International Cartilage Regeneration & Joint Preservation Society

The ICRS Patient Registry

Annual Report May 2019

1st Annual Report

Caitlin Conley, Mike McNicholas, Leela Biant
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 first Annual report of the ICRS cartilage repair database, we hope you find it interesting and informative. We are most grateful for the huge contribution our Manager Caitlin Conley has made to the production of this report. We would like to thank Professor Leela Biant for the sterling work she has put into making the database a reality.

The generous funding from our industry sponsors is vitally important to support the realization of the concept of the first global multi-language cartilage treatment database. 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. The database is now live in eight languages English, Italian, Spanish, Portuguese, Japanese, Greek, Dutch, and Polish. We thank ICRS member who assisted with translations and testing of the translated interfaces.

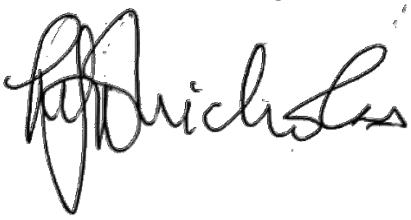
We are proud of the fact that the UK National Institute for Clinical Care Excellence (NICE) has recommended that any patients treated in the UK with mosaicplasty procedures should be documented and followed up into the long term by our database. NICE decisions are often taken up by other Regulatory Authorities, so watch this space!

Another thrilling piece of news is that Swissmedic, the Swiss Medical Regulation Authority, mandated the use of the ICRS Registry for all patients treated using Spherox, by CoDon. The confidence that they have shown in the reliability of the database is testament to its credibility.

We have had all of the usual "teething issues' any registry has to contend with, but thanks to the experience of members of the Steering Committee in running other registries, the learning curve has been restricted to the novel global nature of our Registry. We are presenting our meaningful results just two and a half years of the launch at the Sorrento meeting in 2016. The number of cases appearing in this first report have allowed us to generate the format which we hope you agree gives a clear picture of how the patients are being treated and subsequently progressing. There are a number of mature Cartilage databases which we are in the process of assimilating into ICRS patient registry, this is only possible due to the academic generosity of Prof Daniel Saris, Drs Bill Bugbee, Wayne Akeson, Richard Convery, David Wood, Greg Janes, and Christian Lattermann who have been kind enough to make the necessary consenting arrangements for us to do so. Once the information importing is finished the numbers in our database will be boosted by 1500 cases with follow up periods of up to 10 years.

Finally, on behalf of the Steering Committee, after completing two terms as its' Chair, we thank Professor Leela Biant for all her hard work in instigating, designing, securing industry funding and delivering this project. This first report will be followed by an annual update on the progress of the registry. We hope you enjoy reading it.

On behalf of the Steering Committee,



Mike McNicholas

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Annual Report Prepared by:

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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 eight languages English, Italian, Spanish, Portuguese, Japanese, Greek, Dutch, and Polish. 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 is being used to facilitate the import of data from Scripps (Dr. Bugbee, Dr. Akeson, Dr. Convery & Dr. Meyers) as well as from Prof Saris. Additionally, the tool is to be used to import data from Dr. Lattermann and the data shared by the HFRC, Nedlands, Western Australia, Australia (Dr. Ebert, Dr. Wood. & Dr. Janes).

Language Translations

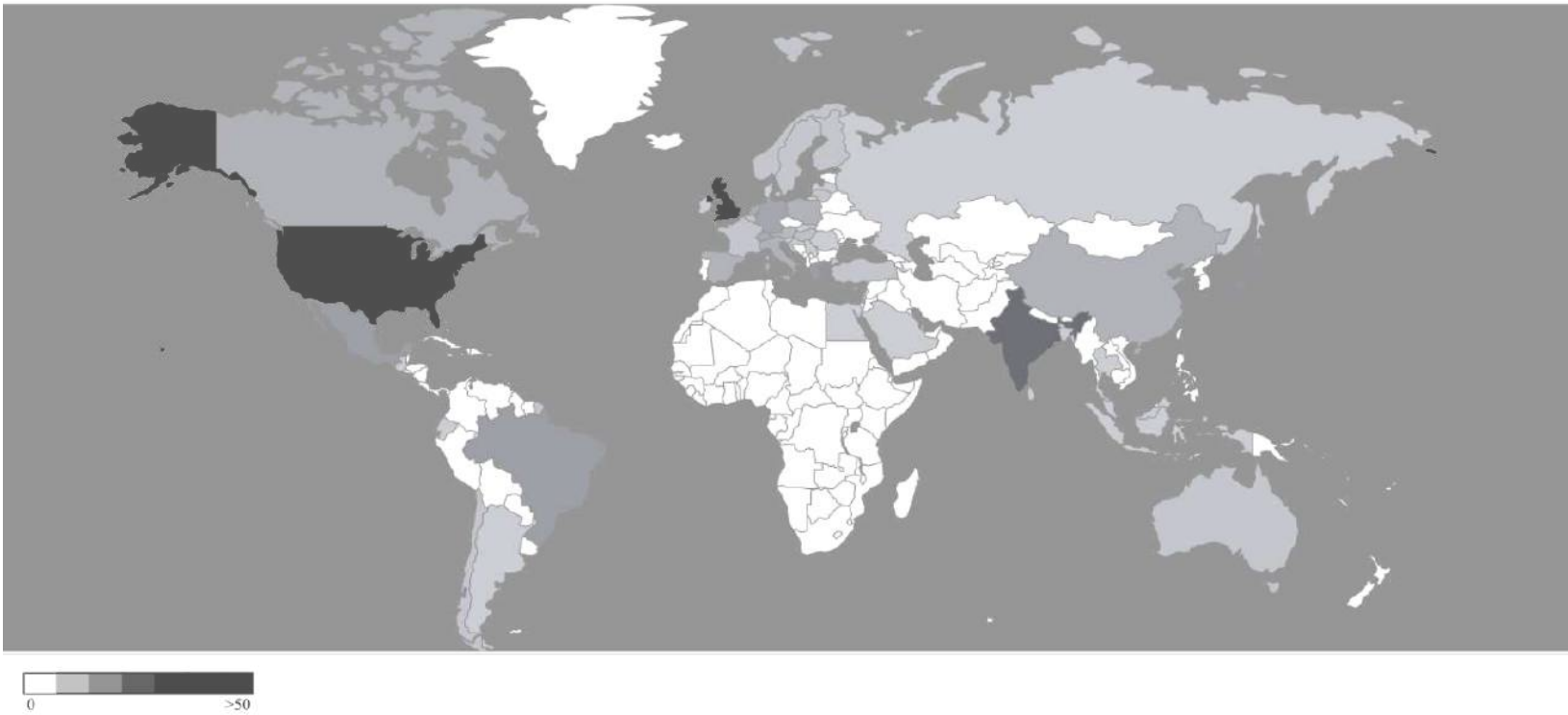
The registry is now live in:

- English, Japanese, Polish, Italian, Spanish, Portuguese, Dutch and Greek

The registry is in the final stages of completing:

- Chinese, Swedish, and German

These three languages will be released in registry in 2019.



Registry Profile

User Locations

The registry is comprised of clinician users and delegate users from all over the world. The map below illustrates the international reach of the registry. A red dot is placed on each country with a user registered (Figure 1).

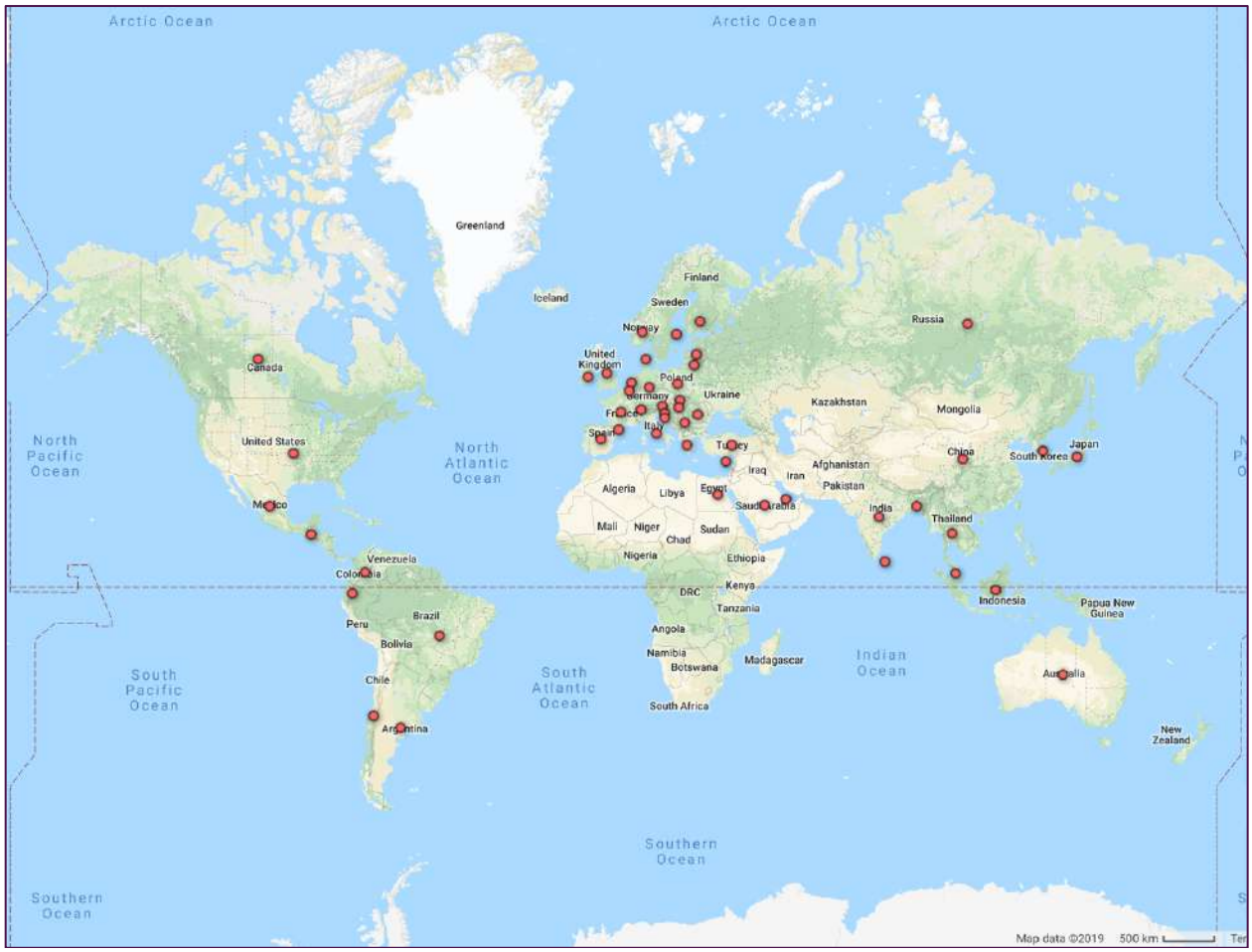


Figure 1 Google fusion tables with a red dot on each country with registered ICRS registry users

The Registry's Reach

The registry has registered users from **50** countries

User Volume

The largest density of registered clinician and delegate users are currently located in the United States of America (61) and the United Kingdom (60). This density is followed by 13 countries who each have between 5 to 15 users (Figure 2).

- Canada
- China
- Italy
- Poland
- Spain
- Netherland
- Switzerland
- Germany
- Brazil
- Greece
- Mexico
- Japan
- India

There are **264** clinician and delegate users in the registry

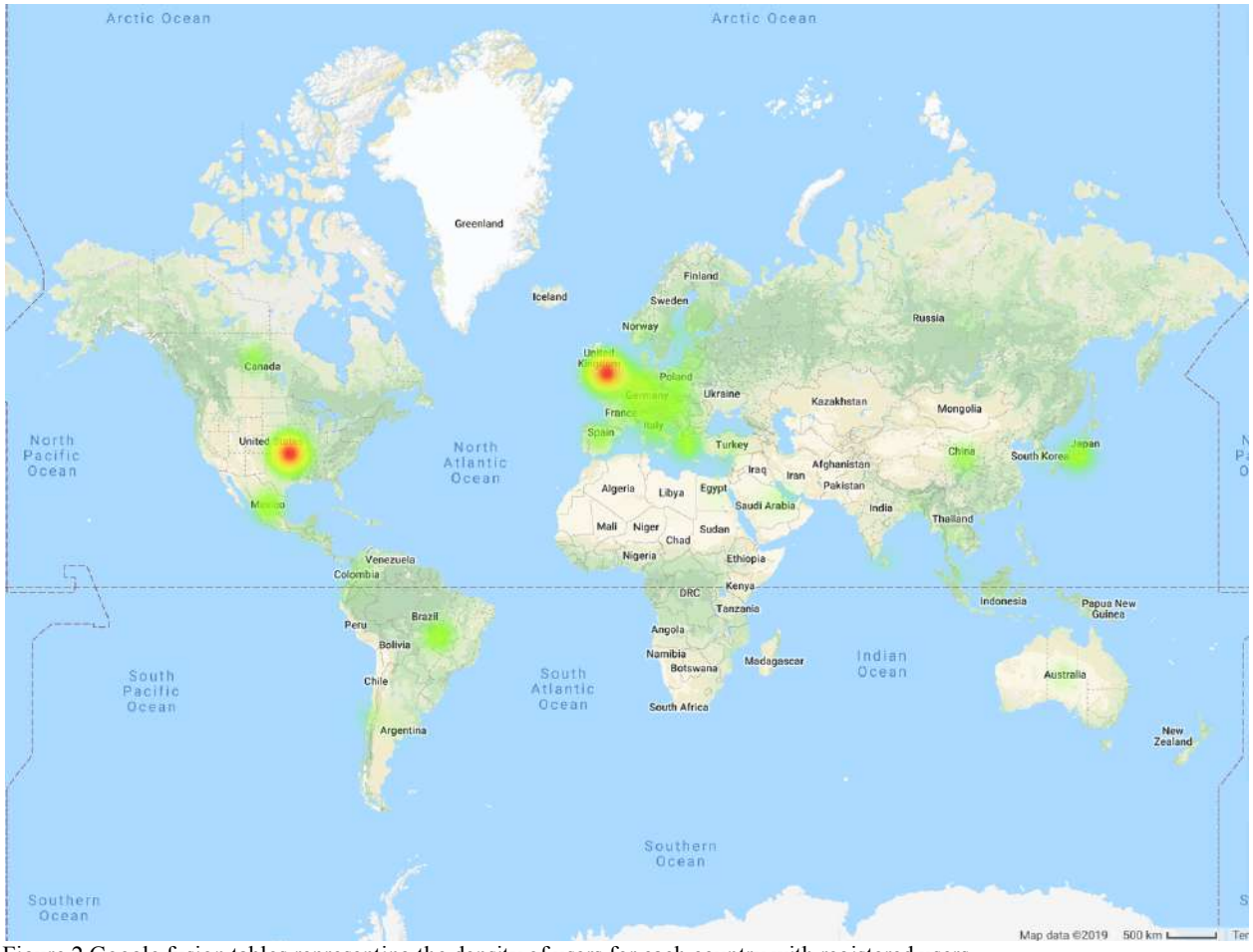


Figure 2 Google fusion tables representing the density of users for each country with registered users. (green = low density, red = high density)

Pathway Volume

There is a total of 535 knee pathways in the ICRS patient registry (Figure 3-4). The pathways have been a combination of live entries and pre-existing data import. The majority of the reported pathways have been live entries with approximately 9% of the 535 pathways created by the import of pre-existing data.

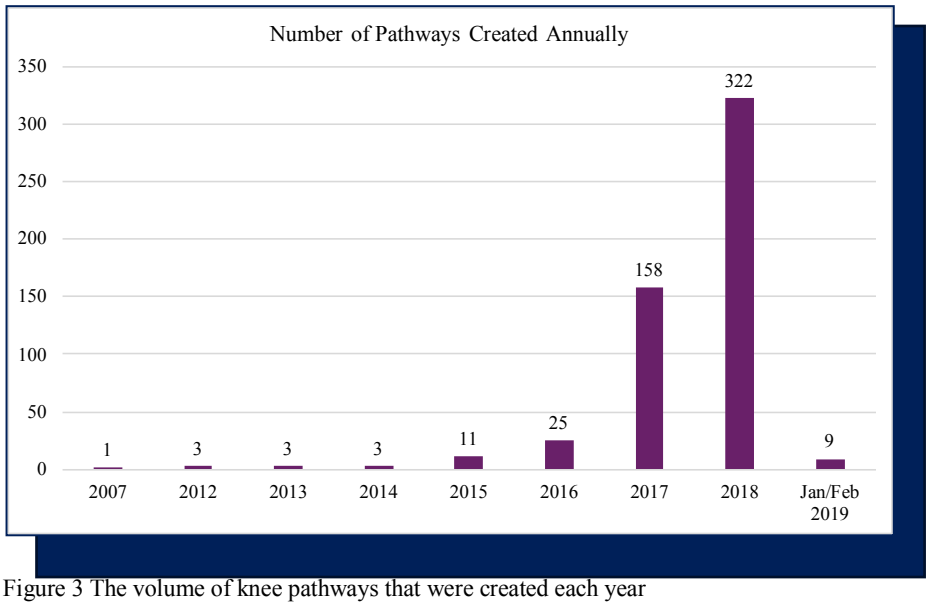


Figure 3 The volume of knee pathways that were created each year

A total of **480** of the 535 pathways were added in both 2017 and 2018

There was a **90%** increase in pathways during the past two years (30% in 2017 and 60% in 2018)

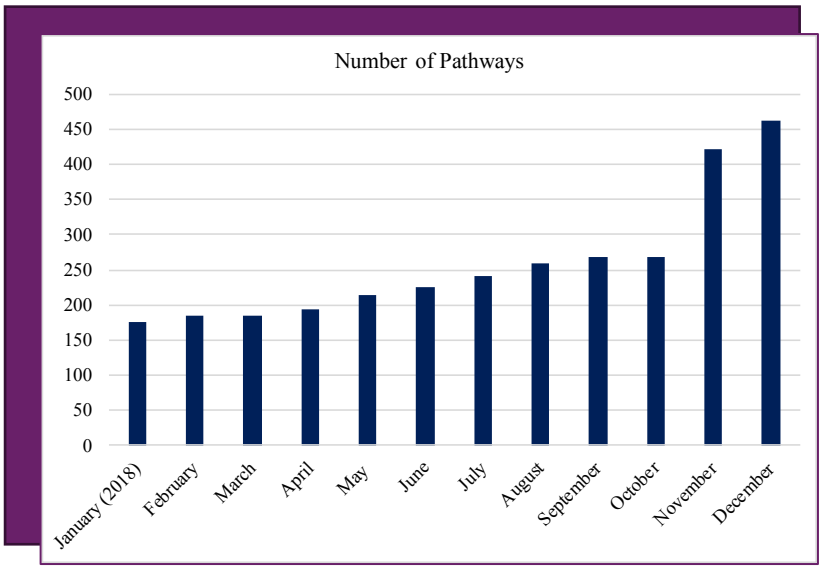


Figure 4 The volume of knee pathways created each month during 2018

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 535 pathways in the registry. The patient's BMI and the affected limb were reported the majority of the time; however, not as consistently.

Sex

The majority of the patients in the registry were female (n=292)(Figure 5). There was a small percentage of patients with their sex listed as unknown (n=5).

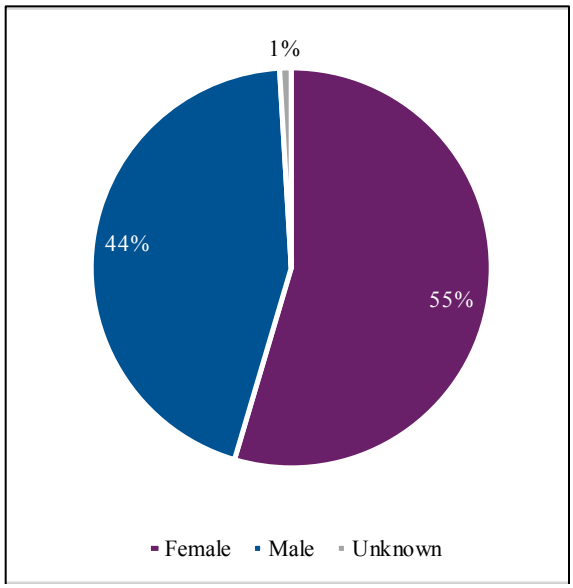


Figure 5 Percentage of sex distribution across all pathways in the registry

Affected Limb

	Count	Percentage
Affected Limb	352	65.8%
Left	180	33.6%
Right	172	32.1%

Table 1 The affect limb for all pathways in the registry

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

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 ± sd
BMI	113	26.49 ± 5.07
Female	56	26.43 ± 6.01
Male	57	26.55 ± 3.99
Unknown	-	-

Table 2 The BMI for all pathways in the registry overall and broken down by sex. (-) none reported.

Smoking Status

	Count	Percentage
Smoking Status	87	16.3%
Ex-Smoker	10	1.9%
Non-Smoker	67	12.5%
Smoker	10	1.9%

Table 3 Current and past smoking status for each patient pathway

Smoking status was only reported for 16.3% 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 (11.5%) and ex-smokers (11.5%).

Age

The patients in the registry ranged in age from 16 to 89 years old (Figure 6). The average age for the patients in the registry was 52±18 years old. Females tended to be slightly older overall than males (Table 4).

	N	Mean ± sd
Age		
Female	292	60 ± 18
Male	238	48 ± 15
Unknown	5	77 ± 8

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

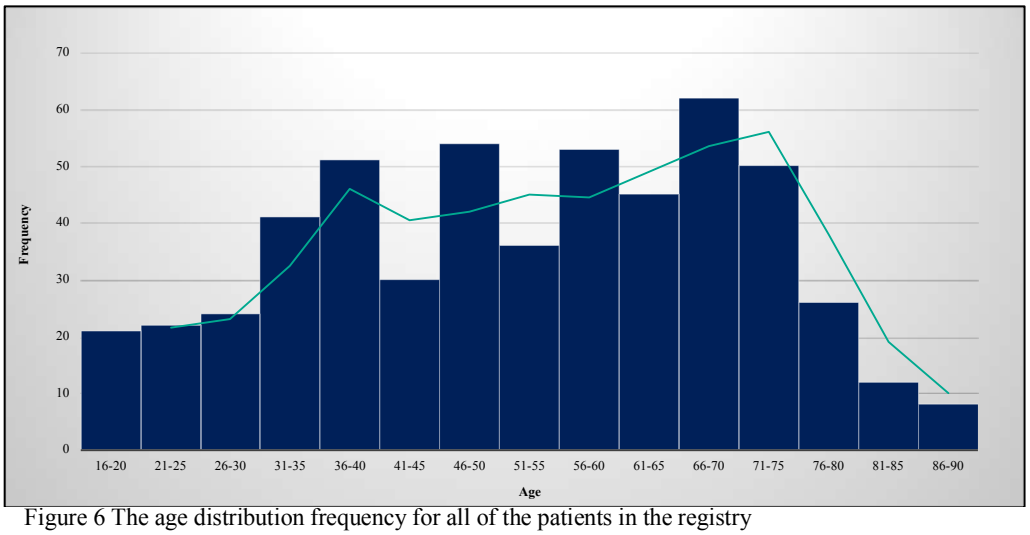


Figure 6 The age distribution frequency for all of the patients in the registry

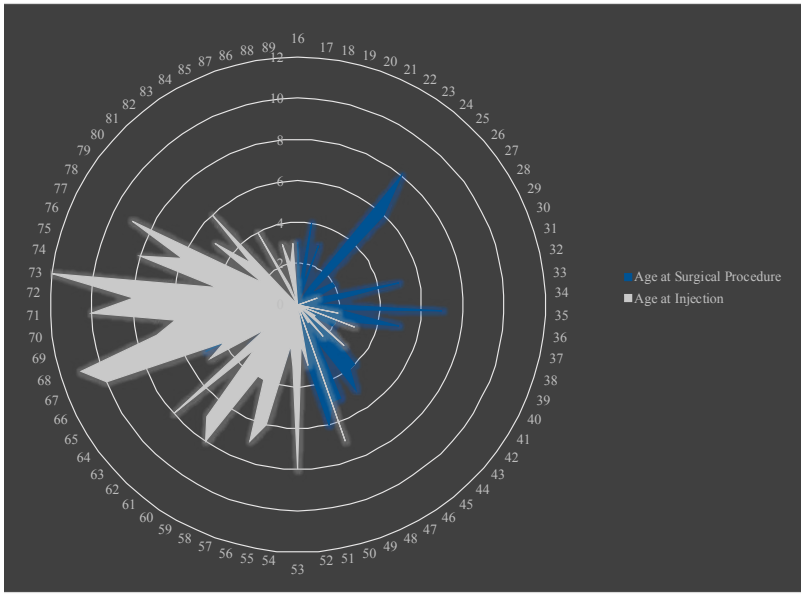


Figure 7 The age distribution frequency for all of the patients in each age category within the registry by procedure. Each age values in the registry is listed on the outside of the circle. The radius on the inside of the circle represents the frequency of each age value listed within the registry.

Patients treated with an injection tended to be older than patients surgically treated as depicted in Figure 7. The distribution of age is represented as a burst with larger age frequencies covering a larger surface area.

There was a large volume of patients age 24 and 25 who were surgically treated. The age distribution for patients treated with an injection was more uniform with a large number of patients treated with injections being between 67 to 73 years old.

Cartilage repair and restoration procedure patients

Pathway volume

A total of 90 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 **61%** in 2017 and **55%** in 2018

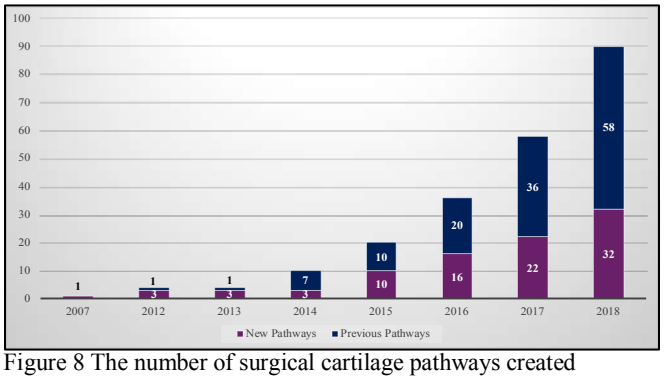


Figure 8 The number of surgical cartilage pathways created each year

Approximately 55% of the surgical cartilage pathways documented were for either *cell therapy* procedures or *osteochondral repair autograft* procedures. Many of the surgical procedures listed as *other* were to document re-fixations.

The volume of pathways document in 2017 accounted for 24% of the total documented surgical cartilage pathways (Table 5). This number increased in 2018 with the volume of documented pathways accounting for 36% of the total (Table 5).

	2007-2011	2012	2013	2014	2015	2016	2017	2018	Total
	%	%	%	%	%	%	%	%	%
Cell Therapy		14%	9%	9%	32%	5%	32%		**100%**
Conservative Treatment of Cartilage Defect						20%	80%		**100%**
Debridement or Chondroplasty Only			14%		14%	29%	29%	14%	**100%**
Debridement or Chondroplasty Only and Microfracture				33%			67%		**100%**
Microfracture					14%	57%	29%		**100%**
Osteochondral Repair Autograft						3%	7%	90%	**100%**
Osteochondral Repair Allograft					25%		25%	50%	**100%**
Osteochondral Repair Other						100%			**100%**
Osteochondral Repair and Other						100%			**100%**
Osteochondral Repair Autograft and Other								100%	**100%**
Scaffold/Carrier Used						50%	50%		**100%**
Other	14%					57%	14%	14%	**100%**
Total	**1%**	**3%**	**3%**	**3%**	**11%**	**18%**	**24%**	**36%**	**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 ± 11 years old (ranging from age 16 to age 57). The largest percentage of patients surgically treated was between 31 – 40 years old and most commonly were treated with either cell therapy or osteochondral repair (Table 6). The average BMI was 26 ± 4 (ranging from 18 to 40).

	15-20 yrs		21-30 yrs		31-40 yrs		41-50 yrs		51-60 yrs		Total	
Procedure Name	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**
Cell Therapy	3	14%	5	23%	10	45%	4	18%			**22**	**100%**
Conservative Treatment of Cartilage Defect			2	40%	2	40%	1	20%			**5**	**100%**
Debridement or Chondroplasty Only	1	14%	3	43%	1	14%	2	29%			**7**	**100%**
Debridement or Chondroplasty Only and Microfracture			3	100%							**3**	**100%**
Microfracture	1	14%	2	29%	1	14%	2	29%	1	14%	**7**	**100%**
Osteochondral Repair	1	3%	4	11%	11	31%	12	34%	7	20%	**35**	**100%**
Osteochondral Repair and Other	1	50%			1	50%					**2**	**100%**
Other	4	57%			2	29%	1	14%			**7**	**100%**
Scaffold/Carrier Used			2	100%							**2**	**100%**
Total	**11**	**12%**	**21**	**23%**	**28**	**31%**	**22**	**24%**	**8**	**9%**	**90**	**100%**

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=52) than females (n=38) with surgical cartilage pathways (Figure 9). However, females and males were similar in age (F 36 ± 12, M 35 ± 11 years) and BMI (F 25 ± 4, M 27 ± 4).

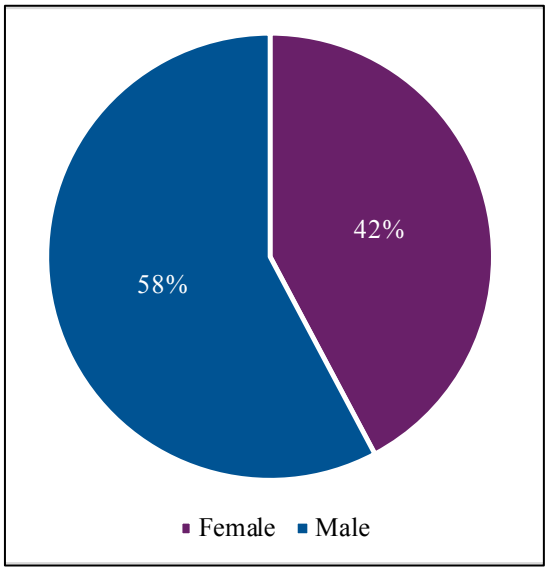


Figure 9 The sex distribution for all surgical cartilage procedure pathways

Cartilage Procedure	Sex	N	Percentage
Cell Therapy			
	Female	10	45%
	Male	12	55%
Conservative Treatment of Cartilage Defect			
	Female	2	40%
	Male	3	60%
Debridement or Chondroplasty Only			
	Female	4	57%
	Male	3	43%
Debridement or Chondroplasty Only and Microfracture			
	Female	0	0%
	Male	3	100%
Microfracture			
	Female	1	14%
	Male	6	86%
Osteochondral Repair			
	Female	16	46%
	Male	19	54%
Osteochondral Repair and Other			
	Female	1	50%
	Male	1	50%
Other			
	Female	2	29%
	Male	5	71%
Scaffold/Carrier Used			
	Female	2	100%
	Male	0	0%
	Total	**90**	

Table 7 The sex distribution for the reported surgical cartilage procedure pathways

Categorizing the pathways by the specific procedure males tended to be treated with a microfracture or microfracture with an associated treatment at a higher percentage than females (Table 7).

Patient demographics continued

Smoking Status

Approximately 60% 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.

	Count	Percentage
Smoking Status		
Previous Smoker	5	9%
Current Smoker	6	11%
Non-Smoker	43	80%
Total	**54**	100%

Table 8 Smoking status for all surgical cartilage procedure pathways

Symptom onset

Just over three fourths of the pathways were not associated with a known injury (Figure 10). In the patients that knew of an associated injury, seven of the pathways were related to sports injuries. The sports predominately varied between basketball (29%) and football (soccer) (43%). The other six known injury pathways were non-sport injuries such as work accidents, traffic accidents, falls, and others.

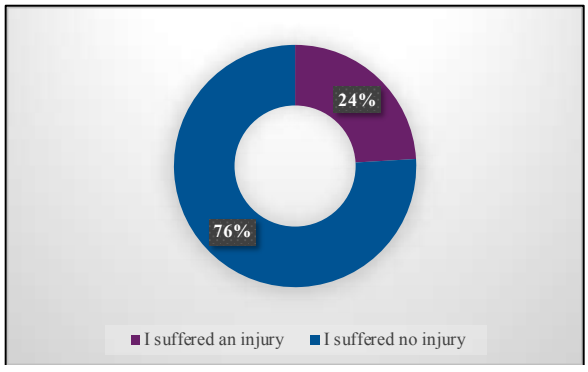


Figure 10 The percentage of pathways with a known injury and those without a known injury

Approach

An open approach was implemented in 62 of the surgical cartilage knee pathways followed by an arthroscopic approach in 23 patients (Figure 11).

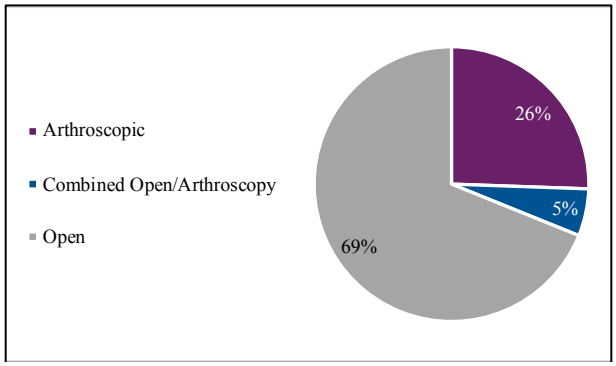


Figure 11 Surgical approach for the cartilage pathway

Defect characteristics

Defect information was reported in 88 of the 90 patients. A total of 119 defects were documented in the registry whether they were treated or not. 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.

	Count	Percentage
Number of Defect		
1	63	72 %
2	20	23 %
3	4	5 %
4	1	1 %
Total	**88**	**100%**

Table 9 The number of total defects reported per pathway

Defect characteristics continued

Defect location & area

Defects, both osteochondral lesions and chondral lesions, were reported in all of the compartments of the knee. The largest percentage of pathways had multiple defects reported (28%)(Figure 12). Defects in the patella (27%) followed by the medial femoral condyle (23%) accounted for 50% of the pathways with only one defect reported.

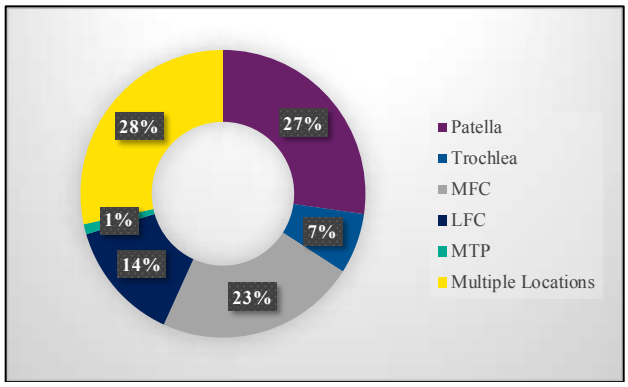


Figure 12 The percentage each defect location was reported. MFC=medial femoral condyle, LFC=lateral femoral condyle, MTP=medial tibial plateau

The area for the 4 most common defect locations is reported in Figure 13. The medial tibial plateau and lateral tibial plateau are not reported separately due the limited sample size in each of the groups (MTP=2, LTP=2).

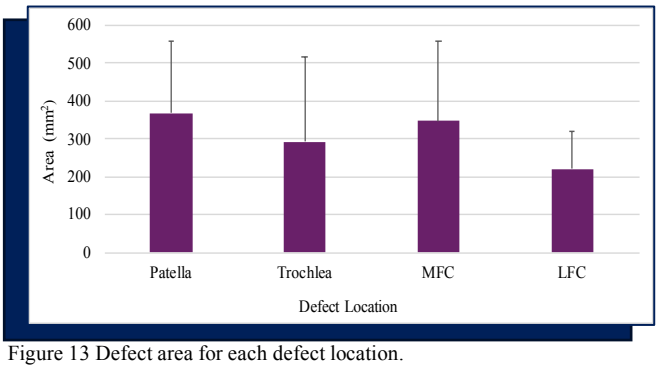


Figure 13 Defect area for each defect location. MFC=medial femoral condyle, LFC=lateral femoral condyle,

Surgical technique

Tourniquet and antibiotic usage

A total of 93% of the pathways reported the tourniquet usage (Figure 14). Out of that reporting a tourniquet 94% reported the pressure (Table 10). Similarly, 94% of pathways reported the antibiotic prophylaxis usage. The implementation of an antibiotic prophylaxis was evenly distributed (Figure 15).

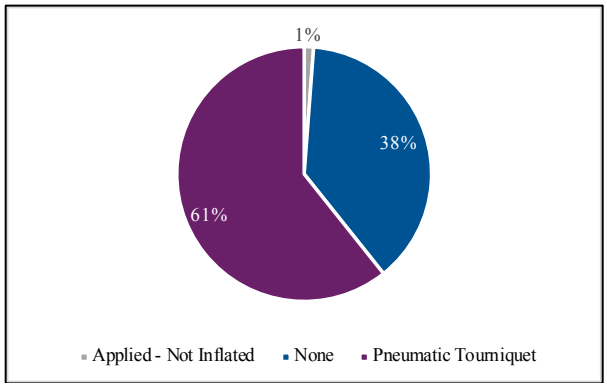


Figure 14 The type of tourniquet utilized during surgery

	Count	Percentage
Tourniquet Pressure		
250 mm Hg	39	80%
300 mm Hg	6	12%
350 mm Hg	1	2%
Other	3	6%
Total	**49**	**100%**

Table 10 The type of tourniquet utilized during surgery

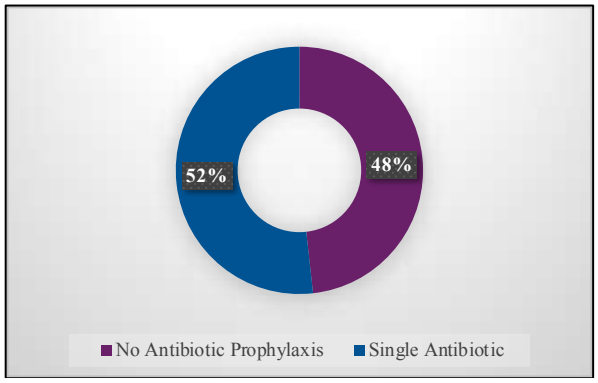


Figure 15 Reported antibiotic prophylaxis usage

Concomitant surgical procedures

In the surgical cartilage pathways, 32% of the pathways had concomitant surgical procedures. The surgical procedures are displayed in Figure 16. Osteochondral repair procedures had the largest number of concomitant procedures followed by cell therapy procedures (Table 11).

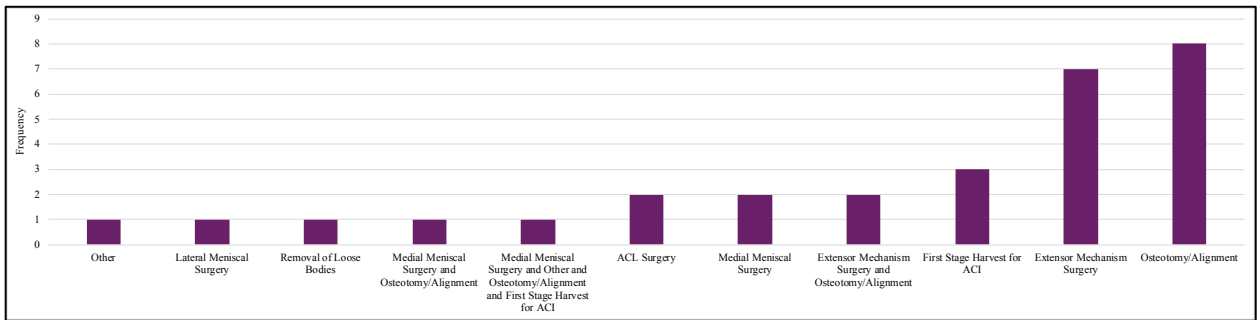


Figure 16 The type of concomitant procedures and the frequency of these procedures

Primary Cartilage Procedure Concomitant Procedures	Count	Percentage
Cell Therapy	**22**	
Extensor Mechanism Surgery and Osteotomy/Alignment	1	5%
First Stage Harvest for ACI	1	5%
Lateral Meniscal Surgery	1	5%
Medial Meniscal Surgery and Other and Osteotomy/Alignment and First Stage Harvest for ACI	1	5%
None	14	64%
Osteotomy/Alignment	3	14%
Removal of Loose Bodies	1	5%
Conservative Treatment of Cartilage Defect	**5**	
First Stage Harvest for ACI	1	20%
Medial Meniscal Surgery	1	20%
Medial Meniscal Surgery and Osteotomy and Alignment	1	20%
None	1	20%
Other	1	20%
Debridement or Chondroplasty Only	**7**	
First Stage Harvest for ACI	1	14%
Medial Meniscal Surgery	1	14%
None	4	57%
Osteotomy/Alignment	1	14%
Debridement or Chondroplasty Only and Microfracture	**3**	
None	3	100%
Microfracture	**7**	
ACL Surgery	1	14%
None	6	86%
Osteochondral Repair	**35**	
Extensor Mechanism Surgery	7	20%
Extensor Mechanism Surgery and Osteotomy/Alignment	1	3%
None	23	66%
Osteotomy/Alignment	4	11%
Osteochondral Repair and Other	**2**	
None	2	100%
Other	**7**	
ACL Surgery	1	14%
None	6	86%
Scaffold/Carrier Used	**2**	
None	2	100%
Total	**90**	

Table 11 The primary procedure and the associated concomitant surgical procedure

Post-operative rehabilitation

Brace utilization and physiotherapy

Post-surgical treatment prescriptions were reported in 99% of the surgical cartilage pathways. Of these patients, a third of them were prescribed an unloader brace (n=28) and 94% were prescribed physiotherapy (n=84)(Figure 17-18). Physiotherapy was prescribed immediately after surgery in 52% of the pathways.

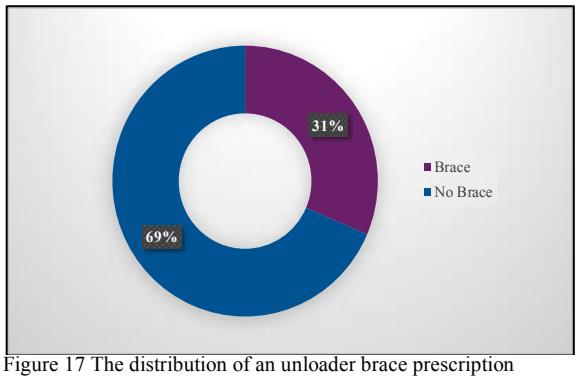


Figure 17 The distribution of an unloader brace prescription documented for the surgical cartilage pathways

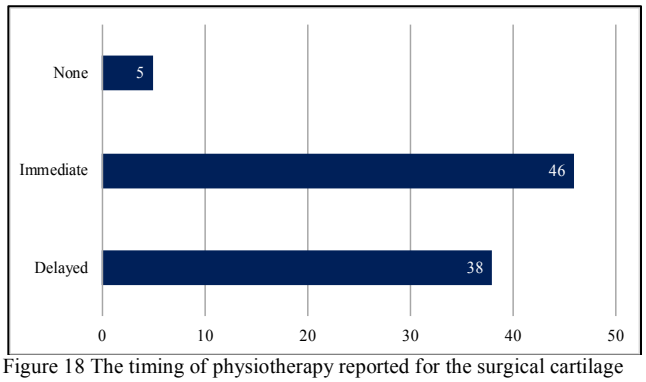


Figure 18 The timing of physiotherapy reported for the surgical cartilage pathways

Weight-bearing

Patients overwhelmingly were prescribed partial weight bearing (Figure 19). The partial weightbearing prescription favored weightbearing as tolerated (n=37), however toe touch weightbearing closely followed (n=27).

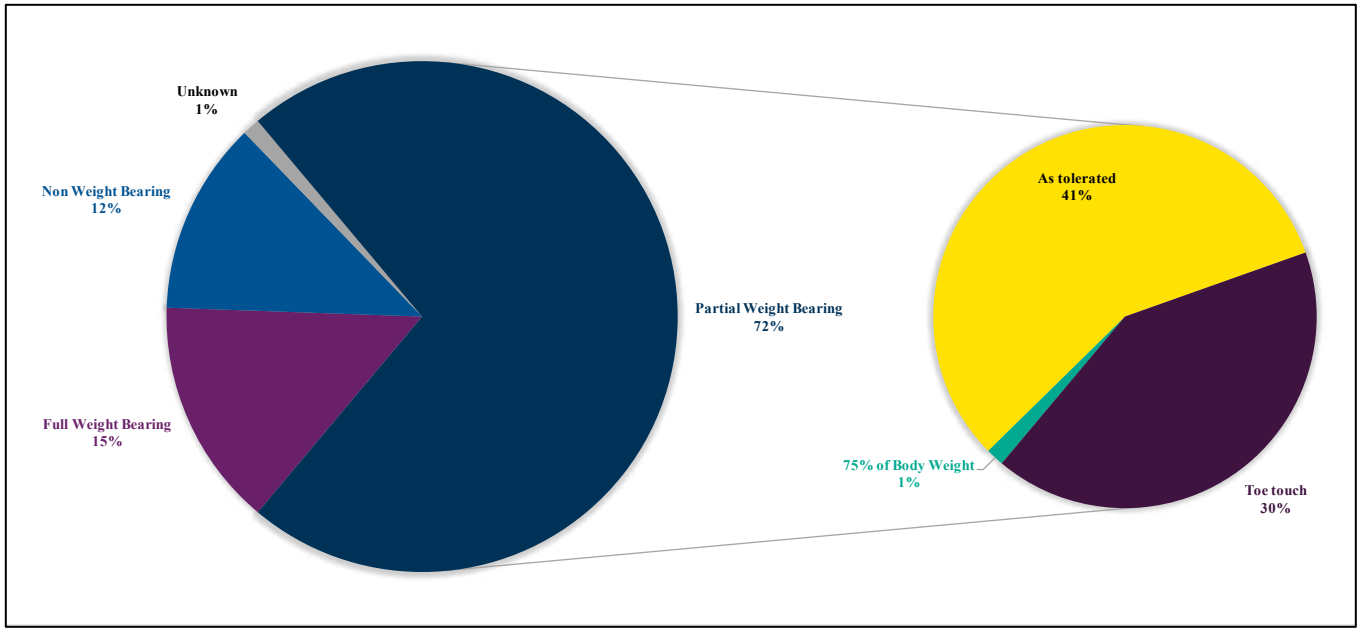


Figure 19 Prescribed weightbearing status for surgical cartilage pathways

Patient reported outcomes

Overview

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

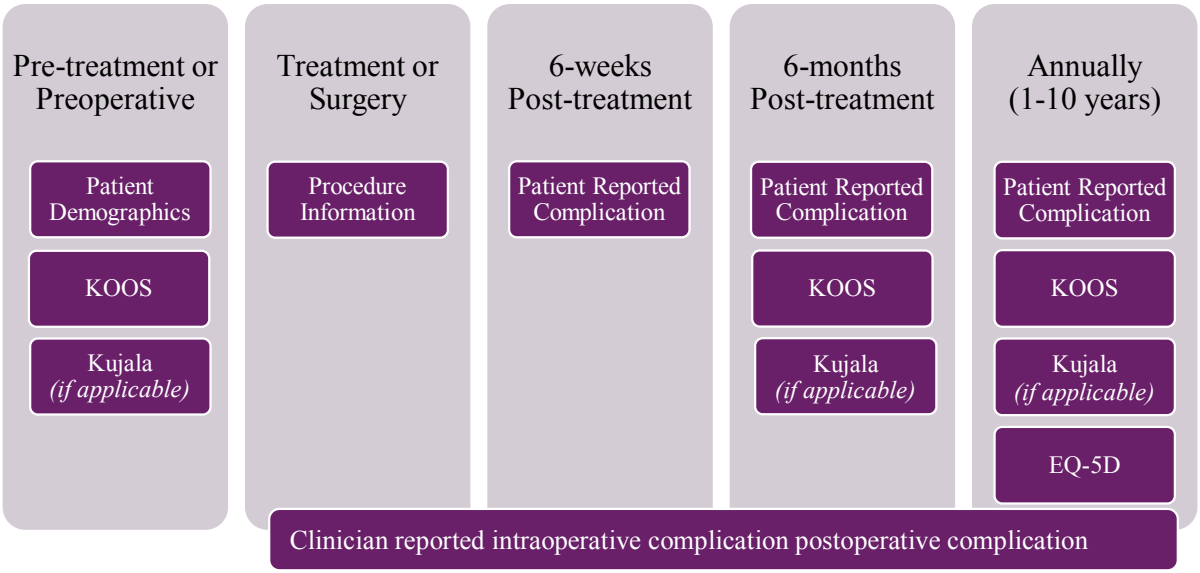


Figure 20 An overview of the registry outcome collection instruments and associated time points

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 31 baseline scores for the surgical cartilage pathways (Figure 21).

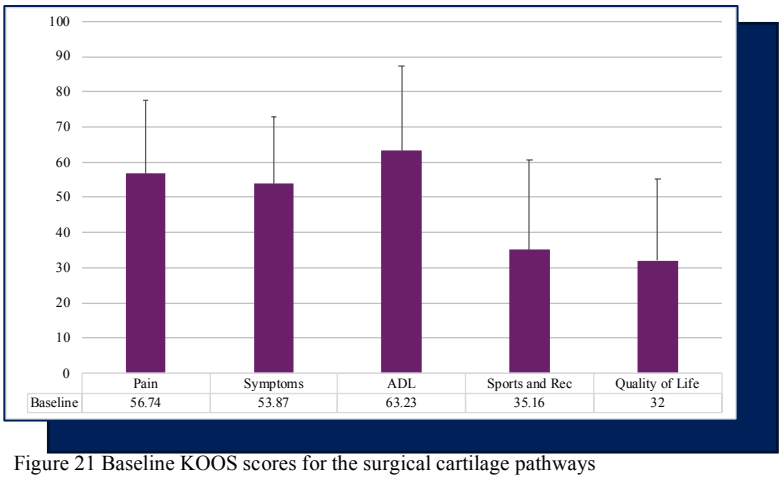


Figure 21 Baseline KOOS scores for the surgical cartilage pathways

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 53 surgical cartilage pathways with baseline EQ-5D data (Figure 22-26).

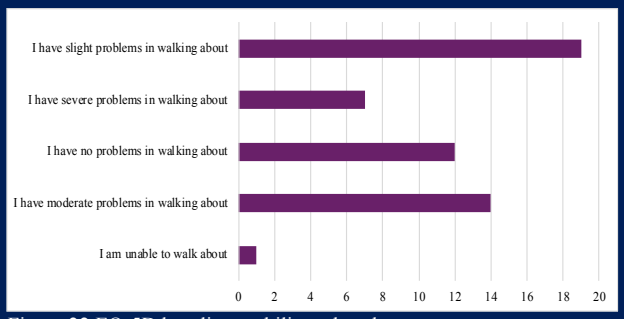


Figure 22 EQ-5D baseline mobility subscale

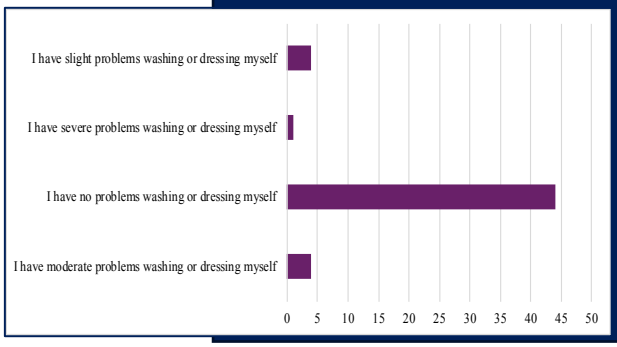


Figure 23 EQ-5D baseline self-care subscale

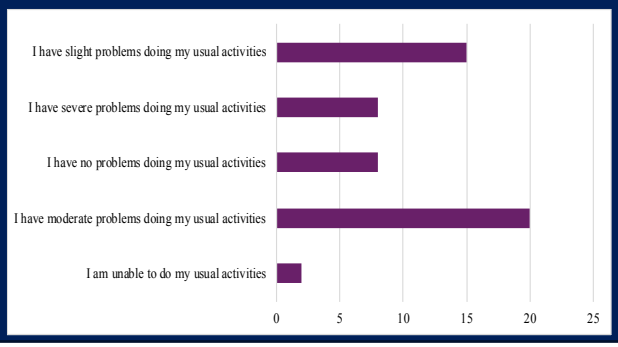


Figure 25 EQ-5D baseline usual activities subscale

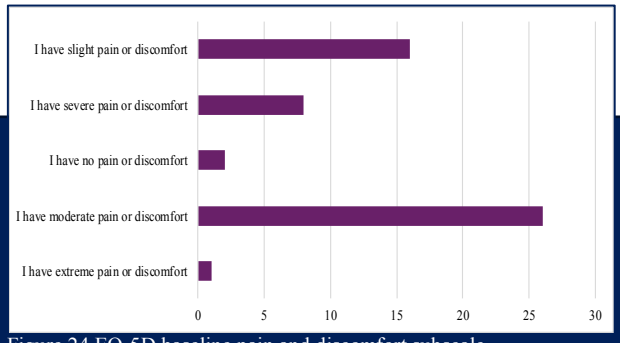


Figure 24 EQ-5D baseline pain and discomfort subscale

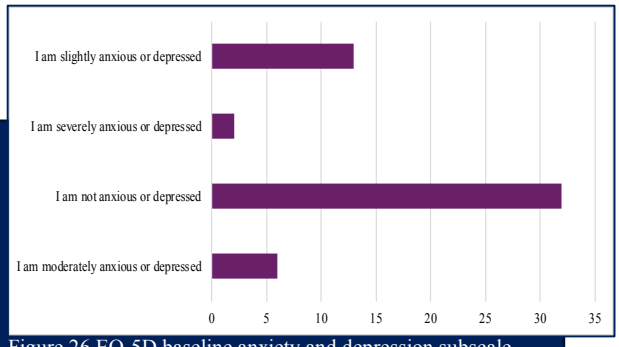


Figure 26 EQ-5D baseline anxiety and depression subscale

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 20 surgical cartilage pathways with baseline Kujala data (Figure 27).

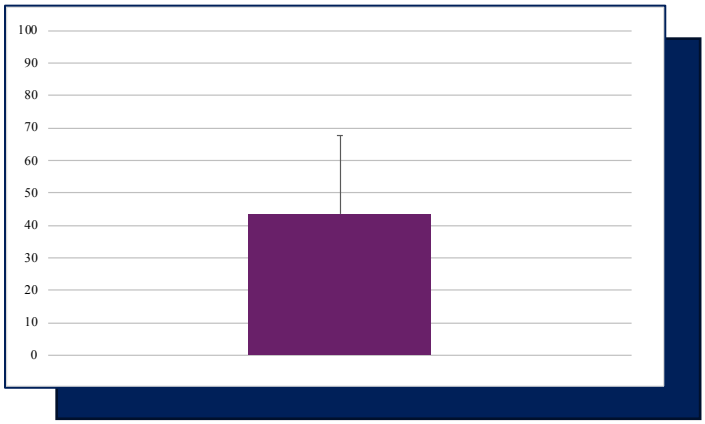


Figure 27 Baseline Kujala scores for the surgical cartilage pathways

Complications

Complications in the registry are documented by both the clinician user as well as the patient. The clinician user has the ability to document complications inter-operatively and post-treatment (surgical or conservative treatment). Out of the 89 surgical cartilage pathways the reported interoperative complications none are reported to have had a complication. At this time there are no post-treatment complications documented in the registry. We encourage all users to report their complications in the future.

Complications

100% of the documented pathways were free of surgical complications

Feature: Users have the ability to add the IKDC or Lysholm to their data collection

Procedures not directly addressing a cartilage defect

Patient demographics

There were 40 pathways in the registry created for surgical procedures not directly addressing a cartilage defect. Approximately 92.5% of the patients undergoing other surgical procedures were over the age of 40 (Figure 28). The average age of the patients was 53±12 years and they were predominately males (62.5%) (Figure 29). Males were slightly older in age than the females (M: 56 ± 9 yrs, F: 50 ± 15 yrs).

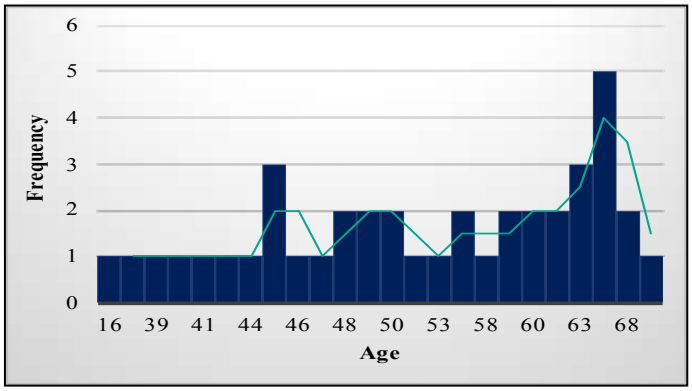


Figure 28 Age distribution for patients undergoing other surgical procedures

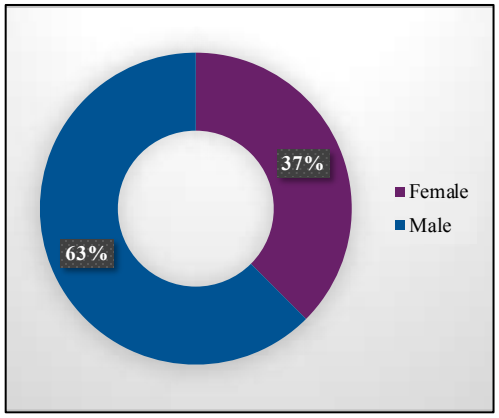


Figure 29 Age distribution between males and females for patients undergoing other surgical procedures

Surgical techniques

The most common surgical procedure reported was a high tibial osteotomy (n=16)(Figure 30). This procedure was closely followed by an arthroscopic procedure – other (14). The other 25% of the procedures reported were comprised of patella re-alignment procedures, extensor mechanism procedures, meniscus procedures, and anterior cruciate ligament procedures.

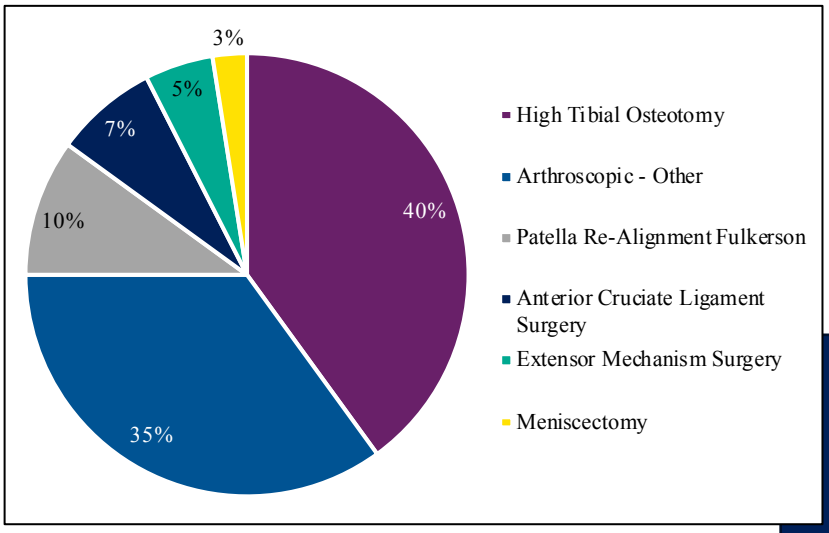


Figure 30 The distribution of other specific surgical procedures documented in the registry

Knee injection procedures

Pathway volume

A total of 218 pathways in the registry documented a knee injection procedure. All of these pathways have been created in the past three years (Figure 31). Beginning in 2016, there has been a steady increase each year in number of injection pathways created in the registry.

Annual Rate Increase

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

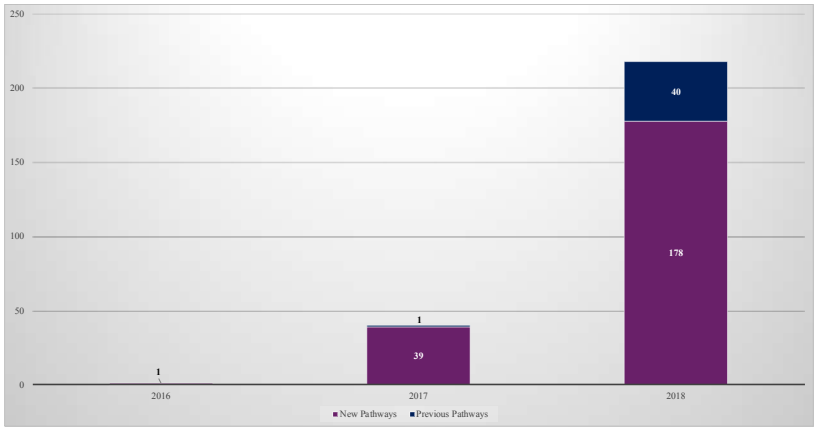


Figure 31 The number of knee injection pathways created each year

The registry had a sizable increase in 2017 adding 39 new injection pathways. The addition in 2017 accounted for 18% of the total registry volume. This was followed in 2018 by the largest increase in the registry where there was a **4-fold** increase in pathway volume.

There were 5 different injection therapies and injection combinations reported in the registry (Table 12). Overall *stem cell injections* (66%) heavily dominated the total registry pathway volume followed by *plasma rich protein injections* (PRP) (27%). The remaining 5 categories of injections reported in the registry accounted for 7% of total pathway volume.

	2016		2017		2018		Total	
	N	%	N	%	N	%	**N**	**%**
Injection Hyaluronic Acid			3	60%	2	40%	**5**	**100%**
Injection Hyaluronic Acid and Stem Cell Injection			2	25%	6	75%	**8**	**100%**
Injection PRP			5	8%	54	92%	**59**	**100%**
Injection PRP and Stem Cell Injection			1	50%	1	50%	**2**	**100%**
Stem Cell Injection	1	1%	28	19%	115	80%	**142**	**100%**
Total	**1**	**0.5%**	**39**	**17.9%**	**178**	**81.7%**	**218**	**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 average age of the knee injection patients was 66 ± 12 years old (ranging from age 31 to age 89). The largest percentage of patients treated was between 71 – 80 years old, most commonly treated with a stem cell injection (Table 13). This was followed closely by patient between 61 – 70 years old, also most commonly treated with a stem cell injection.

	31-40 yrs		41-50 yrs		51-60 yrs		61-70 yrs		71-80 yrs		81-90 yrs		Total	
Procedure Name	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**	**N**	**Percent**
Injection Hyaluronic Acid	4	80%							1	20%			**5**	**100%**
Injection Hyaluronic Acid and Stem Cell Injection					2	25%	5	63%	1	13%			**8**	**100%**
Injection PRP	1	2%	9	15%	12	20%	15	25%	16	27%	6	10%	**59**	**100%**
Injection PRP and Stem Cell Injection									2	100%			**2**	**100%**
Stem Cell Injection	1	1%	7	5%	33	23%	43	30%	47	33%	13	9%	**144**	**100%**
Total	**6**	**3%**	**15**	**7%**	**47**	**22%**	**63**	**29%**	**67**	**31%**	**19**	**9%**	**218**	**100%**

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

Sex

There were more females (n=140) than males (n=73) with knee injection pathways (Figure 32). Females on average were older than males (F 69 ± 10, M 59 ± 12 years). Furthermore, there was a larger percentage of females treated in all the injection type categories, with the exception of hyaluronic acid which had a larger percentage of males (Table 14).

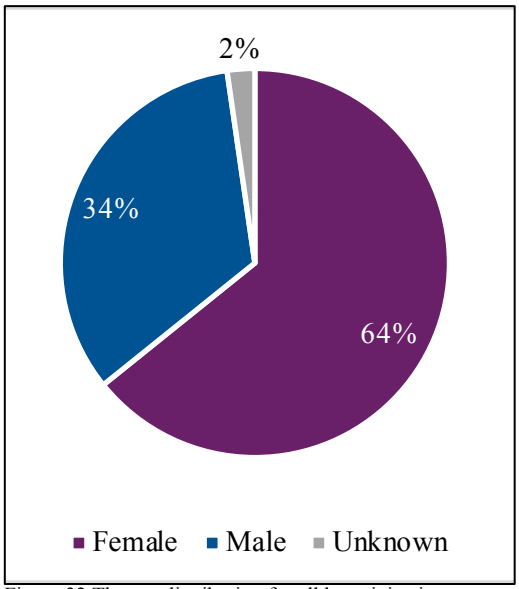


Figure 32 The sex distribution for all knee injection pathways

Injection	Sex	N	Percentage
Injection Hyaluronic Acid			
	Female	1	20%
	Male	4	80%
Injection Hyaluronic Acid and Stem Cell Injection			
	Female	5	63%
	Male	3	38%
Injection PRP			
	Female	37	63%
	Male	22	37%
Injection PRP and Stem Cell Injection			
	Female	2	100%
	Male	0	0%
Stem Cell Injection			
	Female	96	67%
	Male	43	30%
	Unknown	5	3%
	Total	**218**	

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-treatment prescriptions were reported in 71% of the surgical cartilage pathways. Of these patients, over two-thirds of them were prescribed an unloader brace (n=152) and full weight bearing. Physiotherapy not prescribed in the majority of the documented pathways (n=147) (Figure 33-34).

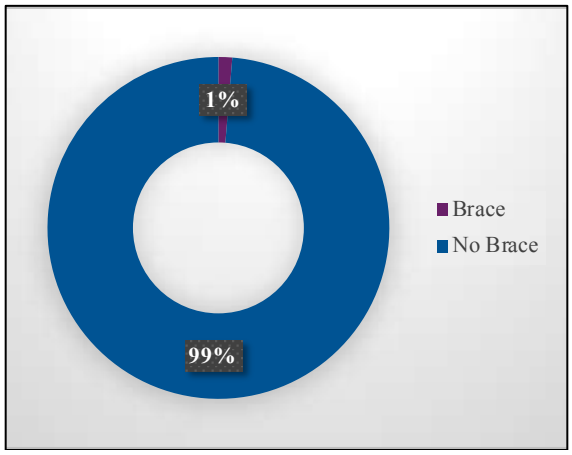


Figure 33 The distribution of an unloader brace prescription documented for the knee injection pathways

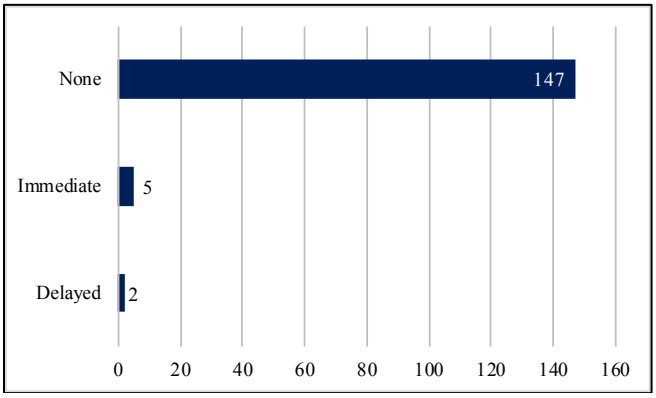


Figure 34 The timing of physiotherapy reported for the knee injection pathways

Weight-bearing

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

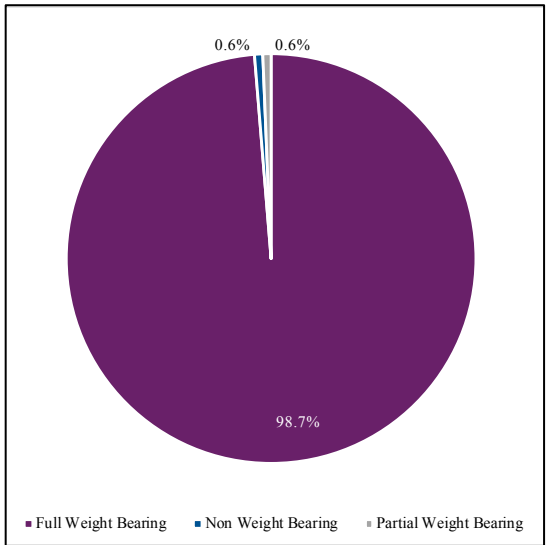


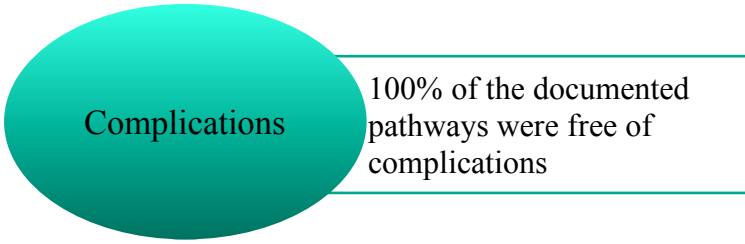
Figure 35 Prescribed weightbearing status for knee injection pathways

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.



Future projects

Language translations

An important step towards the global reach our registry aspires to is to facilitate data entry by both clinician and patient users by having multiple language interfaces available. We are grateful to those ICRS members who have assisted in the translations and ensuring medical accuracy. The registry is currently live in 8 different languages (English, Japanese, Polish, Italian, Spanish, Portuguese, Dutch and Greek) with 3 additional ones being implemented in 2019 (German, Swedish and Chinese). This will bring the total of available languages for the knee pathway to 11 in the ICRS patient registry.

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 2020.

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 (2019-2020) 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 Prof Caitlin Conley at 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 continues to grow in the number of users and pathways they are entering. Our numbers will be boosted significantly by the assimilation of high volume user personal databases.

New patient pathways are increasing exponentially. It is a valuable tool for patient outcome tracking, monitoring of successful treatments and effective independent 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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