sweden. Mike J. McNicholas was a paid consultant for BioPoly, Fort Wayne, IN, USA. Anders Stålman received research funding from Episurf AB, Stockholm, Sweden. Pieter J. Emans served as a speaker for Episurf AB, Stockholm, Sweden. Christoph Becher received research funding from Arthrosurface Inc, Franklin, MA, USA. Andreas B. Imhoff was a paid consultant for Arthrosurface Inc, Franklin, MA, USA. There are no other conflicts.

Ethical approval This work is exempt from institutional board approval.

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