Table 1 Clinical response, % (number of patients assessed)

	DAS28-CRP<2.6 (remission)			CDAI ≤2.8 (remission)		
Initial treatment	MOBILITY (52 weeks)→EXTEND					
Week	148	196	244	148	196	244
Placebo	58.6 (249)	59.3 (231)	63.8 (207)	28.1 (249)	32.9 (231)	36.4 (209)
Sarilumab 150 mg	61.9 (239)	63.0 (219)	63.1 (195)	30.5 (239)	32.6 (221)	34.2 (199)
Sarilumab 200 mg	67.5 (237)	65.3 (225)	70.7 (208)	36.6 (238)	36.7 (226)	39.8 (211)
	TARGET (24 weeks)→EXTEND					
Week	48	96	144	48	96	144
Placebo	38.1 (139)	39.3 (122)	41.0 (117)	15.9 (138)	19.5 (123)	17.2 (116)
Sarilumab 150 mg	44.9 (136)	49.1 (116)	53.8 (104)	18.1 (138)	22.4 (116)	23.4 (107)
Sarilumab 200 mg	41.4 (140)	49.2 (126)	53.5 (114)	15.7 (140)	23.0 (126)	24.3 (115)

Table 2 Treatment emergent adverse event rates per 100 patient-years

	Any AE/SAE	147/9.6
AEs of special interest	AE leading to death/discontinuation	0.4/9.1
	Infections (all/serious/opportunistic/TB)	54.7/3.7/0.9/0.1
	Injection site reactions	24.9
	Hypersensitivity reaction	5.6
	Malignancy (all/excluding NMSC)	0.7/0.5
	MACE (primary/narrow)	0.4/0.5
	Medically adjudicated GI perforation	0.1
	Lupus-like syndrome	0.1

Figure 1 Change in mTSS in patients who completed 52-week double-blind MOBILITY study and subsequently entered open-label EXTEND study. **Conclusions:** Clinical efficacy and inhibition of progression of structural damage with sarilumab plus csDMARDs was sustained up to 5 years of follow-up in patients with diverse prior pharmacologic therapies. The safety profile of sarilumab plus csDMARDs remained stable over >5 years' treatment.

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SAT0173 EFFECTS OF DENOSUMAB, A SUBCUTANEOUS RANKL INHIBITOR, ON THE PROGRESSION OF STRUCTURAL DAMAGE IN JAPANESE PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH CSDMARDs: RESULT FROM THE LONG-TERM TREATMENT OF PHASE 3, DESIRABLE STUDY

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Background: Denosumab is a fully human monoclonal antibody (IgG₂ subclass) that inhibits bone resorption by inhibiting RANKL, a key mediator of osteoclast formation, function, and survival. The effect of denosumab on the progression of joint damage in patients with RA on csDMARDs background treatment from the first 12 months (double-blind, placebo-controlled) of the Phase 3 DESIRABLE study has previously been reported.¹

Objectives: To evaluate the safety and efficacy of long-term treatment with denosumab 60 mg every 6 months (Q6M) or every 3 months (Q3M) with RA patients in long term treatment phase of the DESIRABLE study.

Methods: Upon completion of the 12-month, double-blind phase, all patients were to receive denosumab 60 mg/Q6M or 60 mg/Q3M and calcium and vitamin D daily during the 36-month, open-label extension phase. Patients were randomized in a 1:1:2:2 ratio to receive one of four treatments (figure 1). In this analysis, the continuous administration group received 36 months of denosumab treatment, and the cross-over group received 24 months of denosumab treatment (12 month of placebo in DB phase and 24 months of denosumab treatment phase). The radiographic evaluation was the change from baseline to 12, 24 and 36 months in the van der Heijde modified total Sharp score (mTSS). Radiographs of hands and feet at baseline, 12, 24 and 36 months were scored with blinded time order by 2 readers independently. Average score of the 2 readers is used for the analysis. Missing scores were imputed using linear extrapolation/interpolation.

1): Cross-over group, 2): Continuous administration group

Figure 1 Study design

Characteristic	Visit	Cross-over group		Continuous administration group	
		Placebo/denosumab 60mg Q6M N = 105	Placebo/denosumab 60mg Q3M N = 101	Denosumab 60mg Q6M N = 191	Denosumab 60mg Q3M N = 193
mTSS	12 months	1.29 ± 2.86	1.60 ± 3.62	1.25 ± 4.16	0.98 ± 3.01
	24 months	2.33 ± 4.73	2.05 ± 4.35	2.12 ± 6.10	1.42 ± 4.02
	36 months	2.93 ± 6.56	2.49 ± 4.70	2.26 ± 6.66	1.71 ± 4.59
ES	12 months	0.79 ± 1.76	0.97 ± 2.48	0.70 ± 2.39	0.27 ± 0.98
	24 months	1.23 ± 2.36	1.01 ± 2.48	1.09 ± 3.55	0.36 ± 1.35
	36 months	1.54 ± 3.39	1.18 ± 2.56	0.96 ± 3.36	0.40 ± 1.31
JSN score	12 months	0.51 ± 1.44	0.63 ± 1.75	0.56 ± 2.13	0.71 ± 2.42
	24 months	1.10 ± 2.87	1.04 ± 2.27	1.03 ± 3.13	1.07 ± 3.20
	36 months	1.39 ± 3.63	1.31 ± 2.57	1.30 ± 4.04	1.31 ± 3.67

Data presented are mean ± SD

Table 1 Change from baseline in mTSS, ES and JSN score in DB and long-term treatment phase Data presented are mean ± SD

Results: 667 (placebo/Q6M (P/Q6M), n=113; placebo/Q3M (P/Q3M), n=110; Q6M, n=222; Q3M, n=222) received at least one dose of study drug, and 607 (P/Q6M, n=105; P/Q3M, n=103; Q6M, n=199; Q3M, n=200) completed the DB period and entered the long-term extension. In both continuous administration and

cross-over group, sustained inhibition of mTSS and erosion score (ES) progression was observed during long-term treatment phase (table 1). No effect on joint space narrowing (JSN) was observed (table 1). Overall proportions of patients with no progression (ie, mTSS change ≤ 0.5) at 36 months were 56.8% in P/Q6M, 53.3% in P/Q3M, 66.3% in Q6M group, and 65.7% in Q3M group. Incidence of adverse events (AEs), serious AEs and AEs leading to discontinuation of study drug were similar across treatment groups. No events of atypical femoral fracture were observed.

Conclusions: Denosumab treatment was associated with sustained inhibition of progression of joint destruction for up to 36 months and was generally well tolerated in Japanese patients with RA on csDMARDs. Denosumab has the potential to be a new therapeutic option to inhibit the progression of structural damage for patients with RA.

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SAT0174

DOES ABATACEPT INCREASE PERIOPERATIVE ADVERSE EVENTS IN PATIENTS WITH RHEUMATOID ARTHRITIS COMPARED WITH CONVENTIONAL SYNTHETIC DISEASE MODIFYING DRUGS? - A RETROSPECTIVE MULTICENTER NESTED CASE-CONTROL STUDY

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Background: Abatacept (ABT) is clinically used as the only T-cell modifier available for rheumatoid arthritis treatment and has shown similar efficacy as tumour necrosis factor inhibitors and a safer profile, especially a lower infection ratio in registry data. Latourte et al. recently published the results of perioperative complications of orthopaedic and other types of surgery in patients using ABT. However, they did not compare the complication rates with those in patients who received

csDMARDs. It remains unknown whether ABT is associated with more postoperative complications than conventional synthetic DMARDs (csDMARDs).

Objectives: The aims of this study were to investigate whether ABT is associated with more adverse events after orthopaedic surgery compared with csDMARDs and, if so, to identify significant risk factors for those events.

Methods: A retrospective multicenter nested case-control study was performed in 18 institutions. Patients receiving ABT were matched individually with patients receiving csDMARDs and/or steroid. Serious adverse events were defined as surgical site infection, delayed wound healing, deep vein thrombosis or pulmonary embolism, flare-up, serious infection in other organs. The incidence rates of serious adverse events in both groups were compared with Mantel-Haenszel test. Risk factors for serious adverse events in the ABT group were analyzed by logistic regression model.

Results: A total of 3358 cases were collected. After inclusion and exclusion, 2651 patients were selected for matching, and 194 patients in 97 pairs were chosen for subsequent comparative analyses between the ABT and control groups. No between-group differences were detected in the incidence rates of each adverse event or in the combined incidence rate of adverse events. The odds ratio of the history of serious infection for serious adverse events was 12.6 (95%CI 1.12–141, P=0.04) in patients who received ABT and underwent orthopaedic surgery.

Conclusions: Compared with csDMARDs and/or steroid without ABT, adding ABT to the treatment does not appear to increase the incidence rates of postoperative adverse events in rheumatoid arthritis patients undergoing orthopaedic surgery. A history of serious infection is a significant risk factor for both infection and other serious adverse events, and such patients should be treated with particular caution.

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SAT0175

RESPONSE TO BIOLOGIC TREATMENT IMPROVES SEXUAL HEALTH ASSESSED BY THE QUALISEX SCORE IN RA

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Background: Sexual health of RA patients is an aspect of the care often neglected and about which little is known. Qualisex is a simple (10 questions) and valid tool investigating impact of RA on sexuality. This tool can be useful to assess this important aspect of quality of life. (Gossec and al, Clin Exp Rheum, 2012).

Objectives: Qualisex questionnaire was used in active RA patients of the ROC (Rotation or change) study (Gotteberg et al, JAMA 2016) in order to investigate the association between disease activity and response to a biologic treatment and sexual health.

Methods: Among 153 patients of the randomized controlled trial "ROC", which compared a second anti-TNF to a non-TNF biologic in RA patients with inadequate response to a first anti-TNF. Qualisex questionnaire was proposed to 83 RA patients, and 57 of them filled the questionnaire before and after 6 months of their allocated biologic. Changes in the qualisex score was analyzed according to the variation of the clinical and biological parameters.

Results: The mean age of the 57 RA patients studied was 50.2 (9.6) years. The mean duration of disease was 11.2 (9.5) years, and 43 (75.4%) were female. After 6 months of treatments, 19 were considered with a good response to the treatment according to EULAR response (DAS 28 VS < 3.2 and a variation of 0.6 of the DAS from the base line).

The mean value of qualisex score was 4.05 (+/- 2.53) at V0 and 3.91 (+/- 2.45) after 6 months of treatment. The variation of the qualisex score was more important among the 19 responder patients than among the 43 patients with a persistently active disease. Changes in the qualisex score was significantly correlated to the changes in DAS28, in asthenia, and in SF36 mental score, but not with changes in pain, or in SF36 physical score.