Overview clinical studies knee joint distraction

ArthroSave
joint reviving medical treatment

	Clinical Study	Design	Treatment and duration	Author	Level of evidence	No of patients	Follow-up	Outcome measures	Results
1	Case series: Distraction and microfracture	Retrospective	KJD (hinged customised device) and microfracture; 2-3 months	Deie at al. (2007) & Deie et al. (2010)	IV	6	average 3 years (1.2-4.3)	VAS-pain, JSW, arthroscopy	siginficant increase in knee flexion
2	Case series: Distraction, microfracture and debridement	RCT (vs debridement)	KJD (Illizarov frame), microfracture and debridement; 4 weeks	Aye et al. (2011)	III-2	19	average 5 years (4.8-6.8)	PROMS, JSW	significant increase in PROMS
3	Open prospective long-term follow-up KJD	Open prospective	KJD (Monotube Triax ext fix system); 2 months	Intema et al. (2011), Wiegant et al. (2013), Van der Woude et al. (2017), Jansen et al. (2018), Jansen et al. (2020), Jansen et al. (2022)	IV	20	3, 6, 9 ,12 ,18 months 2, 5, 9, 10 years	WOMAC, VAS-pain, JSW, MRI, systemic biomarkers	significant improvement of pain significant improvement of function significant increase of JSW first year increase in JSW is predictive for long term significant short- and long-term cartilage regeneration, up to 10 years post-treatment survival is 75% after 5 years and 50% after 9 years at average
4	RCT: KJD vs HTO	RCT (vs HTO)	KJD (Monotube Triax ext fix system); 6 weeks	Van der Woude et al. (2017), Jansen et al.(2019), Hoorntje et al. (2020)	II	22-46	3, 6, 9 ,12 months 2 years	WOMAC, VAS-pain, JSW, MRI, systemic biomarkers	significant improvement of pain significant improvement of function significant increase of JSW MRI analyses show relation JSW and cartilage RTW is 91% and RTS is 73% after 6 months no statistic difference with HTO results
5	RCT: KJD vs TKA	RCT (vs TKA)	KJD (Monotube Triax ext fix system); 6 weeks	Van der Woude et al. (2017), Jansen et al.(2019)	II	20-40	1,2 years	WOMAC, VAS-pain, JSW, MRI,	significant improvement of pain significant improvement of function significant increase of JSW MRI analyses show relation JSW and cartilage TKR somewhat better, but original knee joint is lost
6	Osteoarthritis Initiative (OAI)	none	conservative	Van der Woude et al.(2017)	III-1	138	5 years	JSW,MRI	OA has point of no return, gradual degeneration of the joint increase of pain decrease of function
7	Synovial fluid	Prospective	KJD (Monotube Triax ext fix system); 6 weeks	Watt et al. (2020)		20	3, 6, 12 months	KOOS, systemic biomarkers	molecular composition changes during and after KJD and are associated with clinically meaningful responses this reflects the shift from catabolic to anabolic response
8	Open prospective study	Prospective	KJD (KneeReviver); 6 weeks	Jansen et al.(2020) (2021)		65	1 year	WOMAC, VAS-pain, JSW	the user friendliness of the KR contributes to implementation of KJD in regular care no statistical differences between the Monotube results and KneeReviver results
9	Patients with OA (regular care vs clinical trial)	Retrospective	KJD (Monotube Triax ext fix system); 6 weeks	Jansen et al.(2020)	III-2	84-62	1 year	PROMS	similar clinical benefit in clinical practice compared to trial data
	Ongoing/planned Clinical Studies								
10	RCT: KJD vs TKA (KARDS study UK)	RCT (vs TKA)	KJD (KneeReviver); 6 weeks			172-172	recruiting patients	PROMS; radiographs	
11	RCT: KJD vs TKA (GODIVA study NL)	RCT (vs TKA)	KJD (KneeReviver); 6 weeks			600-600	in preparation	PROMS; radiographs	
	Animal studies								
12	Large animal study		KJD (customised device); 2 months	Valburg et al. (2000), Wiegant et al. (2015)		20		biomarkers	abnormal cartilage proteoglycan metabolism changes to the level of control joints KJD as a treatment of experimentally induced OA results in cartilage repair that confirms the structural observations of cartilage repair indicated by surrogate markers in humans
13	Animal study to understand mechanism of cartilage regeneration			Teunissen et al. (2021)		12		biomarkers	both catabolic and reparative response; after 10 weeks it fully shifts to a reparative state