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Capsular fixation limits graft extrusion in lateral meniscal allograft transplantation. --Manuscript Draft--

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Abstract:	<p>Purpose: The main purpose of this investigation was to compare the amount of graft extrusion of lateral MAT performed with a suture-only technique with or without a capsulodesis. Secondly, the assessment of functional results was also covered. We hypothesized that capsular fixation reduces the postoperative degree of allograft extrusion and it does not affect the functional outcomes during the short-term follow-up period studied.</p> <p>Methods: Prospective series of 29 lateral MAT. Fifteen were fixed with a suture-only technique (group A). The remaining 14 cases (group B) also included arthroscopic lateral capsular fixation (capsulodesis). Functional results were assessed with Lysholm, Tegner and VAS for pain. Magnetic resonance imaging (MRI) was performed to determine the degree of meniscal extrusion. Millimeters of extrusion and percentage of extruded meniscal tissue were calculated for both groups. The degree of extrusion was considered minor if it was <3mm or major if it was >3mm.</p> <p>Results: Group A had 11 cases (73.3%) of major extrusion and Group B had 4 cases (28.6%) (p=0.02). The percentage of extruded meniscal tissue was 35% in Group A and 24.6% in group B (p=0.04). At a mean 3.4 years (range 1-4) postoperatively, the Lysholm score had a mean 89.60 ±6.93 and 91.43 ±6.19 points in groups A and B, respectively (p<0.001). The median follow-up Tegner score improved from 4 (range 3-5) to 7 (range 6-9) in Group A (p<0.001) and from 4 (range 3-5) to 7 (range 6-8) in Group B (p<0.001). VAS dropped 5 and 7.3 points in Groups A and B, respectively (p<0.001). There were no complications in this series.</p> <p>Conclusions: In lateral MAT with the suture-only fixation technique, the described capsulodesis minimized meniscal extrusion. In terms of functional results, there were no differences between the groups at a mean 3.4 years follow-up.</p>
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Title:

Capsular fixation limits graft extrusion in lateral meniscal allograft transplantation.

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Short Running Title:

Lateral capsulodesis technique. Graft extrusion and functional results.

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1 **TITLE**

2 Capsular fixation limits graft extrusion in lateral meniscal allograft transplantation.

3

4 **ABSTRACT**

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11 **Methods:** Prospective series of 29 lateral MAT. Fifteen were fixed with a suture-only
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27 capsulodesis minimized meniscal extrusion. In terms of functional results, there were no
28 differences between the groups at a mean 3.4 years follow-up.

29

30 **Keywords**

31 meniscal transplantation, meniscal extrusion, meniscus, knee, capsulodesis

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33

INTRODUCTION

Meniscal allograft transplantation (MAT) was developed in Germany in the mid-1980s [1]. This procedure replaces the lost meniscal tissue to eventually prevent progressive deterioration of the joint due to a previous meniscectomy [2, 3]. To address the problems of meniscectomized patients, there are ongoing efforts to develop techniques for meniscus regeneration or meniscus scaffolding using tissue engineering strategies [4, 5]. Progressively, MAT has become a valid treatment option in relatively young and active patients symptomatic due to a prior meniscectomy [6]. It is currently accepted that MAT provides favorable clinical results on at least the short- and medium-term basis [7]. Several soft-tissue and bone fixation surgical techniques have been described to better fix the graft and to prevent mechanical failures. However, no significant clinical differences have been reported between them to date [7]. Extrusion is an interesting phenomenon that is usually identified shortly after transplantation and seems to be stable over time [8]. It is defined as a tendency toward radial displacement of the graft beyond the tibial margin and has been often observed after MAT [9]. Biomechanically, an extruded meniscus would decrease the resistance to hoop strains. The MAT with suture-only fixation has shown a greater degree of extrusion when compared to bony fixation [10, 11]. Although extrusion has not shown to have any clinical consequences yet, the abnormal position of those grafts causes concern among surgeons. Therefore, different strategies have been suggested to limit or prevent MAT extrusion. Recently, a technique that aims to stabilize the residual meniscus rim or the lateral capsule to the tibial plateau (capsulodesis) has been implemented to reduce extrusion in lateral MAT [12].

59 The main purpose of this investigation was to compare the amount of graft extrusion of
60 lateral MAT performed with a suture-only technique with or without a capsulodesis.
61 Secondly, the assessment of functional results was also covered. We hypothesized
62 that capsular fixation reduces the postoperative degree of allograft extrusion and it does
63 not affect the functional outcomes during the short-term follow-up period studied.

METHODS

A randomized and prospective clinical trial was performed following the CONSORT guidelines. The study protocol was approved by the institutional review board (*ExtMen 2016-01*). Informed consent was signed from each patient. All the surgical procedures were performed by two of the authors (blinded for review). Twenty-nine consecutive patients were operated on with a lateral MAT. The fixation technique in each patient was randomly determined with permuted blocks for the suture-only group (A) or the capsulodesis group (B).

In all the cases, MAT was indicated for lateral joint line pain due to a previous large meniscectomy that had not improved with non-surgical therapies. Although no relationship between malalignment and meniscal extrusion has been established, patients with alignment beyond 5 degrees of varus or valgus were excluded. Patients who had an Ahlback grade greater than II were also excluded. Neither were cases performed with any concomitant surgical procedure or patients with a body mass index greater than 30 considered for this study.

Radiographic and functional evaluations were performed by two independent observers (both, orthopaedic surgeons). With regards to the functional evaluation, the observers were blinded to the type of MAT fixation used.

Surgical technique

Allograft sizing was matched with the donor's morphometric dimensions (weight and size) and double-checked with the method described by Pollard et al. [13]. The

88 allografts were fresh-frozen, non-irradiated and non-antigen matched. They were
89 provided by an authorized local tissue bank.
90

91 The whole surgical technique was performed arthroscopically in all the cases. The
92 specific details of the suture-only [10, 14] as well as the capsulodesis techniques have
93 been previously described [12, 15]. In all the procedures, the remains of the host
94 menisci were assessed and refreshed using a combination of shaving, rasping and high
95 frequency trephination to promote healing [16]. During the surgical procedure, all the
96 allografts were soaked and kept in a vancomycin-saline solution at 36°C [17]. In all the
97 cases, both allograft horns were fixed to 4.5mm transtibial tunnels drilled at the
98 anatomic anterior and posterior meniscal root attachments [18]. Once the allograft was
99 correctly placed, final fixation was accomplished with a combination of all-inside
100 (FasT-Fix; Smith & Nephew, Andover, MA) vertical or horizontal sutures in the
101 posterior half of the meniscus, up to the popliteus hiatus, and with outside-in sutures in
102 the anterior half. The sutures were placed every 5 to 10mm alternating on the superior
103 and inferior aspects of the graft to obtain a better end-position of the MAT and improve
104 its fixation to the original rim or capsule. At the end of the procedure, the sutures placed
105 on the horns were tied together over the tibial cortex.
106

107 All the allografts that were fixed with only transosseous sutures in the anterior and
108 posterior horns were considered as Group A. In group B, prior to the graft
109 transplantation, the lateral meniscal rim or capsule were also fixed to the lateral tibial
110 plateau margin. The redundant or loose lateral capsule was first identified. If any
111 osteophyte was observed on the lateral edge of the tibial plateau, a motorized burr was
112 used to remove it. Two 2.4mm tunnels were drilled from the anteromedial tibial cortex

aiming to the edge of the lateral tibial plateau, leaving a bridge of 10mm between them, where the capsule was seen more laterally displaced (Fig.1). It was done with the help of a tibial ACL guide (Pinn-ACL Guide. ConMed, Largo, Florida). One suture was then passed through each tunnel. The capsule including any meniscal remnant were pierced with an 18-gauge spinal needle loaded with a #2 PDS suture using an outside-in technique. These shuttle sutures were replaced by high strength sutures and pulled down through each tibial tunnel. This maneuver brings the capsule over the LTP, reducing any redundancy (capsulodesis). Finally, the two strands were tied to each other on the tibial cortex, similarly to the meniscal horn fixation (Fig.2). Alternatively, they can be tied over a button. Once the capsulodesis had been done, the meniscal transplantation itself was performed.

Postoperative care

All the patients had the same postoperative protocol. The first 2 weeks, only proprioceptive weight-bearing with a knee brace blocked in full-extension was allowed. Progressive weight-bearing was subsequently encouraged. Full weight-bearing was regularly obtained by week 4 to 6, depending on the patients' tolerance. Range of motion exercises were limited to 90 degrees the first 4-weeks, increased progressively by week six and then to full range of motion afterwards. At 4 months of index surgery, most of the patients returned to normal activity and workloads.

Magnetic Resonance Imaging Evaluation

An MRI was performed on each patient in the supine position before surgery and between the 12 and 36-month follow-up. All the MRI's were done in a 1.5-T superconducting magnet (Prestige 2T, Elscint, Haifa, Israel) using a knee-specific

circular coil. The protocol for each study was: axial fast spin echo T2-weighted with fat saturation, coronal fast spin echo intermediate-weighted, sagittal spin echo intermediate-weighted, and sagittal fast spin echo T2-weighted with fat saturation. The images were evaluated twice, 3 weeks apart. Two independent observers (orthopaedic surgeons) assessed the images. The mean of these 2 measurements was used in the analysis. The PACS workstation (Centricity Enterprise Web V3.0, General Electric Healthcare, Milwaukee, Wisconsin) was used for the study. As reported, the graft position was evaluated on coronal images [16], where extrusion is maximum. In general, those images were at the level of the medial collateral ligament. Measurement was performed drawing 2 lines. One of them was a vertical line intersecting the peripheral margin of the LTP at the point of transition from horizontal to vertical. A perpendicular line was also drawn from the outer margin of the meniscus to the former line. The latter was specifically done to measure the degree of extrusion [19, 20]. Additionally, when the graft was extruded less than 3mm beyond the LTP, it was considered minor extrusion [20]. Conversely, major extrusion was considered when the allograft exhibited more than 3 millimeters of subluxation [20]. The percentage of extruded meniscal tissue was also calculated. Both the percentage of extrusion as well as it being classified as either major or minor extrusion were then compared between groups.

Functional evaluation

Before surgery and at the final follow-up, clinical outcomes were evaluated with the Lysholm score as well as Tegner Activity Scale. A ten-point Visual Analogical Scale (VAS) for pain was also used. Patient satisfaction with a subjective score was also used. It was graded as very satisfied (4 points), satisfied (3 points), neutral (2 points),

somewhat dissatisfied (1 point) and not satisfied at all (0 points). All the results were used to compare outcomes between groups.

Data Analysis

The sample size was based on a priori power calculations for extrusion. While the categorical variables are reflected in percentages and frequencies, the continuous variables are expressed by a mean +/- standard deviation. The interobserver agreement was included using the intraclass correlation coefficient [21]. The values were interpreted based on previous studies [22]. A 95% confidence interval was calculated for all possible variables. The Student's t-Test was used for independent data with a statistical power of 80% and an alpha error of 0.05 to calculate the number of patients needed in each group to detect statistically significant minimum differences of 10% in relation to the degree of meniscal extrusion. There was a standard deviation of 3 and a maximum follow-up loss of 10%. The results obtained using Fisher's exact test to compare two samples leads us to think that it is broad enough for the analysis of the hypotheses of this study. The Student's t-Test was also used to compare meniscal extrusion rates and functional scores between the two groups. The skewness and kurtosis test demonstrate that all the variables followed normal distributions. All data analysis was assessed using the SPSS 19 package (SPSS Inc, Chicago, Illinois). Statistical significance was set at .05.

RESULTS

The average radiological follow-up period with postoperative MR was 1.5 years (range, 1-3), while it was 3.2 years (range, 1-4) for clinical follow-up. All the patients were available for assessment. The series had 19 men (65.5%) and 10 women (34.5%) with an average age of 40.9 years (range, 26 to 54 years). Sixteen (55.2%) MAT were performed in right knees while 13 (44.8%) were performed in left knees. There were 15 cases in Group A (51.7%) and 14 cases in Group B (48.3%). Table 1 shows that both groups were comparable in terms of radiographic findings, gender, age, and the preoperative functional status.

Graft extrusion

In accordance with the extrusion criteria described above, 14 knees (48.3%) showed graft extrusion as minor (<3 mm) while major extrusion (> 3 mm) was observed in 15 patients (51.7%). Within Group A, there were 4 cases (26.7%) of minor extrusion and 11 cases (73.3%) of major extrusion. In Group B, there were major and minor extrusion in 10 (71.4%) and 4 cases (28, 6%), respectively (Table 2) ($p = 0.02$).

If we focus on comparing the degree of meniscus extrusion with the type of fixation used, a lower percentage of extrusion was also observed in group B. In group A, this percentage was 35 ± 9.8 . Conversely, $24.6\% \pm 15.5$ of extruded meniscal tissue was seen in Group B ($p = 0.04$) (Table 3).

Clinical outcomes

A significant improvement in all the assessed scores was observed when the pre and postoperative values were compared., regardless of the technique used. The Lysholm score improved from 62.3 ± 11.8 and 48.8 ± 13.9 to 89.6 ± 6.9 ($p < 0.001$) and 91.4 ± 6.19 ($p < 0.001$), in Groups A and B, respectively (Fig. 3a). Similarly, the mean VAS score decreased from 7.3 ± 2.1 to 1.3 ± 1.40 in group A ($p < 0.001$) and from 8.2 ± 1 to 0.9 ± 1 in group B ($p < 0.001$) (Fig. 3b). The Tegner Activity Score also improved from 4 (range, 3-5) to 7 (range, 6-9) in Group A ($p < 0.001$) and from 4 (range, 3-5) to 7 (range, 6-8) in Group B ($p < 0.001$) (Fig. 3c). Patient satisfaction with the surgery with a maximum of 4 was 3.4 ± 0.3 points in Group A and 3.8 ± 0.2 in Group B. No differences were observed when comparing the functional variables analyzed between the two study groups. The intraclass correlation coefficient was classified as excellent (0.89, 95% CI 0.81 to 0.95). Finally, no complications have been reported in this series.

DISCUSSION

The main finding of this investigation was that capsulodesis decreased the extrusion of a lateral MAT fixed with a suture-only technique. This confirmed the first hypothesis.

Secondly, in terms of function, both groups obtained similar and comparable results in the short term. That fact confirms the second hypothesis of the study.

Several investigations have shown that transplanted menisci tend to extrude more than native menisci [23, 24]. Despite this extrusion, most series have shown good clinical results. Many aspects of meniscal extrusion are still unknown. Regarding the cause, it could be multifactorial. However, it remains unanswered as to whether this abnormal position may cause any alteration of the meniscus' biomechanics or not. However, concern exists that the non-anatomical position of the MAT might likely produce further damage to the knee in the long-term. The extrusion phenomenon seems to occur early after transplantation (<6 weeks) and does not worsen posteriorly [8]. Similarly, those that do not extrude early are unlikely to further extrude [8]. The vast majority of series that deal with this topic investigated the radial displacement of the graft only on the coronal plane. Few authors have assessed MAT extrusion in an anterior or posterior direction [25, 26], which may also be significant in terms of final meniscal behavior.

Several different strategies have been proposed to limit or minimize extrusion.

Although the final cause is unknown, it is quite common to see a very loose and redundant capsule in lateral symptomatic meniscectomized compartments. That is probably the reason that the capsulodesis technique has been so effective at minimizing extrusion in the current series when compared to the otherwise widely used only-suture technique [10].

242

243 As mentioned earlier on, the cause of meniscal extrusion could be multifactorial. The
244 size of the graft [24], as well as the mismatching of recipient and donor [13, 18], the
245 compartment location (medial versus lateral) [26] and, the type of fixation [10, 12, 14],
246 all have been suggested as possible factors related to graft extrusion. With regards to the
247 graft fixation method, investigated in the current study, it may influence both the failure
248 rate and the kinematics of the knee joint. It has been shown, biomechanically, that
249 extrusion might cause abnormal load transmission and later chondral impairment [27,
250 28]. It is likely that the extruded menisci tend to fail due to the incongruence with the
251 femoral condyle. Therefore, maintaining the correct position of the allograft seems
252 crucial to restoring the normal kinematics of the operated knee. While fixation of the
253 graft meniscal body to the capsule or the meniscal remnant is usually performed with a
254 standard meniscal repair technique, meniscal horn fixation is much trickier. Horn
255 attachment is a critical step that requires strong fixation. In lateral MAT, to that end, the
256 two most commonly used techniques are transtibial fixation with either only soft tissue
257 or with a bone-block in the allograft meniscal horns or the bone-bridge in a trough
258 technique [29]. Some authors sustain that bony fixation technique is superior to the
259 only-suture technique in terms of restoring the normal biomechanics of the
260 compartment and having fewer complications [30, 31]. However, MAT without bone
261 fixation has also shown good and excellent results in terms of pain relief and clinical
262 and functional results [23, 32, 33], allowing for a return to sports activities in top-level
263 athletes [34, 35]. As has been recently shown, the graft also exhibits less extrusion when
264 compared to bony fixation if capsulodesis is added to the lateral MAT fixed without
265 bone plugs [12].

266

MAT extrusion is a phenomenon that appears often after transplantation [10, 12, 14, 26, 29, 32, 36-38], and has no relationship with the preoperative position of the meniscal remnant [36]. It is thought that a strong bony fixation technique keeps the meniscal graft in place and so tends to decrease the rate of extrusion even though that better positioning has not been related to clinical, functional or radiological differences when compared to soft tissue fixation [10, 16]. As far as we known, the current study is the first comparing two different methods of MAT fixations without bone plugs. This may also be significant because some tissue banks worldwide only deliver meniscal allografts without bone blocks.

To date, different methods have been described to reduce the degree of MAT extrusion. Jang et al., in his series [24], suggested reducing the size of the graft by 5%. That approach makes for a reduction in the percentage of meniscal extrusion without producing any deterioration at the clinical or radiological level. When using a bone-bridge technique, the greater the obliquity of the trough on the axial plane, the more likely the risk of graft extrusion [38]. Therefore, assuring a correct starting point of the bone trough diminishes the angle and so the tendency of the MAT to laterally dislocate. Moreover, a simple resection of an osteophyte greater than 2mm in the lateral tibial plateau can also reduce the extrusion of lateral MAT [39]. The rehabilitation process may even influence the degree of graft extrusion [37]. When compared to standard rehabilitation, delayed rehabilitation showed less coronal graft extrusion and joint space narrowing on weight-bearing and reduced the progression of degenerative changes. Lastly, to limit graft subluxation, some surgeons have suggested the fixation of the meniscal graft to the tibial plateau. Although that technique can be effective, it has the inherent risk of reducing the normal mobility of the meniscus during knee motion,

particularly in the lateral compartment where the meniscus presents greater extrusion. Therefore, that technique was refined to preserve the meniscal motion by fixing the peripheral capsule or meniscal rim to the tibial plateau instead. Therefore, the MAT is subsequently secured to a firm lateral wall that has been freshened beforehand to promote healing and graft incorporation [40]. This technique emphasizes the role that the fixation of the capsule could have on the tibial plateau. However, those authors used metallic anchors to fix the graft and failed to provide nor radiological neither clinical outcomes [40].

Despite the efforts to reduce graft extrusion after lateral MAT, there are still pre- and postoperative factors related to graft extrusion. Although the native lateral meniscal roots have been well studied [41], some of their peripheral and meniscal body attachments are still relatively unknown. Some authors consider that the lateral meniscotibial ligament (MTL) plays an important role in stabilizing the body of the lateral meniscus [42]. It could then be hypothesized that extrusion of the graft is to some extent due to the lack of MTL reconstruction during the MAT procedure. Thus, the current capsulodesis technique, with the tunnels drilled at the level of the anatomical attachments of the MTL, is somehow reproducing its function and so limiting the extrusion of the allograft [12]. In terms of extrusion, the proposed capsulodesis added to a soft-tissue fixation through bone tunnels positively compares to bony fixation methods [12].

The described technique may thus provide additional biomechanical benefits to the MAT procedure. It is a versatile technique that avoids additional hardware while preserving good bone stock (2.4mm trans-osseous tunnels). It also provides a

satisfactory option to reduce lateral MAT extrusion when the graft is supplied by the tissue bank without bone blocks. Last but not least, being an implant-free technique allows for optimal postoperative MRI assessment (Fig. 4).

Although there is still a big dilemma regarding the impact of the meniscal extrusion on the future of the knee joint, this series showed one of the lowest meniscal extrusion rates to date [7, 9-10, 12, 14, 26, 29, 32, 36-38]. Longer follow-up studies are needed to confirm these results. Anatomical studies are also required to further study the anatomy and biomechanics of the knee lateral structures and their impact on knee kinematics after MAT.

Different limitations to this investigation need to be addressed. A larger sample size could have reflected some differences in the clinical outcomes and thus, the possibility of a type II or beta error can not be excluded. Also, differences in the clinical results could have been different if a longer follow-up had been carried out. However, the main objective of the study was to assess the degree of meniscal extrusion. It is a phenomenon that occurs in the first weeks after the surgery [8]. The intraobserver agreement of the MRI measurement method was not calculated.

CONCLUSIONS

In the lateral MAT suture-only fixation technique, the described capsulodesis minimized meniscal extrusion. In terms of functional results, there were no differences between groups at a mean 3.4 year follow-up.

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462

463 **TABLES**

464 **TABLE 1**

465 **Composition of Both Groups Before Surgery^a**

466

467 Variable	Group A	Group B	Significance (P)
468			
469 Age, y	41 ± 8.5 [33.8, 41.7]	40.9 ± 7.0 [36.8, 45]	0.74
470 Gender, male/female, %	60/40	71.5/28.5	0.55
471 Lysholm	62.3 ± 11.8 [56.3, 68.4]	48.79 ± 13.90 [40.7, 56.8]	0.07
472 Tegner	4 (3-5) [2.96, 4.64]	4 (3-5) [2.95, 4.5]	0.87
473 Visual analog scale	7.3 ± 2.1 [5.17, 7.8]	8.21 ± 1 [7.6, 8.8]	0.51
474 Rx joint space narrowing, mm	3.1 ± 1.4 [2.62, 3.6]	3 ± 1.2 [2.8, 4.0]	0.33
475			

476 ^aValues expressed as mean, standard deviation and 95% CI unless otherwise indicated.

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478

479

480 **TABLE 2**

481 **Frequency of graft extrusion**

	Minor	Major
	4	11
Suture-Only	(26.7%)	(73.3%)
Capsulodesis	10	4
	(71.4%)	(28.6%)
Total		

14	15
(48.3%)	(51.7%)

p=0.02

482

483 TABLE 3

484 Graft Extrusion Percentage

485

Group	Observations	Mean	S.D.
Suture-Only	15	35	9.8
Capsulodesis	14	24.6	15.5

p-value	0.04
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491 **FIGURE LEGENDS**

492 Fig. 1: Left knee, antero-medial view. Lateral capsulodesis tunnels placement using the
493 ACL Pin Guide through the antero-lateral (AL) portal.

494 Fig. 2: Capsular fixation suture passed through transtibial tunnel and tied to each other
495 on the medial cortex fixing the capsule to the tibial plateau.

496 Fig. 3: Overall improvement of functional scores in Group B: a) Lysholm, b) VAS, c)
497 Tegner

498 Fig. 4: MRI at 6 months postoperatively showing the position of the mid-body of lateral
499 meniscus allograft and the lateral capsulodesis tibial tunnel placement. In the superior
500 right quadrant, arthroscopic view of the transplanted allograft performed after the
501 capsulodesis

TABLES

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CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest

ETHICAL APPROVAL

All procedures performed in the studies involving human participants were in accordance with the ethical standards of Ethics Committee of the Hospital Universitari Quiron Dexeus and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the institutional review board (*ExtMen 2016-01*).

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study