



International Cartilage Regeneration
& Joint Preservation Society

The ICRS Patient Registry

Report 2020

2nd Report

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On behalf of the ICRS Registry Steering Committee

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Letter from the Steering Committee

Dear Members,

We are proud to present the second report of the ICRS patient Registry, we hope you find it both interesting and informative. We are grateful for the contributions of our Manager, Laura Asplin, and our former Manager, Caitlin Conley, to the production of this report.

The database is now available in eleven languages. We thank ICRS members who assisted with translations and testing of the translated interfaces. Since the first report we have added German, Chinese and Swedish to the previous English, Italian, Spanish, Portuguese, Japanese, Greek, Dutch, and Polish versions of the database.

Thanks to the efforts of Laurie Goodrich and a team of our Veterinarian Surgical and Basic Science Colleagues, there is soon to be an equine section of the Registry, which will make this the first multispecies global registry! We are also developing a foot and ankle pathway. We aim for these to go live in 2022.

We are truly grateful for the financial contributions of our Industry Sponsors, former and current, whose generous funding is, as ever, vitally important to support this global multi-language cartilage treatment database.

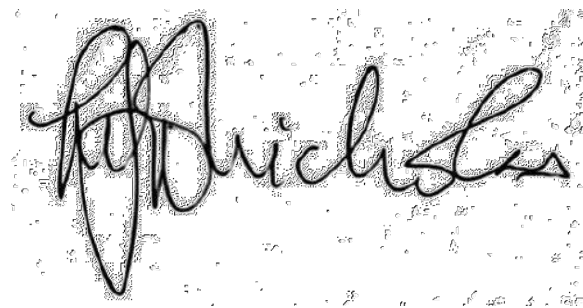
Despite the Covid-19 Global Pandemic severely limiting all our elective surgical practices, the rate of growth we are achieving is very satisfactory. Since the last report, we have grown the database by 363%! This is thanks to the ongoing dedication of all our contributing surgeons to document their new cases. Particular thanks is given to Christian Lattermann, Bill Bugbee, Alberto Gobbi, Daniel Saris and Jay Ebert and their teams working to enable large mature Cartilage databases whose datasets have been reformatted to enable them to be imported and assimilated into our ICRS patient registry.

The number of cases and techniques appearing in this second report have allowed us to build upon the foundations of the format in our first report. These numerous treatment options are clearly outlined, showing how our patients are being treated and subsequently progressing.

As we are all looking forward to restarting our elective surgical practices, we would be grateful for our active contributors to continue their support. For those who are yet to start contributing, please incorporate data input to the Registry as a part of your standard practice. There is minimal work required by yourself. Laura Asplin will be very happy to guide you through the process of getting set up and going.

Together we will achieve the Societies Our aim remains to be the best source of information for our patients and for ourselves as scientists and clinicians working to help those unfortunate enough to suffer the pain and disability associated with articular cartilage lesions.

Finally, on behalf of the Steering Committee, we hope you enjoy reading our second report.

A handwritten signature in black ink, appearing to read 'Mike McNicholas', is written over a light, textured background.

Mr Mike McNicholas.

BSc, MD, FRCS(Tr & Orth).

Chair of the ICRS Patient Registry Steering Committee.

Committees 2019-2020

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Sponsors 2019-2020

The ICRS patient registry would like to thank its sponsors for their continual support.



ICRS Patient Registry

The ICRS Registry is the first global clinical multilanguage database. Our aim is to be the best source of information for our patients, and for ourselves as scientists and clinicians working to help those unfortunate enough to suffer the pain and disability associated with articular cartilage lesions. The registry is now live in ten languages English, Japanese, Polish, Italian, Spanish, Portuguese, Dutch, Greek, German, Chinese and Swedish. The registry was launched at the ICRS Sorrento Meeting in 2016 and is guided by a steering committee comprised of orthopaedic surgeons, equine surgeons, clinician scientists, and research scientists.

The registry can monitor the progress of patients with diagnosed articular cartilage pathology. It can allow a study of the natural history of such lesions whether or not the cartilage damage itself is treated. The response of patients to cartilage damage and treatments can be variable, treatments can also be forefront of medical advances, many are expensive. It is vital that a patient's progress is monitored. All registry users have direct access to their own data and can export their data at any time. Additionally, the ICRS registry pools together large numbers of anonymized patient results to better understand how patients progress after treatment, so that doctors around the world have the most accurate picture of which techniques are working best in which patients. This helps patients of the future with similar injuries or cartilage problems, and rapidly identifies treatments that are showing great benefit, those that may not be performing as well as hoped. The inclusion of the EQ-5D data will enable cost effectiveness and health economic analysis. Irrespective of the health care location in which you practice, it is increasingly required for continued service provision.

Registry mission

Our mission is to create the best source of unbiased outcomes data for treatments of painful articular cartilage lesions in the world, which is paramount for improvement of existing and discovery of new cartilage repair strategies, ultimately beneficial for millions of patients around the world.



Registry Update

Data Imports

A data import format schema was completed in 2018 to assist users with pre-existing data to format their data for import into the registry. This tool has been used to facilitate imports from surgeons globally. The registry is keen to continue to engage with the surgeon community to import their pre-existing data sets and grow the ICRS registry dataset.

Language Translations

The registry is now live in:

- English, Japanese, Polish, Italian, Spanish, Portuguese, Dutch, Greek, German, Chinese and Swedish

Registry Profile

User Locations

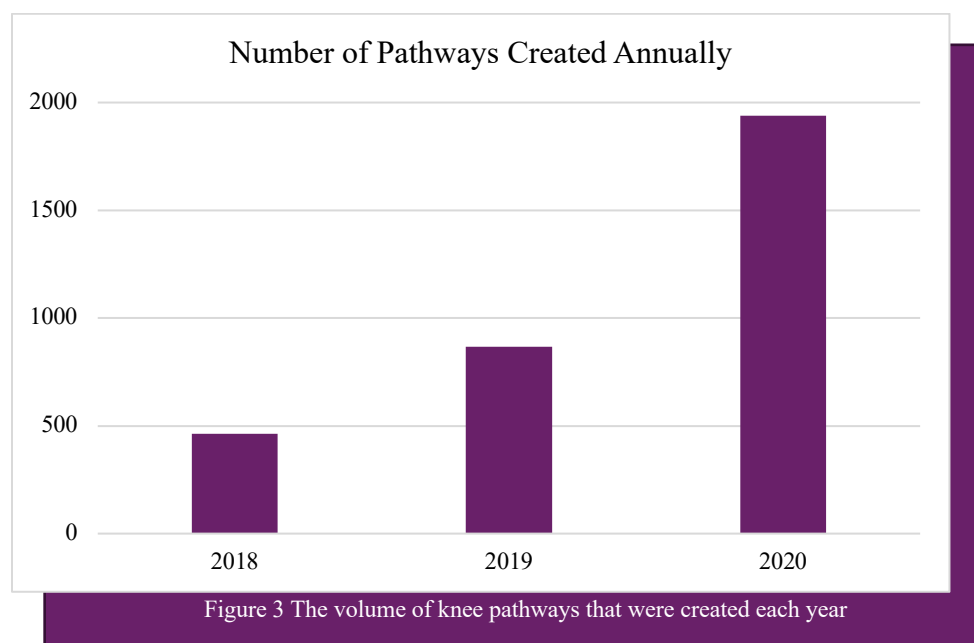
The registry is comprised of clinician users and delegate users from all over the world. The map below illustrates the truly international reach of the registry. A flag is placed on each location where a user is registered (Figure 1).



Figure 1. Map illustrating each country with registered ICRS registry users

Pathway Volume

There is a total of 1,945 knee pathways in the ICRS patient registry, an increase of 363% (535 – 2019). The pathways have been a combination of live entries and pre-existing data imports. Since the registries inception the graph illustrates the registry's growth.



A total of **1,237** of the 1,945 pathways were added in both 2019 and 2020

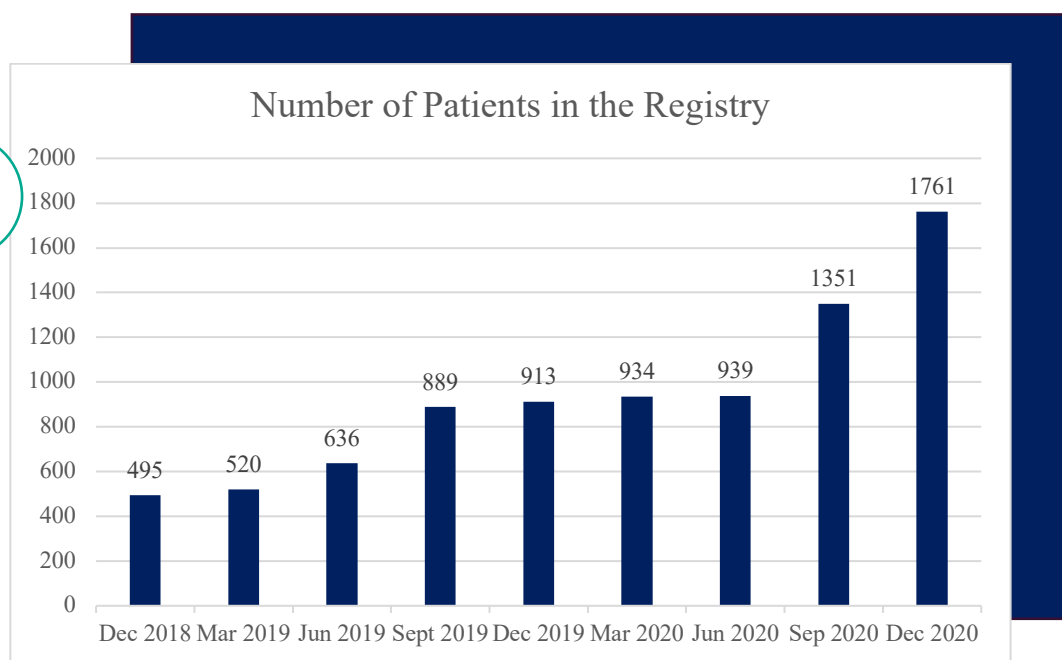


Figure 4 The quarterly volume of patients in the registry

Registry patients

Patient Demographics

Sex, age, smoking status, BMI, and affected limb were captured from the patients entered in the registry. Sex and age were reported for all 1945 pathways in the registry. The patient's BMI and the affected limb were reported the majority of the time; however, not as consistently.

BMI

The registry records patient weight in stones, pounds, and kilograms (Table 2). The registry will then convert the entered weight into a BMI based on the height (imperial or metric) recorded. This allows users more flexibility when recording patient demographics, eliminating the need for a patient or user to do a conversion themselves.

	N	Mean \pm SD
BMI	1022	27.74 \pm 23
Female	415	25.64 \pm 15
Male	607	29.09 \pm 27

Table 2 The BMI for all pathways in the registry overall and broken down by sex.

Sex

Sex. The majority of patients in the registry are male (n = 989). There was a small number of patients registered with their sex unknown (n=8).

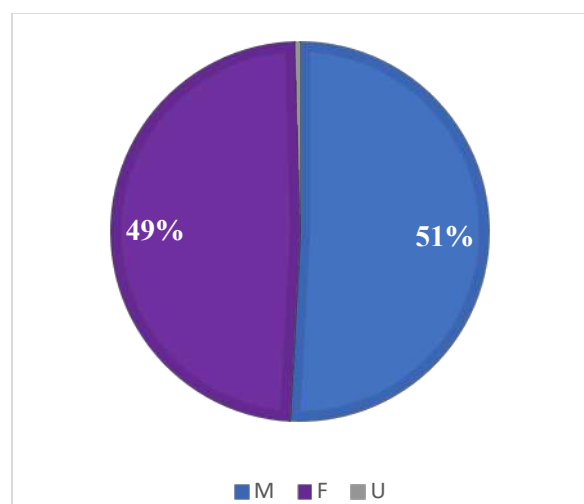


Figure 5 Percentage of sex distribution across all pathways in the registry

Affected Limb

	Count	Percentage
Affected Limb	887	45.6%
Left	445	22.7%
Right	442	22.9%

Table 1 The affected limb for all pathways in the registry

There was a comparable distribution between left and right affected limbs (Table 1).

Smoking Status

	Count	Percentage
Smoking Status	180	9.3%
Ex-Smoker	21	1.1%
Non-Smoker	138	7.1%
Smoker	21	1.1%

Table 3 Current and past smoking status for each patient pathway

Smoking status was only reported for 9.3% of the pathways in the registry (Table 3). For those patients with a record, 77% are non-smokers. There was an even distribution between smokers (n=21) and ex-smokers (n=21).

Age

The patients in the registry ranged in age from 14 to 103 years old (Figure 6). The average age for the patients in the registry was 53 ± 17 years old. Females tended to be slightly older overall than males (Table 4).

	N	Mean \pm SD
Age		
Female	948	57 ± 18
Male	989	49 ± 16
Unknown	8	61 ± 27

Table 4 The age distribution for all of the patients in the registry by sex

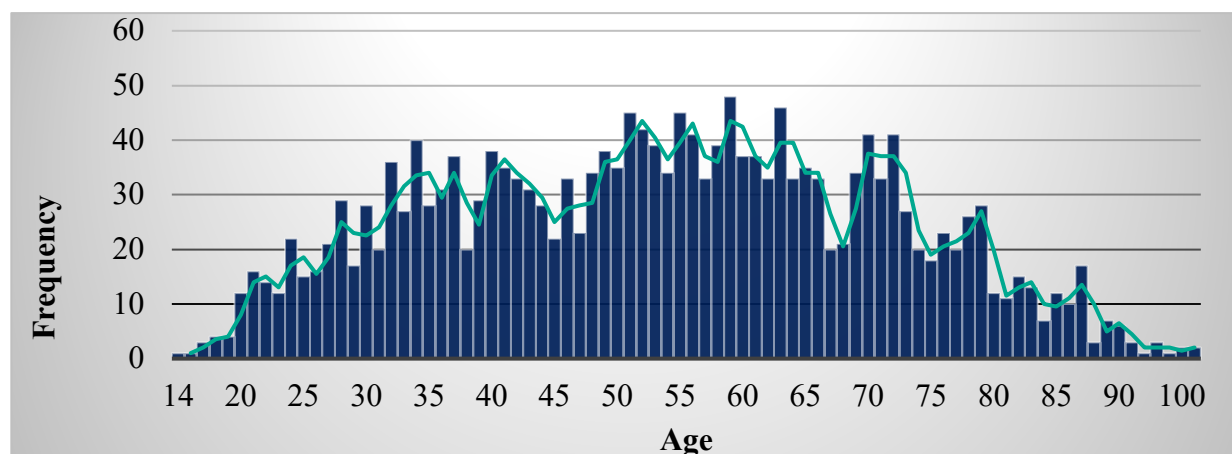


Figure 6 The age distribution frequency for all of the patients in the registry

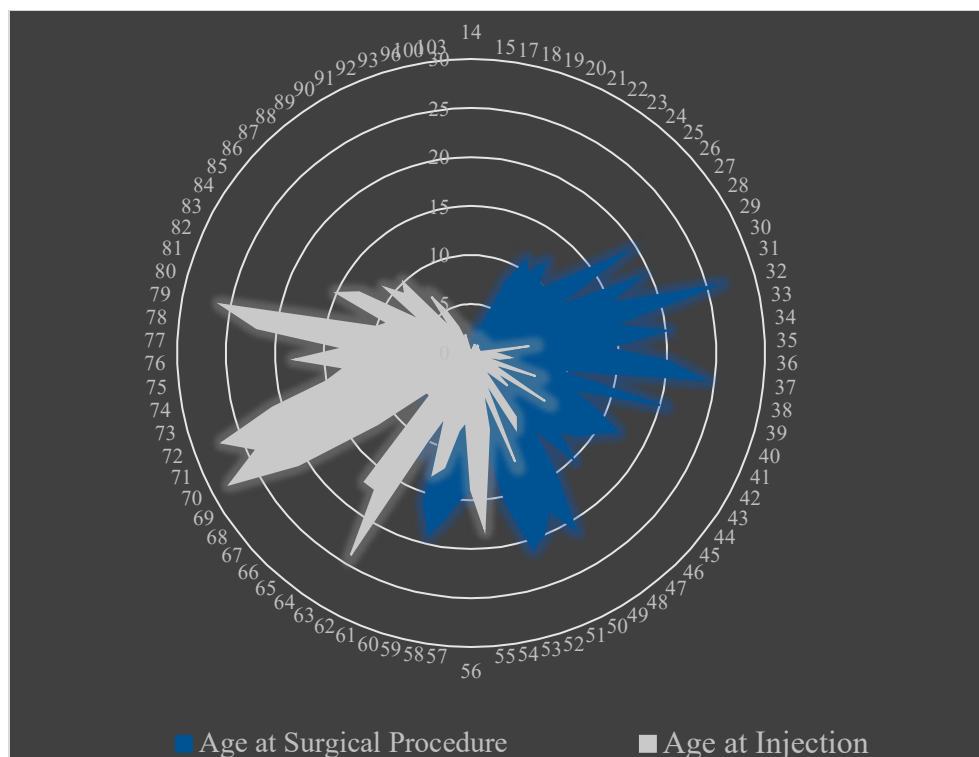


Figure 7 The age distribution frequency for all of the patients in each age category within the registry by procedure. Each age values in the registry is listed on the outside of the circle. The radius on the inside of the circle represents the frequency of each age value listed within the registry.

The distribution of age is represented as a burst with larger age frequencies covering a larger surface area.

Patients treated with an injection tended to be older than patients surgically treated as depicted in Figure 7. There was a large volume of patients age 70 to 72 who were treated with an injection.

The age distribution for patients treated with surgical procedures was more uniform.

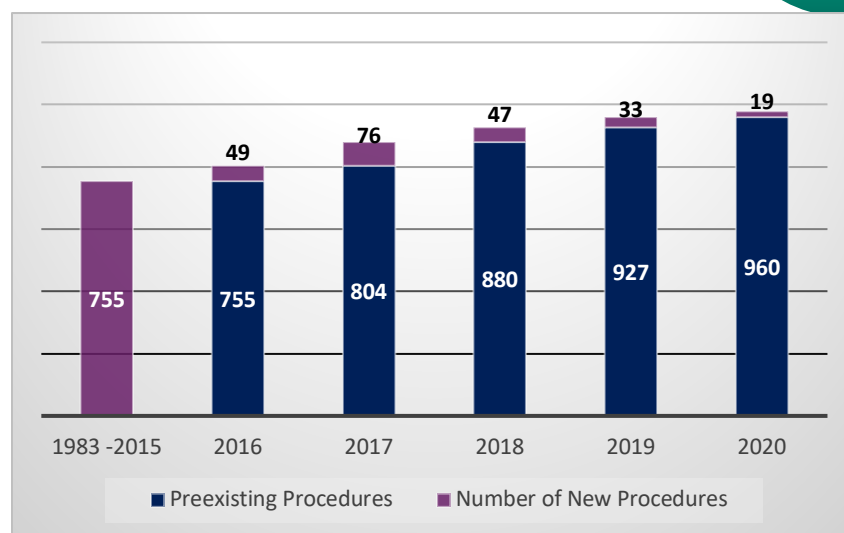
Cartilage repair and restoration procedure patients

Pathway volume

A total of 979 pathways in the registry documented a cartilage repair or restoration procedure. There has been a steady increase each year in number of surgical cartilage pathways created in the registry (Figure 8).

Annual
Rate
Increase

Surgical cartilage pathways in the registry increased by **25%** in the past two years.



Due to the execution of some large data imports the volume of pathways documented in the years prior to the registry's inception accounted for 77% of the pathways.

Approximately 42% of the surgical cartilage pathways documented were for *allograft* procedures. Approximately 21% of the pathways were for *microfracture*, *cell therapy*, *osteochondral autograft transfer* or *osteochondral repair* procedures (Table 5).

Figure 8 The number of surgical cartilage pathways created each year since the registry's inception

	1983-2015	2016	2017	2018	2019	2020	Total
	%	%	%	%	%	%	%
Allograft	93%	5%	2%				100%
Cell Therapy Cartilage Reconstruction	45%	3%	23%	10%	19%		100%
Cell Therapy/Scaffold on Top of Bone Graft Cartilage Reconstruction					100%		100%
Conservative Treatment of Cartilage Defect		17%	50%			33%	100%
Debridement or Chondroplasty Only	25%	25%	25%	25%			100%
Debridement or Chondroplasty Only with Microfracture	33%		67%				100%
Filling of defect with graft bone			100%				100%
Microfracture	13%	50%	25%	13%			100%
Microfracture with Scaffold Cartilage Reconstruction	2%		95%			2%	100%
Multiple Cartilage Procedures	80%	15%	5%				100%
OATS	85%	11%	3%	2%			100%
Osteochondral Repair	1%	6%	4%	52%	32%	4%	100%
Refixation		100%					100%
Scaffold/Carrier Cartilage Reconstruction		50%	50%				100%
Screws removed		100%					100%
Subchondroplasty						100%	100%
Unknown/Missing	96%	0%	1%	1%	1%		100%
Total	77%	5%	8%	5%	3%	2%	100%

Table 5 The reported surgical cartilage procedure volume by year. In some instances, users treated a patient with multiple procedures in the same pathway.

Patient demographics

Age

The average age of the cartilage surgical patients was 35 ± 13 years old (ranging from age 11 to age 71). The largest percentage of patients surgically treated was between 31 – 40 years old and most commonly were treated with an allograft procedure (Table 6). The average BMI was 26 ± 5 (ranging from 16 to 58).

Procedures	10-20 yrs		21-30 yrs		31-40 yrs		41-50 yrs		51-60 yrs		61-71 yrs		Missing		Total	
	N	Percent	N	Percent	N	Percent	N	Percent	N	Percent	N	Percent	N	Percent	N	Percent
Allograft	88	21.2%	96	23.1%	132	31.8%	75	18.1%	22	5.3%	2	0.5%			415	100%
Cell Therapy Cartilage Reconstruction	3	9.7%	5	16.1%	15	48.4%	5	16.1%	3	9.7%					31	100%
Cell Therapy/Scaffold on Top of Bone Graft	1	100.0%													1	100%
Cartilage Reconstruction																
Conservative Treatment of Cartilage Defect	1	16.7%	3	50.0%	1	16.7%	1	16.7%							6	100%
Debridement or Chondroplasty Only	1	12.5%	3	37.5%	1	12.5%	2	25.0%	1	12.5%					8	100%
Debridement or Chondroplasty Only with Microfracture			3	100.0%											3	100%
Filling of defect with graft bone					1	100.0%									1	100%
Microfracture	1	12.5%	2	25.0%	2	25.0%	2	25.0%	1	12.5%					8	100%
Microfracture with Scaffold Cartilage Reconstruction	1	2.4%	2	4.8%	2	4.8%	15	35.7%	9	21.4%	13	31.0%			42	100%
Multiple Cartilage Procedures	5	25.0%	4	20.0%	6	30.0%	4	20.0%	1	5.0%					20	100%
OATS	17	25.8%	15	22.7%	23	34.8%	8	12.1%	3	4.5%					66	100%
Osteochondral Repair	3	4.3%	11	15.9%	20	29.0%	20	29.0%	13	18.8%	1	1.4%	1	1.4%	69	100%
Refixation	3	100.0%													3	100%
Scaffold/Carrier Cartilage Reconstruction			2	100.0%											2	100%
Screws removed	1	100.0%													1	100%
Subchondroplasty							2	15.4%	8	61.5%	3	23.1%			13	100%
Unknown/Missing	36	12.4%	67	23.1%	94	32.4%	57	19.7%	17	5.9%	15	5.2%	4	1.4%	290	100%
Total	161	16.4%	213	21.8%	297	30.3%	191	19.5%	78	8.0%	34	3.5%	5	0.5%	979	

Table 6 The reported surgical cartilage procedure volume by year. In some instances, users treated a patient with multiple procedures in the same pathway.

Sex

There were more males (n=381) than females (n=598) with surgical cartilage pathways (Figure 9). However, females and males were similar in age (F 35 ± 13 , M 34 ± 12 years) and BMI (F 25 ± 5 , M 27 ± 5).

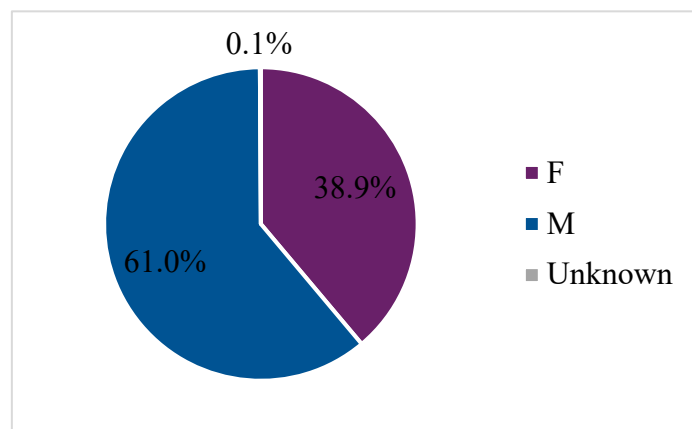


Figure 9 The sex distribution for all surgical cartilage procedure pathways

Categorizing the pathways by the specific procedure both males and females tended to be treated with a allograft compared to other procedures. Approximately 39% of females (n=147) and 45% of males (n=268) were treated with an allograft.

Patient demographics continued

Smoking Status

Approximately 9% of the pathways documented smoking status. A small number of patients were previous smokers or current smokers (Table 8). However, over two thirds of the patients were non-smokers.

Smoking Status	Count	Percentage
Previous Smoker	7	8%
Current Smoker	69	78%
Non-Smoker	13	15%
Total	89	100%

Table 8 Smoking status for all surgical cartilage procedure pathways

Approach

Approximately 19% (n=190) of the pathways documented surgical approach.

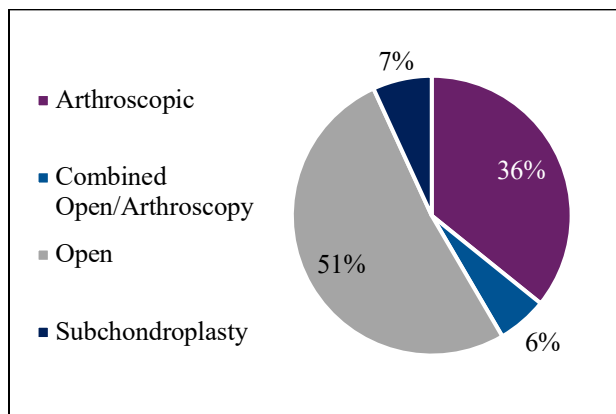


Figure 10 Surgical approach for the cartilage pathway

Defect characteristics

Defect information was reported in 85% of patients (n=832). A total of 832 defects were documented in the registry. The number of defects per pathway reported ranged from 1

to 4 (Table 9). Ninety-four percent of the pathways had either one or two defects reported.

Number of Defects Treated	Count	Percentage
1	511	61.4%
2	244	29.3%
3	55	6.6%
4	19	2.3%
5	1	0.1%
6	2	0.2%
Total	832	100%

Table 9 The number of total defects reported per pathway

Defect location & area

Defect location was reported in 831 of the 979 pathways. A total of 1257 defects were documented in the registry. The number of defects per pathway reported ranged from 1 to 6 (Table 9). Seventy-nine percent of the pathways had either one or two defects reported

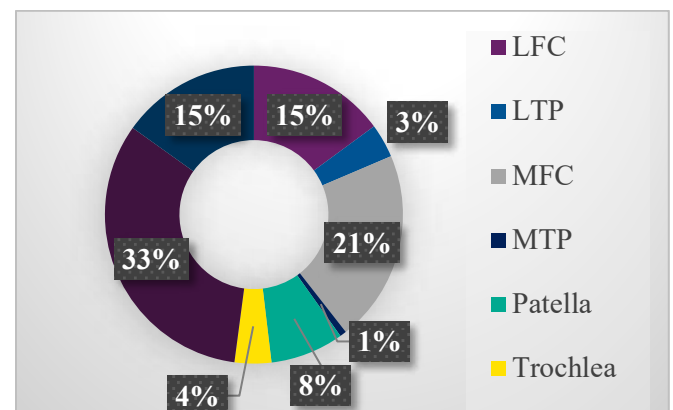


Figure 12 The percentage each defect location was reported. MFC=medial femoral condyle, LFC=lateral femoral condyle, MTP=medial tibial plateau, LTP=lateral tibial plateau

The area for reported isolated defect locations is presented in Figure 13.

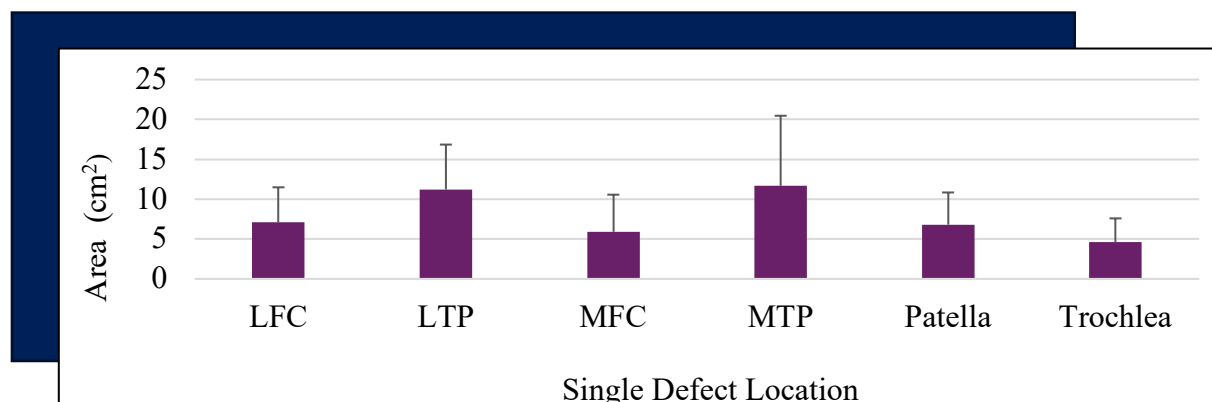


Figure 13 Defect area for each defect location. MFC=medial femoral condyle, LFC=lateral femoral condyle, MTP=medial tibial plateau, LTP=lateral tibial plateau

Surgical technique

Tourniquet and antibiotic usage

A total of 13% of the pathways reported the tourniquet usage, the type is reported in Figure 14. Out of those that reported a tourniquet, 96% reported the pressure (Table 10).

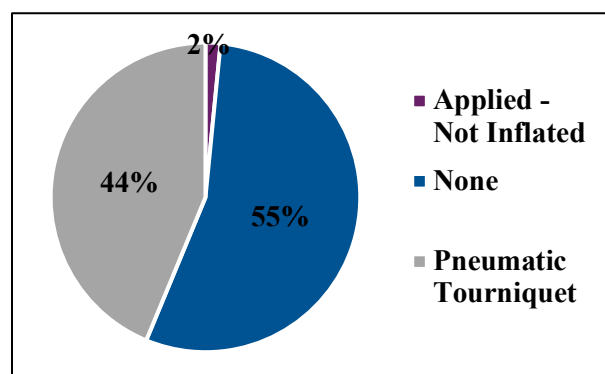


Figure 14 The type of tourniquet utilized during surgery

Tourniquet Pressure	Count	Percentage
250 mm Hg	41	76%
300 mm Hg	9	17%
350 mm Hg	1	2%
Other	3	6%
Total	54	100%

Table 10 The type of tourniquet utilized during surgery

Similarly, 13% of pathways reported the antibiotic prophylaxis usage. The implementation of an antibiotic prophylaxis favored single antibiotic usage (Figure 15).

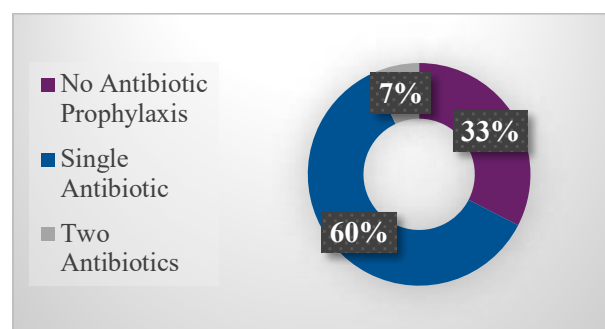


Figure 15 Reported antibiotic prophylaxis usage

Concomitant surgical procedures

30% of the pathways had concomitant surgical procedures.

Surgical Procedure	Count
Arthrolysis	1
Fulkerson	4
Osteotomy	3
High Tibial Osteotomy	29
Meniscectomy	51
Lateral Release	33
Hardware Removal	47
Other	125
Total	293

Table 11: The type of concomitant procedures and the frequency of these procedures

Post-operative rehabilitation

Brace utilization and physiotherapy

Post-surgical treatment prescriptions were reported in 14% of the surgical cartilage pathways. Of these patients, just under a third of them were prescribed an unloader brace (n=37) and 97% were prescribed physiotherapy (n=131) (Figure 17-18). Physiotherapy was prescribed immediately after surgery in 36% of the pathways

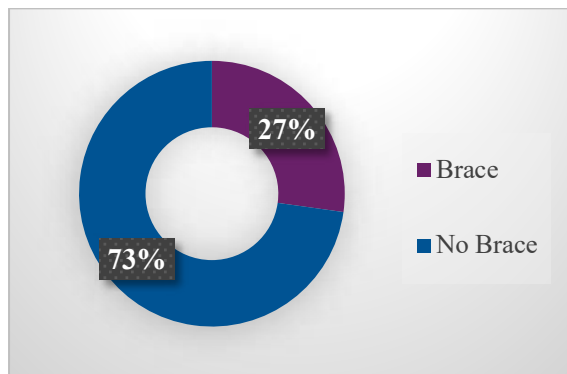


Figure 17 The distribution of an unloader brace prescription documented for the surgical cartilage pathways

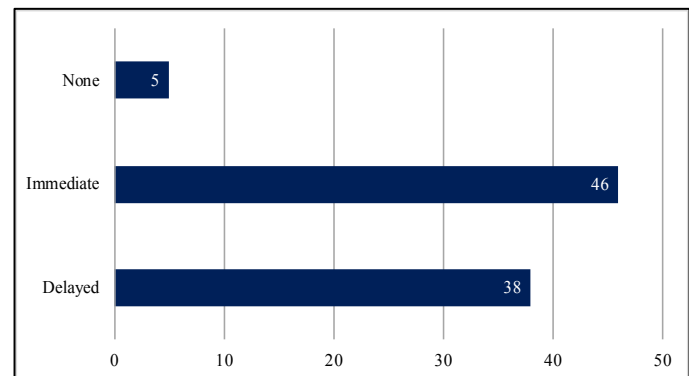
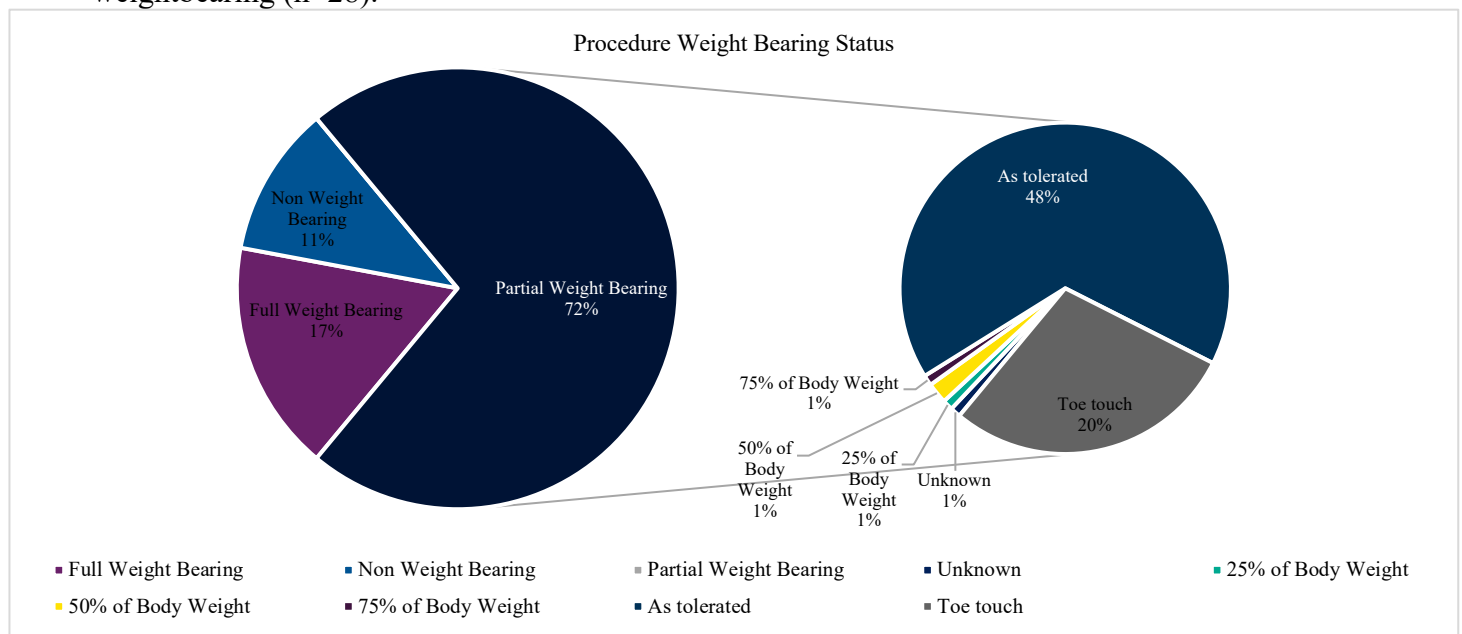


Figure 18 The timing of physiotherapy reported for the surgical cartilage pathways

Weight-bearing

The majority of patients were prescribed partial weight bearing (Figure 19). The partial weightbearing prescription favored weightbearing as tolerated (n=65) followed by toe touch weightbearing (n=28).



Patient Reported Outcomes

Overview

The time points and outcomes collected are depicted in Figure 20.

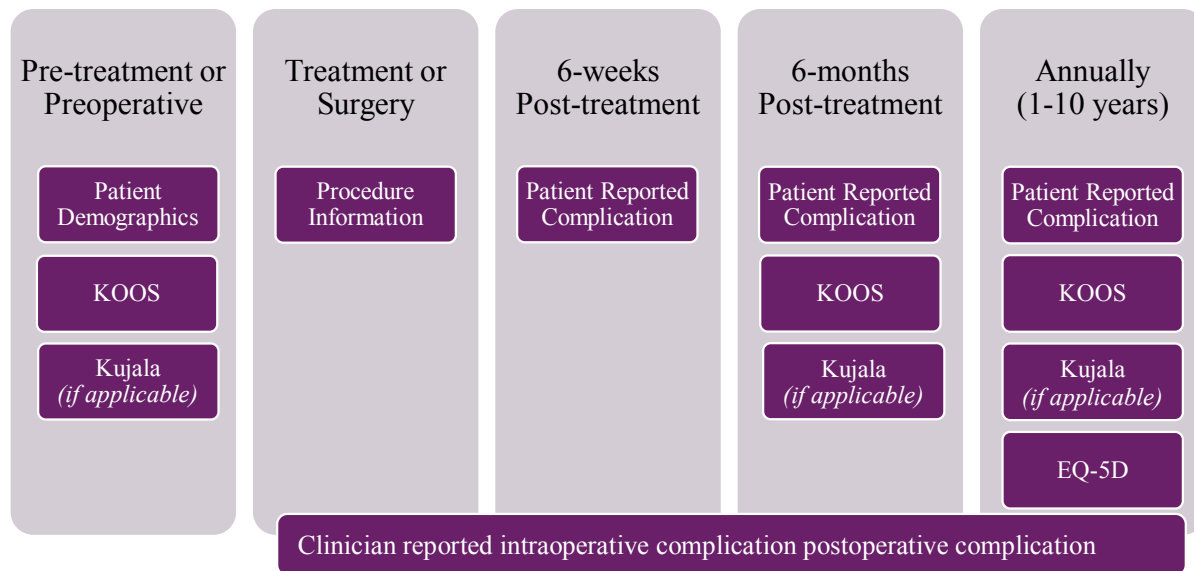


Figure 20 An overview of the registry outcome collection instruments and associated time points

Knee Injury and Osteoarthritis Outcome Scale

The Knee Injury and Osteoarthritis Outcome Scale (KOOS) is patient reported outcome measure evaluating the patients' perception of their knee function. The KOOS out of 100 and is comprised of 5 sub-scales: Pain, Symptoms, Activities of Daily Living, Sports and Recreation, and Quality of Life. The instrument is collected pre-treatment, 6-months, and annually in the ICRS registry. The registry currently has 1447 baseline scores and 142 patients at 1 year (Figure 21).

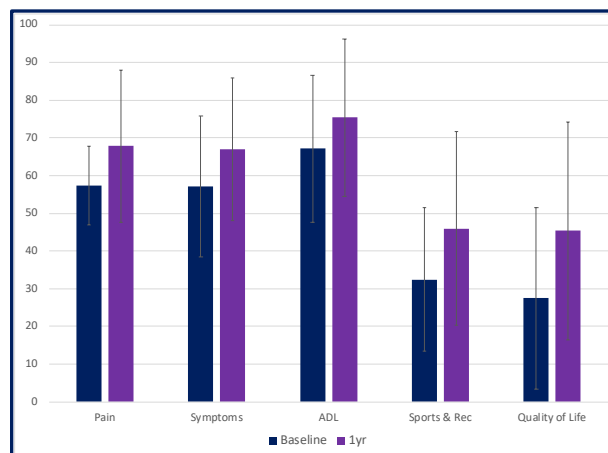


Figure 21 Baseline and 1year KOOS scores

Patient reported outcomes continued

EQ-5D

The EQ-5D is an overall health quality of life scale. The scale was developed by the EuroQol Group and has 5 sub-scales as well as an overall index. The five subscales are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The instrument has a license fee associated with it depending on the user's implementation. However, users of the ICRS patient registry can collect the EQ-5D at no cost. There are 222 pathways with baseline EQ-5D data and 81 pathways with 1 year EQ-5D data (Figure 22-23).

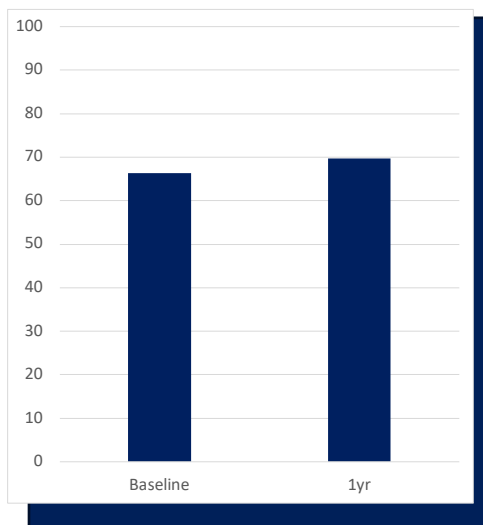


Figure 22 EQ-VAS

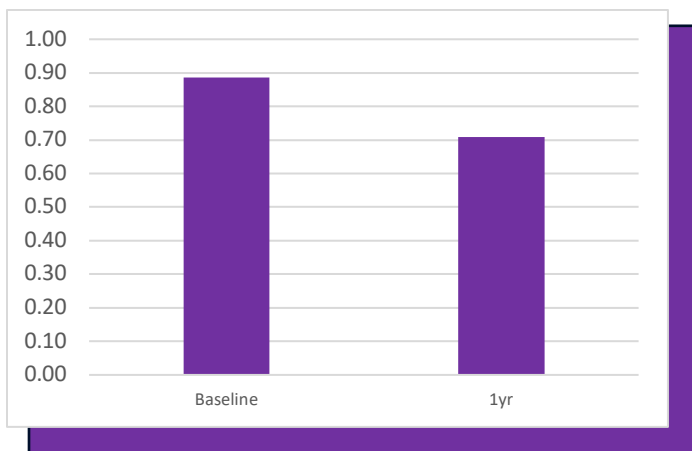


Figure 23 EQ-5D

Patient reported outcomes continued

Kujala Anterior Knee Pain Scale

The Kujala Anterior Knee Pain Scale is a patient reported outcome instrument to measure function and symptoms associated with in patients with patellofemoral disorders. The outcome is out of 100 and has 13 questions. The questions assess the patients' overall pain and swelling as well as the patient's ability to walk, run, climb stairs, and squat. The registry currently has 142 pathways with baseline and 43 at 1year Kujala data (Figure 27).

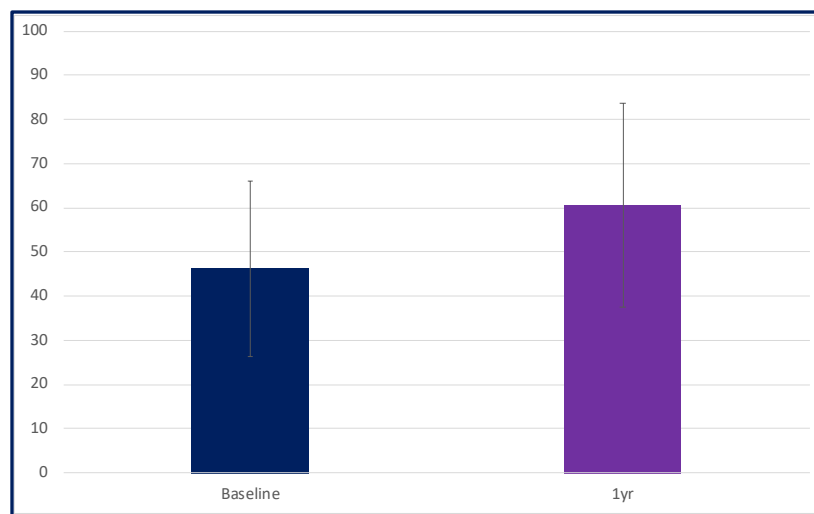


Figure 24 Baseline and 1 year Kujala scores

Knee injection procedures

Pathway volume

A total of 620 pathways in the registry documented a knee injection procedure, this is an increase of 284.4% (218-2019). These pathways have been created since 2016. There has been a steady increase in numbers with a peak in 2017-18 and an understandable pause during 2019-20.

**Annual
Rate
Increase**

Knee injection pathways in the registry had an average annual growth rate of 501% over the three years

There were 7 different injection therapies and injection combinations reported in the registry. Overall, stem cell injections continued to be a major contributor to the total registry volume followed by platelet rich plasma injections (PRP).

Procedure	Pre 2016		2017-18		2019-20		TOTAL	
	N	%	N	%	N	%	N	%
Injection Hyaluronic Acid	2	40	3	60	-	-	5	100
Injection Hyaluronic Acid Injection Steroid	-	-	-	-	1	100	1	100
Injection Hyaluronic Acid Stem Cell Injection	-	-	8	100	-	-	8	100
Injection PRP	47	33	90	64	4	3	141	100
Injection PRP Stem Cell Injection	-	-	2	100	-	-	2	100
Stem Cell Injection	11	2	387	84	64	14	462	100
Other	1	100	-	-	-	-	1	100
Total	60	10	490	79	69	11	620	100

Table 12 The reported knee injection pathway volume by year. In some instances, users treated a patient with multiple procedures in the same pathway.
PRP: plasma rich protein

Patient demographics

Age

The mean age of the knee injection patients was 65 years old (ranging from 17-92). The largest percentage of patients treated was between 70-77 years, closely followed by 62-70 years.

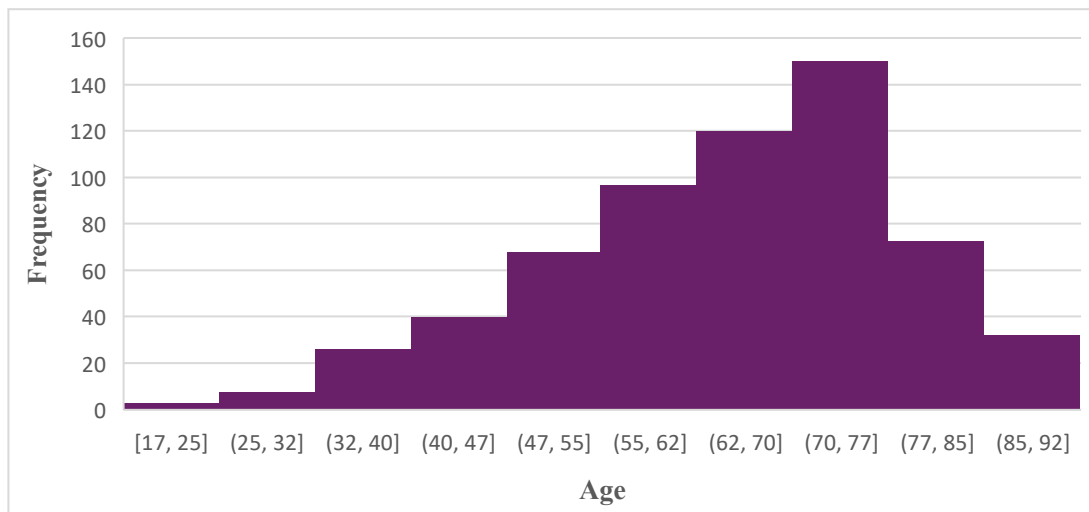


Table 13 The age of the reported knee injection pathway patients by injection category.
PRP: plasma rich protein

Sex

There were more females (n=400) than males (217) with knee injection pathways. Females on average were older than males (F 68, M 59).

In correlation with 2019 there was a larger percentage of females treated in all the injection type categories, with the exception of hyaluronic acid which had a higher percentage of males.

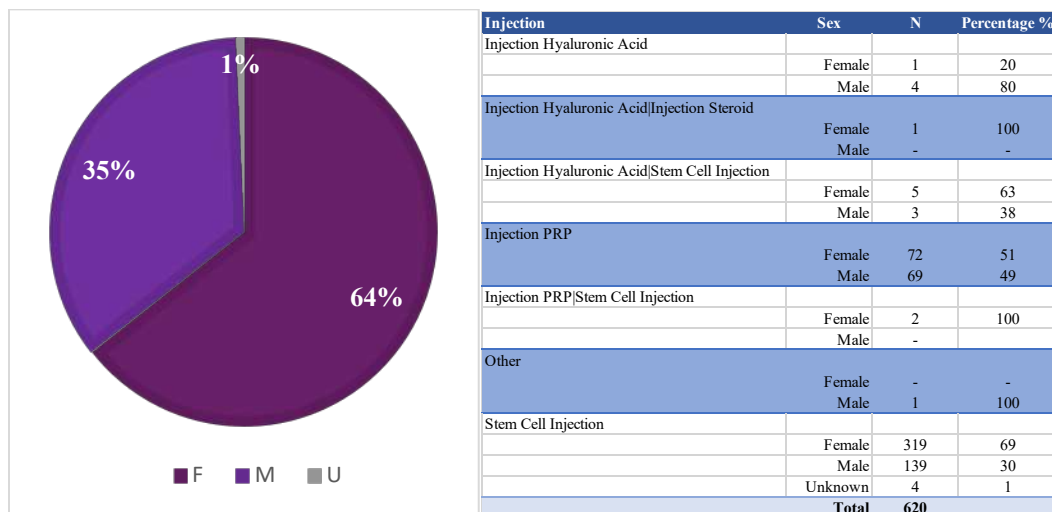


Figure 32 The sex distribution for all knee injection pathways

Table 14 The sex distribution for all knee injection pathways by injection category
PRP: plasma rich protein

Injection therapies

The registry has the capacity to document multiple types of injection procedures. There are 8 types of *hyaluronic acid* injections, 8 types of *plasma rich protein (PRP)* injections, 4 types of *stem cell amniotic-based* injections, 1 types of *stem cell adipose-based* injections, 7 types of *BMAC-based* injections, and 1 types of *autologous anti-inflammatory* injection. Additionally, all of the injection types have an *Other* category allowing the user to document any other type of injection not specifically listed in the registry prepopulated options.

Feature: There are over 25 different knee injection therapies listed in the registry

Currently reported injection therapies

There were 9 different types of injections reported in the 5 injection categories currently reported in the registry (Table 15). The injection type for a small percentage of the reported categories was unknown. In the stem cell injection category adipose-based tissue comprised of the majority of the reported injections.

Injection	Type	N	Percentage
Injection Hyaluronic Acid			
	Supartz	1	20%
	Synvisc 1	1	20%
	Unknown	3	60%
Injection Hyaluronic Acid and Stem Cell Injection			
	Supartz and Adipose based	8	100%
Injection PRP			
	ACP Double Syringe System	5	8%
	Cascade Autologous Platelet System	12	20%
	Unknown	42	71%
Injection PRP and Stem Cell Injection			
	Adipose based	1	50%
	Unknown	1	50%
Stem Cell Injection			
	Adipose-based	140	97%
	Amniotic-based	1	1%
	Unknown	3	2%

Table 15 The distribution of injection type for all knee injection pathways
PRP: plasma rich protein

Post-injection rehabilitation

Brace utilization and physiotherapy

Post injection treatment prescriptions were reported in 29.2% (n = 181) of the injection pathways. Of these 179 patients were not prescribed an unloading bracing. (Figure 33-34).

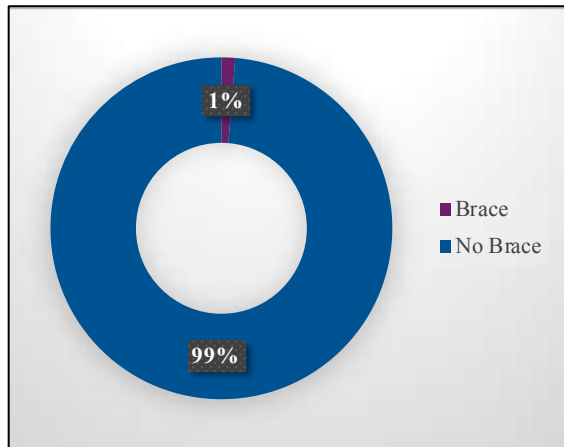


Figure 33 The distribution of an unloader brace prescription documented for the knee injection pathways

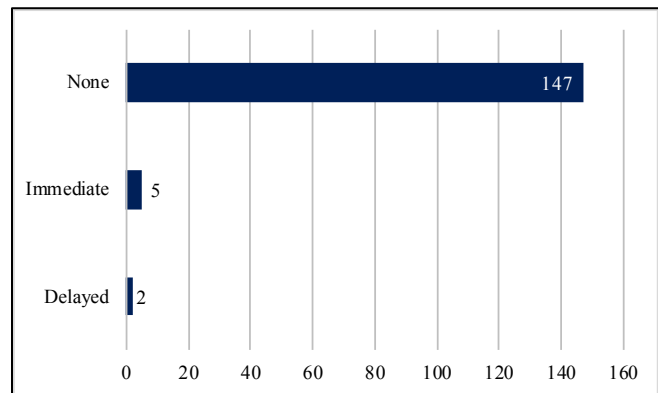


Figure 34 The timing of physiotherapy reported for the knee injection pathways

Weight-bearing

Patients overall were full weight bearing after injection procedures (n=152) (Figure 35).

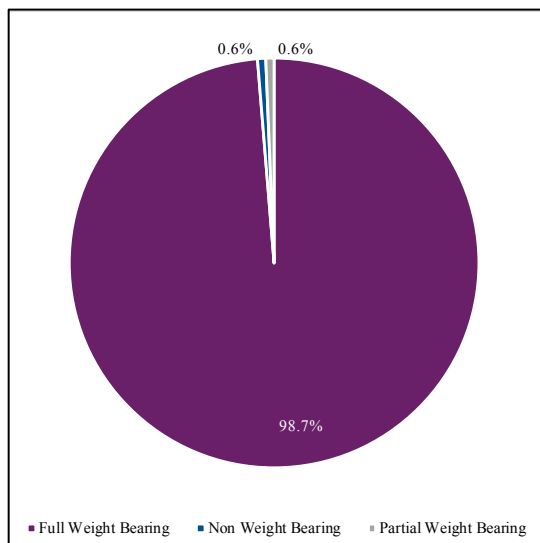


Figure 35 Prescribed weightbearing status for knee injection pathways

Patient reported outcomes

The registry collects KOOS, EQ-5D, and Kujala. However, users have reported collecting the KOOS-Jr. Thus, we are implementing a calculation field to the KOOS for the KOOS-Jr.

Complications

There were no complications documented for any of the knee injection pathways. Similar to the surgical cartilage pathways complications are documented by both the clinician user as well as the patient. We encourage all users to document any complications occurring.

Complications

100% of the documented pathways were free of complications

Future projects

New pathways and features

The registry presently provides a knee pathway for both surgical and conservative treatments. There are developmental project plans to cultivate a foot/ankle pathway and an equine pathway. These new pathways are anticipated to be released in 2022.

A KOOS-Jr calculation field is being added to the knee pathway to meet to needs of current users.

User assistance

In the upcoming year (2021-2022) there are plans to increase the education and information available for the registry. For those wishing to introduce the database to their practice we have ethics information packs, user instructions in the forms of brochures, webinars or slidesets. Please contact registry@cartilage.org to access these or arrange one-to-one troubleshooting sessions.

Your feedback is important to the ongoing development of the registry and subsequent annual reports. Please address feedback to registry@cartilage.org.

Conclusion

The registry has demonstrated significant growth since the first annual report in 2019. The global pandemic of 2020/21 understandably affected elective surgery worldwide and the registry therefore saw a pausable effect on input of new patient data.

The ICRS patient registry remains in its infancy. The registry is a valuable tool for patient outcome tracking, monitoring of successful treatments and effective post market surveillance. It will ultimately enable us to confirm the efficacy and to define the health economic benefit of our treatments.

We thank the ICRS members and sponsors for their continuing support of the registry.

This document is accessible at the ICRS website:
<https://cartilage.org/society/icrs-patient-registry/>

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Every effort was made to ensure that the information presented within this report was accurate at the time of publication. However, in the unlikely event of discrepancies, the ICRS is not liable for issues arising from such an event.





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