

Long-term Assessment of Oral Health-Related Quality of Life Following Surgical Removal of Mandibular Third Molar with Advanced Platelet-rich Fibrin: a Single-blinded Randomized Controlled Trial

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ABSTRACT

Objectives: The aim of this single-blinded randomized controlled trial was to test the hypothesis of no difference in long-term oral health-related quality of life following surgical removal of an impacted mandibular third molar with advanced platelet-rich fibrin (test) compared with natural socket healing (control).

Material and Methods: Eighty patients were randomly allocated to test or control. Patient demographic, mouth opening, wound healing, and neurosensory function were assessed at enrolment (T0), 10 days (T1), 30 days (T2), and one-year (T3) after surgery. Oral health-related quality of life (OHRQoL) was evaluated by OHIP-14 and SF-36 questionnaires.

Results: There was no statistically significant difference between test and control in patient demographic, mouth opening, and wound healing at T0-T3, as well as oral health impact profile-14 (OHIP-14) at T1, T2, and T3 ($P = 0.35$; $P = 0.086$; $P = 0.19$), or SF-36 at T3 ($P = 0.85$). OHIP-14 score was significantly higher at T1 compared with T0 in test and control ($P < 0.001$), indicating impaired OHRQoL immediately after surgical removal of an impacted mandibular third molar, whereas OHIP-14 score was significantly lower in test and control at T3 compared with T0 ($P < 0.001$), indicating improved long-term OHRQoL. SF-36 score was significantly higher at T3 compared with T0 in control ($P = 0.009$), indicating improved OHRQoL, while test revealed no significant difference ($P = 0.79$).

Conclusions: This study demonstrates that surgical removal of an impacted mandibular third molar is associated with long-term improvement in oral health-related quality of life. However, application of advanced platelet-rich fibrin in the extraction socket does not have a beneficial effect on oral health-related quality of life compared with natural socket healing.

Keywords: patient reported outcome measures; randomized controlled trial; surgery; surveys and questionnaires; third molar; quality of life.

Accepted for publication: 28 March 2026

To cite this article:

Starch-Jensen T, Giordano R, Alsadi DM, Bruun NH, Arendt-Nielsen L.

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J Oral Maxillofac Res 2026;17(1):e1

URL: <http://www.ejomr.org/JOMR/archives/2026/1/e1/v17n1e1.pdf>

doi: [10.5037/jomr.2026.17101](https://doi.org/10.5037/jomr.2026.17101)

INTRODUCTION

Surgical removal of an impacted mandibular third molar (SRM3) is frequently necessary due to pain, infection, caries, periodontal disease, or root resorption of the adjacent second molar. SRM3 is usually accompanied by pain, facial swelling, trismus, and temporary impairment of oral health-related quality of life (OHRQoL) [1-3]. Those sequelae are a normal physiological response due to the surgical trauma and usually resolves within 7 to 10 days [1]. However, prolonged convalescence and persisting pain have been reported following SRM3 causing significant deterioration of OHRQoL as well as pronounced restrictions or limitations in work attendance as well as social and physical activities [4-6]. Increasing age, gender, smoking, systemic diseases, body mass index, presence of pain or pericoronitis prior to surgery, length of surgery, intraoperative complications, surgeon's experience, and contamination of the surgical wound are well-known potential risk factors affecting the duration and intensity of postoperative pain and deterioration of OHRQoL [7,8]. Various pharmacological and preventive strategies have, therefore, been proposed to diminish the length and intensity of postoperative pain including modification of the surgical technique, sufficient intra- and postoperative pain control as well as prophylactic methods like cryotherapy, hyaluronic acid, corticosteroids, acupuncture, kinesio tape, and low-level laser therapy, although convincing efficiency of these prophylactic methods to diminish postoperative pain, facial swelling, and deterioration of OHRQoL have not yet been documented in the literature [9-18]. Advanced platelet-rich fibrin (A-PRF) is a centrifuged fibrin matrix composed of concentrated growth factors, platelet cytokines, and blood cells, which possesses the ability to accelerate wound healing by facilitating angiogenesis, cell recruitment, and release of anti- and pro-inflammatory cytokines and mediators [19,20]. Application of A-PRF within the extraction socket has been advocated to diminish pain, facial swelling, trismus, and accelerate wound healing following SRM3 [21-24]. However, the clinical efficiency of A-PRF on postoperative recovery and OHRQoL is debatable, as reported in systematic reviews and meta-analysis [25-30]. Moreover, long-term assessment of OHRQoL following SRM3 with application of A-PRF in the extraction socket has never previously been investigated. The objective of this single-blinded randomized controlled trial is, therefore, to test the hypothesis of no difference in long-term oral health-related quality

of life following surgical removal of an impacted mandibular third molar with advanced platelet-rich fibrin compared with natural socket healing.

MATERIAL AND METHODS

A detailed description of the applied material and methods have previously been published reporting patient's perception of recovery [31]. Thus, only a short summary of the study design is presented.

Study design

The protocol was prepared according to CONSORT (CONsolidated Standards Of Reporting Trials) Statement (<http://www.consort-statement.org>) (Figure 1) and approved by The North Denmark Region Committee on Health Research Ethics (Approval No: N-20230048) and listed in Clinicaltrials.gov (registration no: NCT06377839). Patients were recruited through social media or admitted to the Department of Oral and Maxillofacial surgery, Aalborg University Hospital for surgical removal of a symptomatic third molar. Candidates were meticulously examined for possible inclusion according to well-defined inclusion and exclusion criteria (Table 1).

Power calculation and randomization

A mean difference in pain VAS score at the first postoperative day was used for sample size calculation. A pain score improvement of 20 was considered clinically relevant. Sample size was calculated using online Sample Size Calculator by ClinCalc (ClinCalc LLC; Illinois, USA - <http://clincalc.com/stats/samplesize.aspx>). A total of 35 patients per group provide a statistical power of 0.8 with an alpha value of 0.05. Forty patients were included in each group to compensate for possible 15% dropouts. A total of 80 patients with a semi or fully impacted symptomatic mandibular third molar were included and randomly allocated to SRM3 with A-PRF (test) or natural socket healing (NSH) (control). A computer-aided block randomisation allocated the patients into two groups of identical size.

Blood samples

A venous blood sample (40 ml, distributed in four 10-ml glass-coated plastic tubes) was collected via venipuncture in the cubital fossa from all patients and centrifuged at 700 g for 8 min (A-PRF 12 - Process for PRF Sarl.; Nice, France) [32].

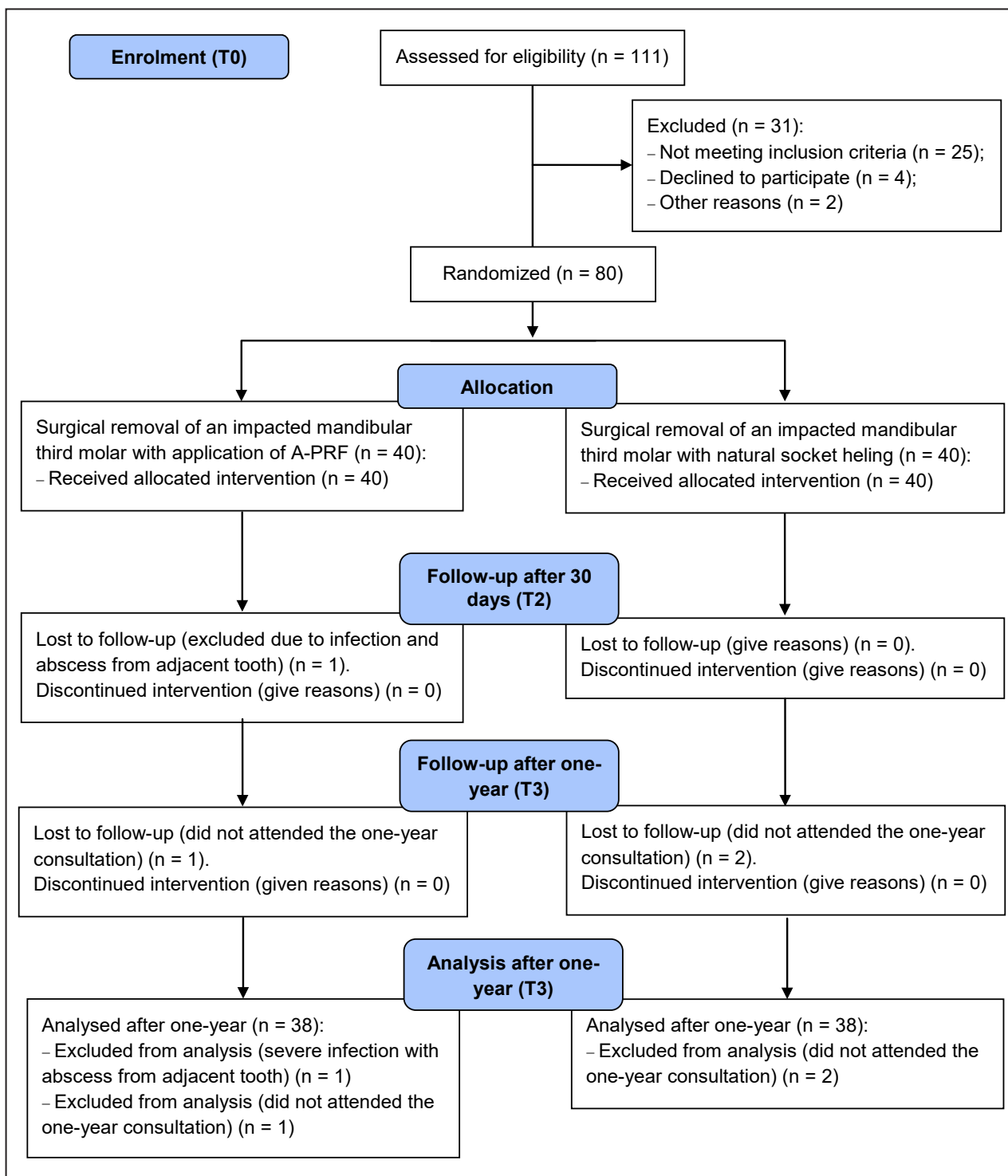


Figure 1. CONSORT flow diagram.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Age ≥ 18 years
	Presence of a semi- or fully impacted mandibular third molar
	Indication for surgical removal of an impacted mandibular third molar
Exclusion criteria	Patients suffering from chronic pain syndrome
	Patients in need of daily analgesic
	Pregnancy
	Psychiatric problems or unrealistic expectations

The centrifuged blood rested in the tubes for 10 min to enhance the consistency of the fibrin clot before A-PRF membrane preparation [32,33].

Surgical procedure

Immediately prior to surgery, a sealed randomization envelope was drawn to assign each patient to either test or control. Patients were blind to their allocation group. An identical surgical approach was used by a trained surgeon (T.S-J.) using standardized and aseptic conditions. A marginal incision from the mandibular ramus to the lower first molar was made. A mucoperiosteal flap was raised and covering bone around the third molar was removed with a round burr under irrigation with 0.9% saline solution. If necessary, the tooth was sectioned with a fissure bur before elevation. The extraction socket and surround bone were irrigated with 0.9% saline solution. In the test group, A-PRF membranes were applied within the extraction socket, while no intervention was applied in the control group. The wound was sutured (Ethicon™ Vicryl Rapide® suture 3-0 - Johnson & Johnson Medical GmbH, Norderstedt, Germany). A compulsory analgesic regime was prescribed for five days including 500 mg paracetamol, 2 tablets 3 times a day (Pamol® - Takeda Pharma A/S; Medical Affairs, Vallensbæk Strand, Denmark), and 400 mg ibuprofen (Burana® - Teva Denmark A/S; Søborg, Denmark), 1 tablet 3 times a day.

Clinical assessment

Clinical examination and questionnaire completion were conducted at enrolment (T0), 10 days (T1), 30 days (T2), and one-year (T3) after surgery, respectively. Patients were informed of their allocation group after the clinical assessment and self-reported questionnaires were completed at T3.

Maximum interincisal mouth opening was measured in mm with a ruler between the upper and lower incisal edges at T0, T1, T2, and T3.

Wound healing was rated using Landry Healing Index at T1, T2, and T3 [34]. Response formats range from very poor = 1, poor = 2, good = 3, very good = 4, excellent = 5, according to tissue colour, response to palpation, granulation tissue, and incision margin.

Oral health-related quality of life assessment

OHRQoL was assessed by validated self-reported questionnaire including oral health impact profile-14 (OHIP-14) and Short Form Health Survey (SF-36). OHIP-14 questionnaire was completed at T0, T1,

T2, and T3. OHIP-14 assess quality-of-life related to people's perception of oral disorders on their well-being [35,36]. OHIP-14 contains seven conceptual dimensions including, functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. OHIP-14 consists of 14 items and two items are used to measure each dimension. The response options are "never/I don't know" = 0, "hardly ever or nearly never" = 1, "occasionally" = 2, "fairly often or many times" = 3, and "very often" = 4. OHIP-14 scale, therefore, range from 0 to 56 and dimension score range from 0 to 8. The total value of the 14 items and each dimension are summed to calculate the severity score, with higher scores indicating poorer OHQoL.

SF-36 questionnaire was completed at T0 and T3. The SF-36 questionnaire is a generic instrument using a 36-item scale that summarize the subject perceived physical- and mental health related quality of life across eight domains of physical and emotional component scores including physical functioning, physical health, emotional problems, energy and fatigue, well-being, social function, bodily pain, general health, and health change [37,38]. The SF-36 score (0 to 100) was calculated using an open-source software SF-36--OrthoToolKit (<https://orthotoolkit.com/sf-36>). Higher scores indicate less disability, while lower scores indicate more disability. A score of 100 is equivalent to no disability.

Statistical analysis

Data management and analysis were conducted using STATA version 19.5 (StataCorp LLC; Texas, USA). Continuous data were expressed as mean and standard deviation (M [SD]). Mixed random intercept by patient regressions were used to compare outcomes between test and control at different time points. Robust variance estimation was applied to account for potential heteroskedasticity and to improve the reliability of standard errors. Results are reported as point estimates with 95% confidence intervals (CI). Wald tests were used in the mixed regression for tests in the mixed regression. P level of significance was ≤ 0.05 .

RESULTS

Patient demographic

Inclusion of patients was initiated at the 7th of December 2023 and the one-year observation period was finalized the 21th of May 2025. In the test

group, one patient was withdrawn before T1 due to severe pain, infection, and abscess caused by apical periodontitis of the adjacent second molar, and one patient did not attend the final consultation at T3. In the control group, two patients did not attend the final consultation at T3. Thus, a total of 76 patients attended the one-year consultation (n = 38 test group and n = 38 control group).

There was no statistically significant difference in patient demographic parameters including gender (P = 0.64), age (P = 0.52), smoking habits (P = 0.6), alcohol consumption (P = 0.56), body mass index

(P = 0.63), indication for SRM3 (P = 0.45), preoperative nervous level (P = 0.77), education level (P = 0.19) or employment (P = 0.56), Pell and Gregory's A, B, and C classification (P = 0.2, P = 0.32, P = 0.08), Decayed Missing Filled Teeth index (P = 0.06), The Modified Dental Anxiety Scale (P = 0.06), and Pain Anxiety Symptoms Scale (P > 0.05) at T0 (Table 2). Moreover, there was no statistically significant difference in intraoperative measurements including surgical time (P = 0.54), frequency of tooth sectioning (P = 0.72), or intraoperative visualization of the inferior alveolar nerve (P = 0.72) (Table 3).

Table 2. Patient demographic

		SRM3 with A-PRF (No. 40)	SRM3 with NSH (No. 40)	P-value ^a	
Gender (female/male)		24/16	26/14	0.64	
Age at the time of surgery (year)	Mean (SD)	32.2 (7.7)	33.4 (9)	0.52	
	Range	20; 51	20; 55		
Smoking (≥ 10 cigarettes per day)		3	2	0.6	
Alcohol (> 7 units per week)		2	1	0.56	
48/38 (FDI dental notation)		22/17	13/27	0.04*	
Body mass index	Mean (SD)	26.3 (4.4)	26.8 (4.5)	0.63	
	Range	20.2; 39	19.5; 37		
DMFT index	Mean (SD)	4.4 (4.3)	6.6 (5.9)	0.06	
	Range	0; 17	0; 19		
Nervous for SRM3 (VAS: 0 - 100)	Mean (SD)	40.2 (28.1)	42.3 (32.5)	0.77	
	Range	0; 100	0; 100		
MDAS	Mean (SD)	9 (3.4)	11 (5.5)	0.06	
	Range	5; 18	4; 25		
Education	Elementary school	4	6	0.19	
	High school	8	14		
	University	28	20		
Employment	Student	8	7	0.56	
	Homebound	1	1		
	Employment	31	30		
	Unemployment	0	2		
Indication for SRM3	Pain	25	22	0.45	
	Pain and infection/swelling	10	14		
	Decay	5	4		
Radiographic signs of pathology	Radiolucency	28	22	0.02*	
	Decay	8	4		
	None	4	14		
Pell and Gregory's classification	IA/IIA/IIIA	2/9/0	0/8/0	0.2	
	IB/IIB/IIIB	6/13/8	4/21/6	0.32	
	IC/IIC/IIIC	0/2/0	0/0/1	0.08	
PASS-20	Total score	Mean (SD)	25 (18.1)	22.7 (14.5)	0.62
		Range	0; 89	0; 61	
	Cognitive	Mean (SD)	10.2 (5.7)	10.4 (5.9)	0.76
		Range	0; 25	0; 22	
	Escape/avoidance	Mean (SD)	6.6 (4.8)	6.5 (4.3)	0.96
		Range	0; 21	0; 15	
	Fear	Mean (SD)	3.9 (5.2)	3.0 (4.5)	0.34
		Range	0; 19	0; 20	
	Physiological anxiety	Mean (SD)	4.1 (4.9)	2.9 (3.3)	0.23
		Range	0; 24	0; 14	

^aChi-square tests for categorical data and t-test for continuous data. *Statistically significant at P < 0.05.

A-PRF = advanced platelet-rich fibrin; DMFT = Decayed Missing Filled Teeth index; PASS = Pain Anxiety Symptoms Scale; NSH = natural socket healing; SD = standard deviation; SRM3 = surgical removal of an impacted mandibular third molar.

Table 3. Intra- and postoperative registrations

		SRM3 with A-PRF (No. 39)	SRM3 with NSH (No. 40)	P-value ^a
Surgical time (min)	Mean (SD)	11.6 (4.1)	11 (3.8)	0.54
	Range	6.2; 22.4	5.2; 22.4	
Intraoperative	Tooth sectioning	26	30	0.72
	Visualization of IAN	5	4	1.00
Days of additional analgesic	Mean (SD)	4.6 (2.5)	4.9 (2.8)	0.64
Infection treated with antibiotic		5	4	1.00

^aStatistically significant at P < 0.05 (chi-square tests for categorical data and t-test for continuous data).
A-PRF = advanced platelet-rich fibrin; IAN = inferior alveolar nerve; NSH = natural socket healing; SD = standard deviation; SRM3 = surgical removal of an impacted mandibular third molar.

No incidence of temporary or permanent neurosensory disturbances of the inferior alveolar nerve was observed in the test or control group at T1, T2, or T3. In the control group, one patient complained of persistent pain as well as loss of perception and taste sensation on the left side of the tongue at T1, T2, and T3. Lingual nerve reconstruction was subsequently performed, with a beneficial symptom-relieving effect.

Clinical assessment

The interincisal mouth opening in the test group was 50 mm (95% CI = 48.4 to 51.5), 42.5 mm (95% CI = 39.9 to 45.2), 50.8 mm (95% CI = 49.2 to 52.4), and 53.4 mm (95% CI = 51.7 to 55.1), at T0, T1, T2, and T3, respectively. Corresponding control group values were 49.2 mm (95% CI = 47.4 to 50.9), 43.7 mm (95% CI = 41.8 to 45.5), 49.4 mm (95% CI = 47.9 to 50.9), and 51.8 mm (95% CI = 50.8 to 53.5) (Figure 2). There was no statistically significant difference in maximum interincisal mouth opening between the test and control group at T0 (P = 0.5), T1 (P = 0.49), T2 (P = 0.2), and T3 (P = 0.18) (Table 4).

Wound healing in the test group was 4.1 (95% CI = 3.9 to 4.2), 4.9 (95% CI = 4.8 to 5), and 5.0 (95% CI = 4.9; 5.0), at T1, T2, and T3, respectively. Corresponding control group values were 4.1 (95% CI = 3.9 to 4.2), 4.9 (95% CI = 4.8 to 4.9),

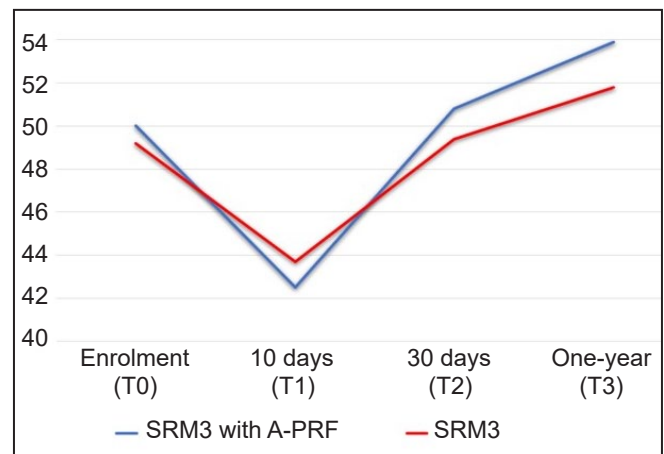


Figure 2. Interincisal mouth opening (mm).
A-PRF = advanced platelet-rich fibrin; SRM3 = surgical removal of an impacted mandibular third molar.

5 (95% CI = 4.9 to 5.1). There was no statistically significant difference in wound healing between the test and control group at T1 (P = 1.00), T2 (P = 0.45), and T3 (P = 0.89) (Table 5).

Oral health-related quality of life assessment

The total OHIP-14 score in the test group was 183, 537, 260, and 50 at T0, T1, T2, and T3, respectively (Table 6). Corresponding control group scores were 287, 618, 368, and 100 (Table 7).

Table 4. Interincisal mouth opening

IMO	SRM3 with A-PRF	SRM3 with NSH	Differences	P-value ^a
Time	Mean (95% CI)	Mean (95% CI)	MD (95% CI)	
T0	50 (48.4; 51.5)	49.2 (47.4; 50.9)	0.8 (-1.5; 3.1)	0.5
T1	42.5 (39.9; 45.2)	43.7 (41.8; 45.5)	-1.1 (-4.3; 2.1)	0.49
T2	50.8 (49.2; 52.4)	49.4 (47.9; 50.9)	1.4 (-0.8; 3.6)	0.2
T3	53.4 (51.7; 55.1)	51.8 (50.8; 53.5)	1.7 (-0.8; 4.1)	0.18

^aStatistically significant at P < 0.05 (Wald test in mixed regression).
A-PRF = advanced platelet-rich fibrin; CI = confidence interval; IMO = interincisal mouth opening; MD = mean difference; NSH = natural socket healing; SRM3 = surgical removal of an impacted mandibular third molar.

Table 5. Wound healing

Wound healing Time	SRM3 with A-PRF Mean (95% CI)	SRM3 with NSH Mean (95% CI)	Differences MD (95% CI)	P-value ^a
T1	4.1 (3.9; 4.2)	4.1 (3.9; 4.2)	-0 (-0.2; 0.2)	1.00
T2	4.9 (4.8; 5)	4.9 (4.8; 4.9)	0 (-0.1; 0.2)	0.45
T3	5 (4.9; 5)	5 (4.9; 5.1)	-0 (-0.1; 0.1)	0.89

^aStatistically significant at P < 0.05 (Wald test in mixed regression).

A-PRF = advanced platelet-rich fibrin; CI = confidence interval; MD = mean difference; NSH = natural socket healing; SRM3 = surgical removal of an impacted mandibular third molar.

Table 6. OHIP-14 questionnaire following SRM3 with A-PRF

Q	T0						T1						T2						T3					
	0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS
Q1	39	0	1	0	0	2	28	8	2	1	0	31	36	2	1	0	0	16	38	0	0	0	0	1
Q2	40	0	0	0	0		32	1	3	3	0		31	5	2	1	0		37	1	0	0	0	
Q3	10	16	12	2	0	71	3	5	12	9	10	180	9	13	13	2	2	93	29	6	3	0	0	22
Q4	21	13	6	0	0		5	4	15	10	5		15	10	13	0	1		32	2	4	0	0	
Q5	27	8	5	0	0	40	30	4	3	1	1	78	34	3	2	0	0	25	34	2	1	1	0	12
Q6	25	10	4	0	1		11	7	12	6	3		26	9	3	1	0		35	2	0	1	0	
Q7	35	5	0	0	0	18	17	6	9	4	3	88	27	8	2	1	1	39	36	1	1	0	0	5
Q8	29	9	2	0	0		17	9	8	5	0		26	7	5	1	0		36	2	0	0	0	
Q9	25	10	5	0	0	28	15	9	12	3	0	57	26	5	8	0	0	30	37	1	0	0	0	8
Q10	34	4	2	0	0		30	5	2	2	0		33	3	3	0	0		35	0	2	1	0	
Q11	33	6	1	0	0	12	22	10	6	1	0	57	25	8	6	0	0	35	38	0	0	0	0	1
Q12	37	2	1	0	0		22	8	4	4	1		29	6	3	1	0		37	1	0	0	0	
Q13	35	2	3	0	0	12	23	8	4	4	0	46	28	10	0	1	0	22	38	0	0	0	0	1
Q14	36	4	0	0	0		27	7	4	1	0		32	5	2	0	0		37	1	0	0	0	
Total OHIP-14 score: 183						Total OHIP-14 score: 537						Total OHIP-14 score: 260						Total OHIP-14 score: 50						
Mean SDS: 4.58 (SD 4.22)						Mean SDS: 13.43 (SD 9.98)						Mean SDS: 6.5 (SD 7.3)						Mean SDS: 1.25 (SD 2.56)						

A-PRF = advanced platelet-rich fibrin; OHIP = Oral Health Impact Profile; Q = question; SD = standard deviation; SDS = subscale dimension score; SRM3 = surgical removal of an impacted mandibular third molar.

0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

T0 = enrolment; T1 = 10 days after SRM3; T2 = 30 days after SRM3; T3 = one-year after SRM3.

Table 7. OHIP-14 questionnaire following SRM3 with natural socket healing

Q	T0						T1						T2						T3					
	0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS
Q1	38	2	0	0	0	6	27	4	6	3	0	44	34	6	0	0	0	22	37	1	0	0	0	7
Q2	37	2	1	0	0		34	0	2	1	3		31	4	4	0	1		36	0	1	0	1	
Q3	4	12	20	4	0	110	3	5	12	11	9	188	7	8	17	6	2	128	27	8	2	1	0	29
Q4	13	11	13	3	0		6	5	10	11	8		10	6	19	4	1		29	6	2	0	1	
Q5	28	2	4	5	1	69	30	3	5	2	0	79	28	5	5	2	0	55	33	1	2	1	1	24
Q6	20	5	11	3	1		14	6	9	8	3		20	9	8	3	0		32	2	2	2	0	
Q7	31	6	2	1	0	31	11	9	8	9	3	110	22	7	8	1	2	59	34	2	1	0	1	12
Q8	26	10	4	0	0		12	15	10	1	2		21	14	4	1	0		35	2	1	0	0	
Q9	26	8	4	2	0	39	11	8	16	3	2	77	21	12	5	2	0	40	33	2	2	1	0	17
Q10	32	2	4	1	1		29	4	5	2	0		31	6	3	0	0		35	0	2	0	1	
Q11	33	4	3	0	0	14	20	10	7	2	1	67	29	7	3	1	0	33	34	4	0	0	0	4
Q12	37	2	1	0	0		21	10	6	1	2		28	9	2	0	1		38	0	0	0	0	
Q13	31	6	2	1	0	18	25	4	9	1	1	53	28	6	4	0	2	31	36	0	1	0	1	7
Q14	36	3	1	0	0		26	8	3	2	1		35	3	1	0	1		37	1	0	0	0	
Total OHIP 14 score: 287						Total OHIP 14 score: 618						Total OHIP 14 score: 368						Total OHIP 14 score: 100						
Mean SDS: 7.17 (SD 5.93)						Mean SDS: 15.45 (SD 9.63)						Mean SDS: 9.2 (SD 7.56)						Mean SDS: 2.5 (SD 5.28)						

OHIP = Oral Health Impact Profile; Q = question; SD = standard deviation; SDS = subscale dimension score; SRM3 = surgical removal of an impacted mandibular third molar.

0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

T0 = enrolment; T1 = 10 days after SRM3; T2 = 30 days after SRM3; T3 = one-year after SRM3.

There was a statistically significant higher total OHIP-14 score in the control group compared with the test group at T0 (P = 0.025), while no statistically significant difference was observed between the test and control group at T1 (P = 0.35), T2 (P = 0.086), and T3 (P = 0.19) (Table 8 and Figure 3). In the test group, the total OHIP-14 score at T1 was statistically significant higher as compared with T0 (P < 0.001) revealing an immediately deterioration of OHRQoL following SRM3, while no statistically significant difference was observed at T2 (P = 14). The total OHIP-14 score at T3 was statistically significant lower as compared with T0 (P < 0.001) indicating a long-term improvement in OHRQoL following SRM3. In the control group, the total OHIP-14 score at T1 was statistically significant higher as compared

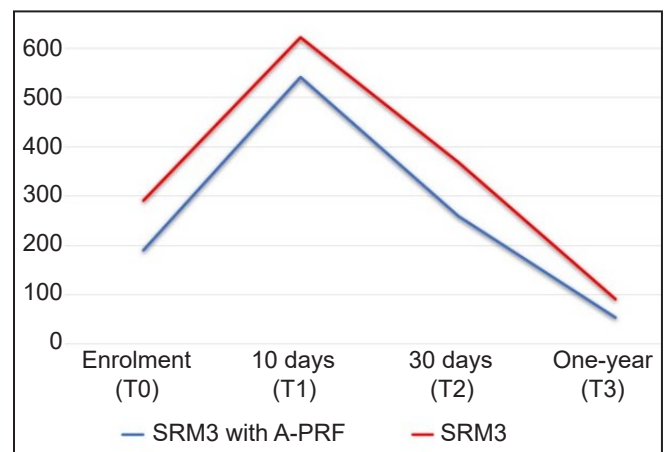


Figure 3. Total oral health impact profile-14 (OHIP-14) score. A-PRF = advanced platelet-rich fibrin; SRM3 = surgical removal of an impacted mandibular third molar.

Table 8. Comparison of OHIP-14 scores

OHIP-14 score	Time	SRM3 with A-PRF	SRM3 with NSH	Differences	P-value ^a
		Mean (95% CI)	Mean (95% CI)	MD (95% CI)	
Total	T0	4.6 (3.2; 5.9)	7.2 (5.4; 9)	-2.6 (-4.9; -0.3)	0.025*
	T1	13.4 (10.3; 16.6)	15.5 (12.6; 18.3)	-2 (-6.3; 2.2)	0.35
	T2	6.5 (4.3; 8.7)	9.2 (7.1; 11.3)	-2.7 (-5.8; 0.4)	0.086
	T3	1.3 (0.2; 2.3)	2.5 (0.8; 4.2)	-1.3 (-3.1; 0.6)	0.19
Functional limitation	T0	0.1 (-0.1; 0.2)	0.2 (-0; 0.3)	-0.1 (-0.3; 0.1)	0.35
	T1	0.8 (0.4; 1.2)	1.1 (0.5; 1.7)	-0.3 (-1; 0.4)	0.38
	T2	0.4 (0.2; 0.6)	0.5 (0.3; 0.8)	-0.1 (-0.5; 0.2)	0.4
	T3	0 (-0.1; 0.1)	0.2 (-0.1; 0.4)	-0.1 (-0.4; 0.1)	0.29
Physical pain	T0	1.8 (1.3; 2.2)	2.8 (2.3; 3.2)	-1 (-1.6; -0.3)	0.002*
	T1	4.5 (3.8; 5.2)	4.7 (4; 5.4)	-0.2 (-1.2; 0.8)	0.69
	T2	2.3 (1.8; 2.9)	3.2 (2.6; 3.8)	-0.9 (-1.7; -0.1)	0.034*
	T3	0.6 (0.2; 0.9)	0.7 (0.3; 1.2)	-0.2 (-0.7; 0.4)	0.54
Psychological discomfort	T0	1 (0.6; 1.4)	1.7 (1.1; 2.3)	-0.7 (-1.5; 0)	0.054
	T1	2 (1.4; 2.5)	2 (1.5; 2.5)	-0 (-0.8; 0.7)	0.95
	T2	0.6 (0.3; 0.9)	1.4 (0.9; 1.8)	-0.8 (-1.3; -0.2)	0.01*
	T3	0.3 (-0.1; 0.7)	0.6 (0.1; 1.1)	-0.3 (-0.9; 0.3)	0.31
Physical disability	T0	0.5 (0.2; 0.7)	0.8 (0.4; 1.1)	-0.3 (-0.8; 0.1)	0.15
	T1	2.2 (1.5; 2.9)	2.8 (2.1; 3.4)	-0.6 (-1.5; 0.4)	0.24
	T2	1 (0.5; 1.4)	1.5 (1; 1.9)	-0.5 (-1.2; 0.2)	0.13
	T3	0.1 (-0; 0.3)	0.3 (0; 0.6)	-0.2 (-0.5; 0.2)	0.31
Psychological disability	T0	0.7 (0.4; 1)	1 (0.6; 1.4)	-0.3 (-0.8; 0.2)	0.26
	T1	1.4 (1; 1.9)	1.9 (1.5; 2.4)	-0.5 (-1.2; 0.2)	0.13
	T2	0.8 (0.4; 1.1)	1 (0.7; 1.3)	-0.2 (-0.7; 0.2)	0.3
	T3	0.2 (-0.1; 0.5)	0.4 (0; 0.8)	-0.2 (-0.7; 0.3)	0.35
Social disability	T0	0.3 (0.1; 0.5)	0.3 (0.1; 0.6)	-0 (-0.4; 0.3)	0.79
	T1	1.4 (0.9; 1.9)	1.7 (1.2; 2.1)	-0.2 (-0.9; 0.4)	0.48
	T2	0.9 (0.5; 1.3)	0.8 (0.4; 1.2)	0.1 (-0.5; 0.6)	0.86
	T3	0 (-0.1; 0.1)	0.1 (-0; 0.2)	-0.1 (-0.2; 0.1)	0.4
Handicap	T0	0.3 (0.1; 0.5)	0.4 (0.2; 0.7)	-0.1 (-0.5; 0.2)	0.41
	T1	1.1 (0.7; 1.6)	1.3 (0.8; 1.8)	-0.2 (-0.8; 0.5)	0.6
	T2	0.5 (0.2; 0.9)	0.8 (0.3; 1.2)	-0.2 (-0.8; 0.3)	0.41
	T3	0 (-0.1; 0.1)	0.2 (-0.1; 0.4)	-0.1 (-0.4; 0.1)	0.25

^aWald test in mixed regression. *Statistically significant at P < 0.05.

A-PRF = advanced platelet-rich fibrin; CI = confidence interval; NSH = natural socket healing; OHIP = Oral Health Impact Profile; MD = mean difference; SRM3 = surgical removal of an impacted mandibular third molar. T0 = enrolment; T1 = 10 days after SRM3; T2 = 30 days after SRM3; T3 = one-year after SRM3. 0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

with T0 (P < 0.001) revealing an immediately deterioration of OHRQoL following SRM3, while no statistically significant difference was observed at T2 (P = 0.15). The total OHIP-14 score at T3 was statistically significant lower as compared with T0 (P < 0.001) indicating a long-term improvement in OHRQoL following SRM3.

OHIP-14 domain scores were assessed at T0, T1, T2, and T3 (Table 8). There was no overall statistically significant difference between test and control group at T0, T1, T2, and T3 in functional limitation (P = 0.35; P = 0.38; P = 0.4; P = 0.29), physical pain (P = 0.002; P = 0.69; P = 0.034; P = 0.54), psychological discomfort (P = 0.054; P = 0.95; P = 0.01; P = 0.31), physical disability (P = 0.15; P = 0.24; P = 0.13; P = 0.31), psychological disability (P = 0.26; P = 0.13; P = 0.3; P = 0.35), social disability (P = 0.79; P = 0.48; P = 0.86; P = 0.4), and handicap (P = 0.41; P = 0.6; P = 0.41; P = 0.25). However, physical pain was statistically significant higher in the control group at T0 (P = 0.002), and T2 (P = 0.034) as well as psychological discomfort at T2 (P = 0.01) (Table 8).

The total SF-36 score in the test group was 765.4 and 761.3 at T0 and T3, respectively.

Corresponding control group scores were 715.8 and 765.8 (Table 9). There was a statistically significant difference in total SF-36 score between test and control group at T0 (P = 0.028), and no statistically significant difference at T3 (P = 0.85). The total SF-36 score statistically significant increased from T0 to T3 in the control group (P = 0.009), indicating a long-term improvement in OHRQoL, whereas no statistically significant difference was observed in the test group from T0 to T3 (P = 0.79).

SF-36 domain scores were assessed at T0 and T3 (Table 9). There was no statistically significant difference between test and control group at T0 and T3 in physical health (P = 0.44; P = 0.28), emotional problems (P = 0.58; P = 0.42), energy (P = 0.12; P = 0.63), well-being (P = 0.089; P = 0.24), and health change (P = 0.7; P = 0.78). In the test group, there was a statistically significant higher score at T0 in physical function (P = 0.006), social functioning (P = 0.003), pain (P = 0.004), and general health (P = 0.032), while no statistically significant difference between test and control group in physical function (P = 0.33), social functioning (P = 0.46), pain (P = 0.85), and general health (P = 0.43) was observed at T3.

Table 9. Comparison of SF-36 scores

SF-36	Time	SRM3 with A-PRF	SRM3 with NSH	Differences	P-value ^a
		Mean (95% CI)	Mean (95% CI)	MD (95% CI)	
Total SF-36 score	T0	765.4 (744.1; 793.1)	715.8 (677.9; 753.7)	49.6 (5.2; 93.9)	0.028*
	T3	761.3 (729.4; 793.1)	765.8 (738.7; 792.9)	-4.6 (-51.1; 42)	0.85
Physical functioning	T0	98.7 (97; 100.4)	94.9 (92.7; 97.1)	3.8 (1.1; 6.6)	0.006*
	T3	97.1 (94.4; 99.8)	95.2 (92.4; 98)	1.9 (-2; 5.8)	0.33
Physical health	T0	97.4 (94.4; 100.5)	95 (89.6; 100.4)	2.4 (-3.7; 8.6)	0.44
	T3	88.8 (80.2; 97.5)	94.4 (89.5; 99.4)	-5.6 (-15.7; 4.6)	0.28
Emotional problems	T0	89.7 (82.2; 97.3)	86.7 (78.5; 94.9)	3.1 (-7.7; 13.9)	0.58
	T3	89.5 (81.3; 97.7)	93.5 (87.8; 99.2)	-4 (-14; 5.9)	0.42
Energy	T0	70.3 (65.1; 75.4)	64 (57.7; 70.3)	6.3 (-1.7; 14.2)	0.12
	T3	72.1 (66.5; 77.8)	74 (68.7; 79.4)	-1.9 (-9.6; 5.8)	0.63
Well-being	T0	82.6 (78.8; 86.3)	77.5 (73.1; 81.9)	5.1 (-0.8; 10.9)	0.089
	T3	86.8 (83.1; 90.4)	83.5 (79.5; 87.5)	3.3 (-2.1; 8.7)	0.24
Social functioning	T0	95.5 (92.3; 98.7)	83.7 (76.6; 90.7)	11.8 (4; 19.6)	0.003*
	T3	95.4 (92.3; 98.5)	93.4 (89.2; 97.6)	2 (-3.2; 7.2)	0.46
Pain	T0	92 (88; 96.1)	81.3 (75.3; 87.3)	10.7 (3.5; 18)	0.004*
	T3	91.5 (86.5; 96.5)	90.8 (86.2; 95.4)	0.7 (-6.4; 7.7)	0.85
General health	T0	82.7 (77.9; 87.5)	74.6 (69.2; 80)	8.1 (0.7; 15.4)	0.032*
	T3	83.6 (79; 88.2)	81 (76.8; 85.2)	2.6 (-3.8; 8.9)	0.43
Health change	T0	56.4 (51.1; 61.7)	58.1 (51.5; 64.8)	-1.7 (-10.3; 6.9)	0.7
	T3	56.6 (52; 61.2)	57.6 (52.5; 62.7)	-1 (-7.9; 5.9)	0.78

^aWald test in mixed regression. *Statistically significant at P < 0.05.

T0 = enrolment; T3 = one-year after SRM3.

A-PRF = advanced platelet-rich fibrin; CI = confidence interval; MD = mean difference; NSH = natural socket healing; SF = Short Form Health Survey; SRM3 = surgical removal of an impacted mandibular third molar.

DISCUSSION

The objective of the present single-blinded randomized controlled clinical trial was to test the hypothesis of no difference in long-term OHRQoL following SRM3 with A-PRF compared with NSH. The hypothesis could not be rejected as no statistically significant difference in OHRQoL was revealed, one-year after SRM3 as evaluated by OHIP-14 and SF-36 questionnaires. SRM3 with A-PRF or NSH showed a statistically significant improvement in OHRQoL as demonstrated by a decrease in total OHIP-14 scores, one-year after SRM3 as compared with pre-operative scores. SRM3 of a symptomatic impacted mandibular third molar, therefore, seems to improve the long-term OHRQoL. Moreover, application of A-PRF in the extraction socket following SRM3 seems not too beneficial improve convalescence or OHRQoL as compared with NSH.

To the best of our knowledge, the present randomized controlled clinical trial is the first study to report long-term changes in OHRQoL following SRM3 with A-PRF compared with NSH. However, this study contains various limitations including inhomogeneous mandibular third molar impaction within the groups as well as limited number of questionnaires and applied evaluation methods. Moreover, only the patients were blinded to the group assignment, while the surgeon, nurses, data collectors, outcome assessors, and statisticians were not blinded.

SRM3 may be associated with persisting pain, trismus, and risk of delayed infections causing prolonged convalescence and long-term deterioration of OHRQoL [39,40]. Pain is generally the most feared nuisance following SRM3 [41]. The highest pain intensity score is usually reached during the first postoperative days and then gradually decreases within the first week [1,42]. In the present study, the mean number of days with pain was 8.7 and 10.2 following SRM3 with A-PRF or NSH, respectively [31]. Various predictors, socio-psychological variables, and patient-specific risk factors may amplify the perceived pain threshold, leading to prolonged convalescence and deterioration of OHRQoL. Age, gender, smoking, fear, dental anxiety, past dental history, socio-economic factors, systemic diseases, body mass index, pain, pericoronitis, length of surgery, complications, surgeon's experience, and wound contamination are potential risk factors, which may aggravate the intensity and duration of pain following SRM3 [7,8]. In the present study, patient demographic, length of surgery, experience of the surgeon, and tooth

sectioning were similar, which diminish the influence of confounding variables on patients' perception of OHRQoL.

OHRQoL reflects patients' perception of their oral health status and how the oral health affects their general well-being, including physical comfort, emotional well-being, and social functioning [43]. OHRQoL is, therefore, a complex interaction between various factors including biological, social, psychological, and cultural parameters [44]. OHIP-14, SF-36, oral impacts on daily performances (OIDP), 16-item United Kingdom OHRQoL (UK-OHQoL-16), and postoperative symptom severity scale (PoSSe) are validated self-administrated questionnaires, which are frequently used to assess the impact of SRM3 on OHRQoL [5,44-47]. In the present study, OHRQoL was assessed by OHIP-14 and SF-36 questionnaires. These questionnaires have also been used to assess the impact of neurosensory disturbance of the lingual nerve and the inferior alveolar nerve on general health and OHRQoL following SRM3, disclosing poorer OHRQoL in patient's med nerve deficit [38]. These results seem comparable to the present study as the patient with lingual nerve deficit responded 77.5 and 80 in SF-36 pain score and general health.

A previously published systematic review and meta-analysis concluded that OHRQoL is negatively affected immediately following SRM3 [2]. In the present study, the mean number of days with sick leave was 1.3 and 1.6 following SRM3 with A-PRF or NSH, respectively [31]. It can thus be concluded that a short-term recovery period is often necessary before patients can resume too their usual daily routine, including ability to eat, chew, speak, and sleep as well as working ability, social life and recreational activities.

Intraoperative application of A-PRF in the extraction socket may potentially alleviate the psychological distress and social avoidance following SRM3 by reducing postoperative pain, facial swelling, restricted mouth opening, and improve wound healing [24-30,48]. However, the beneficial effect of A-PRF on those sequelae and OHRQoL is debatable, as reported in systematic reviews and meta-analysis [24,25]. In the present study, no beneficial effect of A-PRF on patients' perception of recovery, numbers of days with pain or sick leave, mouth opening, or OHRQoL was revealed as compared with NSH [31]. Therefore, further high-quality randomized controlled trials are needed to document the benefits of A-PRF on postoperative sequelae and OHRQoL, before routine use of A-PRF in conjunction with SRM3 can be recommended.

CONCLUSIONS

This study demonstrates that surgical removal of an impacted mandibular third molar of a symptomatic mandibular third molar is associated with a long-term improvement in oral health-related quality of life. However, intraoperatively application of advanced platelet-rich fibrin within the extraction socket does not have a beneficial effect on oral health-related quality of life compared with natural socket healing.

ACKNOWLEDGMENTS AND DISCLOSURE STATEMENTS

The authors wish to thank Ms. Louise Fibiger Vangdal

(Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, Aalborg, Denmark) for organization the current research project and Ms. Lene Boelsmand Henriksen, Ms. Anja Winther Toft, and Ms. Rikke Stang von Kelaita (Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, Aalborg, Denmark) for valuable assistance during the surgical procedures. Centre for Neuroplasticity and Pain (CNAP) is supported by the Danish National Research Foundation (DNRF121).

All authors declare no financial interest or conflict of interest, either directly or indirectly, in the products or information listed in the article.

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To cite this article:

Starch-Jensen T, Giordano R, Alsadi DM, Bruun NH, Arendt-Nielsen L.

Long-term Assessment of Oral Health-Related Quality of Life Following Surgical Removal of Mandibular Third Molar with Advanced Platelet-rich Fibrin: a Single-blinded Randomized Controlled Trial

J Oral Maxillofac Res 2026;17(1):e1

URL: <http://www.ejomr.org/JOMR/archives/2026/1/e1/v17n1e1.pdf>

doi: [10.5037/jomr.2026.17101](https://doi.org/10.5037/jomr.2026.17101)

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