Trend in the use of breast implants of Ibero Latin American plastic surgeons. FILACP study 2010-2020

José SAINZ ARREGUI* and María del Mar VAQUERO PÉREZ**

Abstract

Background and objective. Since its creation in 2010, the Implant Registry Committee of FILACP (Ibero Latin American Federation of Plastic Surgery) an international entity that gathers the 22 National Societies of Plastic Surgery of Spanish and Portuguese language, has worked to know the common preferences and uses among its members in breast augmentation surgery with implants.

With this aim, between 2010 and 2020, it carried out a series of periodic surveys to investigate the variables involved in breast surgery with implants carried out by plastic surgeons from Iberolatinamerica and how the incidence of breast implants associated anaplastic large cell lymphoma (BIA-ALCL) and its possible etiopathogenic relationship with certain types of implants might have influenced them.

We present in this article the data obtained and analyze the observed trends.

Methods. Comparative study of data collected in 4 surveys sent to 5000 FILACP members: the first one presented in 2012, with 25 questions on primary breast surgery with implants and 18 on secondary surgery; the second one presented in 2016 with 31 questions on primary surgery and 52 on secondary surgery; the third one in 2018 with 40 questions on both primary and secondary surgery; and the fourth one in 2020, with 13 general questions.

Results. General data reflects a preference of Iberolatinamerican plastic surgeons for the use of round implants, with a tendency to increase the use of smooth cover versus textured implants, with a preferential surgical periareolar approach, submuscular placement, and awareness growing need for surgical capsulectomy in secondary surgeries, and for the pathology study of the removed capsule. They also report a good knowledge of BIA-ALCL and the variables involved in its diagnosis and treatment.

As of April 2020, we also collected the cases of BIA-ALCL reported by the FILACP National Societies: 106 cases in 9 countries, with 2 deaths.

Conclusions. The trend among our respondents, surely influenced by the knowledge of the factors related to the etiology of BIA-ALCL, is towards the increasing use of smooth and round-shaped implants, and represents an important and updated estimate of the uses of a highly representative professional collective in an international environment that usually collects only data from anglo-saxon professionals and publications.

Key words
Breast implants, Breast augmentation,
BIA-ALCL, Survey.

Level of evidence
5c Epidemiologic

Received (this version)
15 April/2020

Accepted
30 May/2020

Conflict of interests: The authors declare that they have no financial interest related to the content of this article.

Disclosures: The computer support for conducting the surveys was financed by FILACP.
Introduction

In 2010, the Ibero-Latin American Federation of Plastic Surgery (FILACP), an international entity that brings together the national societies of Plastic, Reconstructive and Aesthetic Surgery of the 22 Ibero-American countries of Spanish and Portuguese languages, decided, at the proposal of its President in that period, Dr. José Tariki, to create an Implant Registry Committee to know the use in these countries of implants in breast augmentation surgery. The proposal was to launch a survey to all FILACP members and to analyze the variables involved in breast surgery with implants carried out by plastic surgeons from Ibero-Latin America.

Since then, this committee has been carrying out periodic surveys to update data based on new knowledge related to breast implants and the contingencies derived from their use, among which the most interesting in recent times was the pathology known as Breast Implant Associated Anaplastic Large Cells Lymphoma (BIA-ALCL)\(^ 1\) and how knowledge about its possible etiopathogenic relation to certain types of implants, and methods of diagnosis and treatment, could have influenced the selection and use of breast implants made by Ibero-Latin American plastic surgeons.

The objective of the studies carried out by the FILACP Breast Implant Registry Committee is to provide a novel database obtained from an international scientific community united by the same language, with a great experience in the use of breast implants, high patient casuistry and a significant consumption of implant units, which should undoubtedly be taken into account among other international references. This way, we could present data from a breast implant market in which, except Spain and Portugal that are under the CE marking regulations, and some Latin American countries that individually follow the same, never had other restrictions or moratoriums to the use of different brands and models of breast implants, and which has only recently been affected by the worldwide recall of Allergan Biocell\(^ \) textured breast implants (Allergan plc. (NYSE: AGN), Dublin, Ireland). This makes this study completely different from those carried out in other international communities that are under the restrictions on the use of brands and models of implants by the FDA (Food and Drugs Administration) or by some countries of the European Community such as the recent case of France in 2019.\(^ 3\)\(^-\)\(^5\)

As a result of a 10-year follow-up, we present in this article the trends in the use of breast implants of plastic surgeons in the Ibero-Latin American countries from 2010 to 2020, analyzing the results of surveys carried out periodically by the FILACP Implant Registry Committee and presented in the successive international meetings of this international federation.

Methods

Work was carried out by means of surveys of several questions, each one with several answer options. These surveys were designed to be sent by personalized email (server and mailmarketing platform) to FILACP members and to be answered from a web platform (server and Question\(^ \) platform) available 24 hours a day for a specified period of time in each study. Although the submission was personalized, the responses were recorded anonymously, in encrypted data tables, for joint analysis. In the last survey a whatsapp server and message platform and an availability notification system was also used, with answers connection to the same usual web platform.

Between 2010 and 2020, 4 surveys were launched including FILACP plastic surgeons in 22 countries. In the first 3 surveys, between 2012 and 2018, we tried to analyze the general trend in the selection and use of implants of this professional group, both in primary and secondary breast surgery; while in the fourth one, in 2020, once all these global data and their consistency or evolution over an important period of time were known, we focused on the influence that BIA-ALCL and its relationship with certain texturing could be having among the FILACP plastic surgeons in those preferences for selection and management of breast implants.

About primary surgery, questions were directed to investigate demographic patients data: age, reason for implants surgery; data on the implants: models and shape, type of texturing, content and size; data related to the surgery itself, such as: delivery of informed consent before surgery, type of anesthesia, incision, implant placement plane, use of antibiotic prophylaxis and postoperative therapy, use of drains and delivery of identifying documentation of the implants in the postoperative period; and finally, clinical control and imaging data both pre and postoperatively.

About secondary surgery, questions focused on identifying reasons, preoperative tests, intraoperative sample collection and study, management of the periprosthetic capsule, management of the removed implants, placement or not of new implants, notification of incidents to health authorities and manufacturers, and use of guarantees. In the third survey we already included a question about detection of BIA-ALCL cases.

Finally, once all these general data were known, in the fourth survey, with fewer questions, we asked about the
influence that the non-renewal of the CE marking for Allergan Biocell® and Microcell® textured breast implants in December 2018, which subsequent global withdrawal from the market at the request of the manufacturer itself in July 2019 and the influence of BIA-ALCL, could be having on the decisions of FILACP plastic surgeons regarding the choice of implants, the treatment of the periprosthetic capsule and the number of reported BIA-ALCL cases.

All the surveys were launched to a growing base of email addresses of FILACP members, which ranged from 3800 in the first one, in 2012, to 5000 in the following surveys.

The first survey was available since early October to the end of December 2011, with 25 questions on primary breast surgery with implants and 18 on secondary surgery and had 555 complete answers.

The second survey was available since early October to the end of December 2015, with 31 questions on primary surgery and 52 on secondary surgery and had 376 complete answers.

The third survey was available since early December 2017 to early April 2018, with 40 questions referred to both, primary and secondary surgery, and had 444 complete answers.

The fourth survey was available since early February to early April 2020, with 13 general questions and had 535 complete answers.

Collected data were presented to FILACP members: those of the first 3 surveys at FILACP international meetings held respectively in Medellín (Colombia) May 2012, Punta del Este (Uruguay) March 2016 and Lima (Peru) May 2018, while the latter, scheduled to be presented at FILACP international congress in Punta Cana (Dominican Republic) in early May 2020, postponed by the COVID-19 pandemic, was finally presented on May 20th 2020 through videoconference organized by the FILACP Continuous Medical Training Program, open to all its members.

In order to improve data collection, we considered the first survey as a test model to identify those misleading or difficult to interpret questions; as a result, in the second and third surveys we made some variations, increasing the number of questions in the 2016 survey and reducing and unifying all the questions about primary and secondary surgery in a single listing in the 2018 survey. Finally, once obtained the main data on the choice and use of implants by the study population and comparatively analyzed over time, in the fourth survey we eliminated questions on surgical technique and included questions related to how incidence of BIA-ALCL and the withdrawal from the market of some types and models of breast implants have modified the Ibero Latin American plastic surgeon preferences for implant use.

Regarding the way in which we presented the data obtained to FILACP members in the mentioned conferences and in the final videoconference, in the first 3 surveys we did it in a comparative way: data from 2016 with those from 2012; 2018 data with those of 2016, and finally 2020 data with those of 2018 and 2016. So we try to evaluate the persistence or variation over time of the preferences collected and the way in which knowledge about BIA-ALCL and its possible relationship with certain types of implants could influence our population and geographical study environment.

In this paper we are presenting in 2 blocks the comparative results of this last presentation:

- Part 1, with general data regarding: delivery of informed consent to patients before surgery, mean age of patients, reason for breast implant surgery, preoperative imaging studies, type of anesthesia, incision, implant placement plane, use of antibiotic prophylaxis, use of drains and implants size. These data were extracted from 2012, 2016 and 2018 surveys.

- Part 2, with data related to implants content, surface and shape, and those related to the manage in secondary surgery: treatment of the periprosthetic capsule, pathological study, knowledge about BIA-ALCL, incident reporting and diagnosis of BIA-ALCL cases. In this part 2 we analyze the variable “influence of BIA-ALCL in surgical practice and in the choice of breast implants by FILACP plastic surgeons”. These data were extracted from 2012, 2016, 2018 and 2020 surveys.

Finally, and to know the number of cases of BIA-ALCL collected by FILACP National Societies of Plastic Surgery, we asked a question on the subject by email or whatsapp to their respective presidents who, either gave us directly the information collected and updated in their records, or put us in contact with the person in charge. So, we were able to create a contact list in each country and to collect diagnosed cases.

**Results**

**Answers received**

Visits ranged from 652 in 2016 survey, to 2451 in 2018 survey and 1206 in 2020 survey. Data for starting, dropping out and for those who completed them in each year are presented in Table I and used to calculate the completion rate of each survey that varied from 23.31% in 2016, to 18.1% in 2018 and to 44.36% in 2020.

Regarding responses received by countries, the highest number came in all surveys from those with the
largest number of members in FILACP: Mexico, Spain, Argentina and Colombia, with a participation rate that in the last survey reached respectively 12.9%, 12.5%, 11.8% and 6%. It’s noteworthy that, considering this participation rate by number of members for countries with the fewest number of surgeons, participation from Nicaragua with 50% of its members, Peru with 37.5%, Honduras with 21.7%, Ecuador with 14%, Venezuela with 13.7%, Dominican Republic with 12.9%, Bolivia with 12.22% and Guatemala with 10.25%, was very considerable.

## Results Part 1

Ninety-five percent of the respondents give preoperative informed consent to their patients.

Average age of patients who undergo breast surgery with implants is between 25 and 35 years.

Regarding reason for implant placement: in 2012 survey it was aesthetic in 78%, reconstructive in 11% and secondary surgery in 11%; in 2016 the aesthetic reason was present in 78.6%, reconstructive in 8.9% and secondary surgery in 12.5%; finally, in 2018 survey, aesthetic reason decreased to 69.4%, reconstructive increased to 13.6%, and secondary surgery increased significantly to 17%.

Regarding preoperative imaging breast exams, ultrasound study was preferred by 55% in 2012 survey, decreased to 39% in 2016 survey and increased again in 2018 to 44.38%. Regarding the use of preoperative mammography, it went from 40% in 2012 to 30.1% in 2016 and to 15.7% in 2018. On the other hand, magnetic resonance, according to 2012 survey, was performed in a 5% to descend to 1.9% in 2016, observing a very important increase in its preoperative use in 2018, where it reaches 19.44%. Also note that an average of 20.48% of respondents in the 3 surveys said not to carry out any preoperative imaging tests.

About type of anesthesia for breast implants surgery, the most widely used was general anesthesia, in progressive increase from 58% in 2012 to 66% in 2016 and to 72.30% in 2018. Local anesthesia plus sedation was more used in 2012 survey with 40%, and it was reduced to 15.5% in 2016 and 15% in 2018. The use of high epidural anesthesia, about which we asked in 2016 and 2018 surveys, was used by 18.4% and 12.1% of the respondents respectively, and in terms of performing the surgical procedure only with local anesthesia, it ranged from 2% in 2012, 0.1 in 2016 and 0.5% in 2018.

Preferred incision for breast implant placement in all surveys was periareolar one, with 56% in 2012 that fell to 47.7% in 2016 and increased again to 51.7% in 2018. Secondly, inframammary incision with 36% in 2012, a slight increase to 48.9% in 2016, and a further decrease to 42.7% in 2018. Axillary incision presented a much reduced use, 6% in 2012, 2.1% in 2016 and 3.5% in 2018. To the option “other incisions”, affirmative answers were between 1.5 and 2.5% in the 3 surveys.

The most used plane for breast implants placement was the submuscular one, with an increase from 33% in 2012, to 38% in 2016 and to 39.6% in 2018; in parallel, subglandular plane decreased from 30% in 2012, and from 28.2% in 2016 to 22.1% in 2018. The subfascial plane also decreased from 20% in 2012, through 17.2% in 2016 and reaching 15.1% in 2018. Finally, being dual plane the least used in the surveys of 2012 and 2016 with 17% and 16.6% respectively, we detected a slight increase in its use, up to 23.3%, in 2018.

Regarding the use of antibiotic prophylaxis, most of the respondents stated to use it: 95% in 2012 survey, decreased to 75% in 2016 and increased again in 2018 to 88%. Notice that, on a constant basis, most of the answers specified using it in the intraoperative period, and up to almost 94% said to continue using antibiotics in the postoperative period for an average of 3 to 7 days, with amoxicillin-clavulanic acid and cephalosporin being the most frequently employed.

About the use of drains in the postoperative period, most of the responses were against, with 57% in 2012 and an increase to 65.2% and 68.2% respectively in 2016 and 2018. For those who use them, the preferred type was aspiration drainages and the average days to maintain them were between 1 and 3.

Finally, in terms of implants size, throughout the 3 surveys we found as preferred a mean of 200 to 300 cc for 39% of the respondents and 300 or 400 cc for 48%, although it should be noted an increase in the use of those over 400 cc in 2018: from 7% in 2012 to 8.9% in 2016, to reach 11% in 2018.

Ibero-Latin American surgeons use mainly silicone gel implants compared to saline implants, also following an increase in this preference from 80% in 2012, to 97.7% in 2016 and 99.1% in 2018. Silicone gel used was

### Table I. Survey response data

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visits</td>
<td>652</td>
<td>2451</td>
<td>1206</td>
</tr>
<tr>
<td>Just show</td>
<td>401</td>
<td>1572</td>
<td>520</td>
</tr>
<tr>
<td>Start</td>
<td>251</td>
<td>870</td>
<td>686</td>
</tr>
<tr>
<td>Complete</td>
<td>152</td>
<td>444</td>
<td>535</td>
</tr>
<tr>
<td>Dropouts</td>
<td>99</td>
<td>45</td>
<td>151</td>
</tr>
<tr>
<td>Completion rate</td>
<td>23.31%</td>
<td>18.1%</td>
<td>44.36%</td>
</tr>
</tbody>
</table>
mostly cohesive, and its choice also increased from 80% in 2012, to 96.5% in 2016 and 96.9% in 2018.

Following investigation points were about implant surface and shape and the actions to detect BIA-ALCL using 3 questions introduced in 2020 survey:
- How has influenced your practice the global withdrawal from the market of Allergan Biocell® implants: 25.37% of the respondents stated that they had stopped using them for this reason compared to 74.6% who did not since they were not users of this implants.
- Knowing that the prohibition of some national health agencies for the use of certain implants brands and models does not currently affect FILACP countries, how has that prohibition influenced your use of polyurethane implants?: 72.13% said they have never used them; 17.51% said that has stopped using them (although that prohibition does not affect his country); and 10.35% said to use and continuing using them (since that prohibition does not affect his country).

From here, we proceeded to compare the answers to the following questions adding to the data obtained from the 2012, 2016 and 2018 surveys, those from the 2020 survey.

About breast implants surface, use of smooth surface was 27% in 2012, 12.7% in 2016, increased up to 24% in 2018, to reach 42 % in 2020. Textured implants were chosen in 63% of cases in 2012, significantly increased their choice to 85% in 2016, fell again to 71% in 2018, and collected 53.8% of surgeons who used textured surface implants of any type in 2020. About polyurethane-coated implants, choice ranged from 10% in 2012, to 2.6% in 2016, 4.9% in 2018, and remained relatively stable in 2020 with 4.2% (Table II).

Table II. Implant surface

<table>
<thead>
<tr>
<th>COMPARATIVE</th>
<th>2012</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMOOTH</td>
<td>27%</td>
<td>12.7%</td>
<td>24%</td>
<td>42%</td>
</tr>
<tr>
<td>TEXTURED</td>
<td>63%</td>
<td>85.1%</td>
<td>71.1%</td>
<td>53.5%</td>
</tr>
<tr>
<td>POLYURETHANE</td>
<td>16%</td>
<td>2.3%</td>
<td>4.9%</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

Table III. Implant shape

<table>
<thead>
<tr>
<th>COMPARATIVE</th>
<th>2012</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANÁTOMICO</td>
<td>23%</td>
<td>19.3%</td>
<td>18.5%</td>
<td>19.49%</td>
</tr>
<tr>
<td>REDONDO</td>
<td>77%</td>
<td>80.7%</td>
<td>81.5%</td>
<td>80.52%</td>
</tr>
</tbody>
</table>

Note: Excluded from the general responses Spain and Mexico due to their wide difference in the use of anatomical implants that could cause a bias in the general results, the preference for round implants reached 80.7% in 2016, 81.5% in 2016, 2018 and 92.6% in 2020.

Table IV. Management of the periprosthetic capsule in secondary implants breast surgery

<table>
<thead>
<tr>
<th>COMPARATIVE</th>
<th>2012</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPSULOTOMY</td>
<td>------</td>
<td>28%</td>
<td>19.1%</td>
<td>15.06%</td>
</tr>
<tr>
<td>PARCIAL CAPSULECTOMY</td>
<td>51%</td>
<td>17%</td>
<td>33.8%</td>
<td>28.76%</td>
</tr>
<tr>
<td>COMPLETA CAPSULECTOMY</td>
<td>41%</td>
<td>23%</td>
<td>43%</td>
<td>41.5%</td>
</tr>
<tr>
<td>NADA</td>
<td>8%</td>
<td>8%</td>
<td>3.7%</td>
<td>1.71%</td>
</tr>
</tbody>
</table>

Table V. Pathology study of the periprosthetic capsule in secondary implant breast surgery

<table>
<thead>
<tr>
<th>COMPARATIVE</th>
<th>2012</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>SÍ</td>
<td>54%</td>
<td>54.5%</td>
<td>52.5%</td>
<td>62.9%</td>
</tr>
<tr>
<td>NO</td>
<td>46%</td>
<td>45.5%</td>
<td>47.5%</td>
<td>37.1%</td>
</tr>
</tbody>
</table>

Table VI. BIA-ALCL cases in FILACP countries (data provided by National Societies April-2020)

<table>
<thead>
<tr>
<th>Country</th>
<th>Cases</th>
<th>Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Brasil</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>Chile</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Colombia</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>España</td>
<td>26</td>
<td>0</td>
</tr>
<tr>
<td>México</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Panamá</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Portugal</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Venezuela</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>106</td>
<td>2</td>
</tr>
</tbody>
</table>
Regarding implants shape, there was a clear preference in the responses for round implants which was maintained and even increased throughout the years, from 77% in 2012, to 80.7% in 2016, 81.5% in 2018 and 80.52% in 2020. The use of anatomical implants reflected a decrease from 23% in 2012, to 19.3% in 2016, 18.5% in 2018 and 19.48% in 2020 (Table III).

About the management of the peri-prosthetic capsule in secondary implants surgery, we highlight a progressive increase of surgeons who perform surgical capsulectomy compared to those who do nothing or do capsulotomy. This capsulectomy was complete in 41% of the responses in 2012, 23% in 2016, 43% in 2018 and 41.5% in 2020, compared to partial capsulectomy with 51% in 2012 survey, 17% in 2016, 33.8% in 2018, and a decrease to 28.7% in 2020 (Table IV).

Asked if they carry out any anatomopathological study of the excised peri-prosthetic capsule, we see a progressive increase over the years of those who affirm to carry out this type of study compared to those who do not, with 54% in 2012, 54.5% in 2016, 52.5% in 2018, and up to 62.9% in 2020 (Table V).

Finally, in order to assess the knowledge of Ibero-Latin American plastic surgeons about BIA-ALCL, we asked the following questions in the 2020 survey, obtaining the respective answers:

- Given the current knowledge and protocol for the suspicion, diagnosis and treatment of BIA-ALCL: do you consider that FILACP has provided you with sufficient information in this regard?: 77.02% answered yes.
- Given the current knowledge and protocol for the suspicion, diagnosis and treatment of BIA-ALCL: do you consider that your National Society has provided you with sufficient information in this regard?: 78.53% answered yes.
- Have you diagnosed any case of BIA-ALCL?: 13.37% answered yes in 2020 compared to 1.6% in 2018.
- If you have diagnosed a case, have you notified your National Society of Plastic Surgery?: 57.97% answered yes.
- If you have diagnosed a case, have you notified your national health authorities?: 60.87% answered yes.
- If you have diagnosed a case, have you notified the implant manufacturer?: 60.87% answered yes.

Cases of BIA-ALCL in FILACP countries

We collected BIA-ALCL cases provided by FILACP National Societies on April 2020. In the case of Spain, the data was publicly communicated in February 2019 by the Spanish Agency for Medicines and Health Products (AEMPS), the entity in charge of reporting incidents related to the use of breast implants in our country; so far, there has been no new communication, which was expected for April-May 2020, but surely delayed by the COVID 19 pandemic. In total, 106 cases: 13 from Argentina, 28 from Brazil with 1 death, 5 from Chile, 18 from Colombia with 1 death, 26 from Spain, 13 from Mexico, 1 from Panama, 1 from Portugal and 1 from Venezuela (Table VI).

Discussion

Surveys sent to FILACP members over a period of 10 years have given us a general idea of breast implants selection and more frequent uses by a group of experienced plastic surgeons such as the Ibero-Latin American, a professional universe that, in general, is not accounted for by the Anglo-Saxon organizations that more frequently publish their data. We must consider that out of those Ibero-Latin American colleagues who participate in international English-speaking associations in a personal capacity, as these are mainly scientific associations of members and not of national groups, FILACP is today possibly the largest international organization of national Plastic Surgery societies united by a common language, and with the guarantee of have given to the world great specialists and pioneering techniques.

In our opinion, this research was necessary in a world of breast implant use publications dominated by the Anglo-Saxon and mainly the American experience, which however, for many years was subject to regulations that discontinued the use of silicone gel breast implants or that when reauthorized, keep on having severe restrictions for brands and models. By the contrary, the Ibero-Latin American breast implant market, outside the short moratorium for the use of silicone gel implants in 1992 and the selection of products in Europe that the CE mark imposes, has been a totally open market, where practically all implant models and brands are and have been available. This leads us to the premise that all the answers provided by FILACP plastic surgeons would be based on an interesting experience of use and availability of numerous variants of breast implants.

It was not in the spirit of these surveys to obtain firm statistical data with demonstrated evidence. Perhaps we leave this for future research once the initial means have been raised and that the exercise of serial surveys in 10 years has sown the need to participate by responding in order to obtain data of the interest of all FILACP members. But we do believe that the consistency in the answers, or the way in which the last variables introduced in the questions regarding the influence of the BIA-ALCL...
have shown some interesting changes, give us a clear idea about the world of breast implants surgery in the Ibero-Latin American area.

Now is time to comment on the data obtained and to compare it with others published with similar interests. And we say similar, not the same, because as far as we have been able to verify, we have not found other studies with the same framework, not only in terms of geographical environment, but also in terms of time analyzed or type of questions to investigate.

We first look at the participation and response data. Specifically, the 535 responses from our 2020 survey of 5000 sent emails represent a 10.7% participation rate, which would be far from the 21.46% of responses obtained in 2016 by Hidalgo and Sino survey on breast augmentation trends and controversies, with 1067 responses on 4972 referrals to surgeons members of ASPS (American Society of Plastic Surgeons), or 28.4% of Benito’s 2017 survey on the use of breast implants by Spanish plastic surgeons, published in this journal, with 216 responses to 760 shipments. But we must take into account the smaller universe of respondents in these last two surveys, a single national society, in front of the FILACP survey directed at 22 national societies of plastic surgeons. In this sense, and returning to our 10.7% of responses, it acquires a different perspective if we compare it with other surveys that are also international in scope, such as the one carried out by ISAPS (International Society of Aesthetic Plastic Surgery) since 2010 on general questions of aesthetic surgery (not just breast implants), that in 2017 presented results on questionnaires sent to 35000 plastic surgeons around the world with 1329 responses, that represent a 3.77%, a number certainly reduced in our opinion for a survey that nevertheless it handles data accepted as an international model in most publications, both scientific and general media. It has not been possible to validate the percentage of responses to the last survey that ISAPS published in 2019 since shipping and response data do not appear, only says that the specific data for each country is only shown for those countries that provided a sufficient number of responses to the survey to be considered valid, without specifying those validity criteria.

We do consider remarkable in our study the perspective regarding the evolution of responses that we present in Table I: from 652 visits in 2016, to 2451 in 2018 and 1206 in 2020, but with a percentage of loyalty and continuation until completing the questionnaire that has always been increasing: from 152 in 2012, to 444 in 2016 and 535 in 2020, which represent a completion rate ranging from 23.31% to 44.36%. This data, although they are not as numerous as we would like, give us the idea that more and more of those who consult the surveys and start them, are completing them to the end.

Regarding general demographic data, the average age of patients who undergo breast implants surgery is between 25-39 years of age, which is in line with the data provided by ISAPS surveys.

General perioperative management data shows that 94.5% of FILACP plastic surgeons provide informed consent to their patients, in which, since 2018, this international federation urged all its member societies to introduce an informative clause on BIA-ALCL. Also noteworthy in this perioperative security line is that all the FILACP National Societies signed in 2017 a consensus document committing to the creation in each country of a Security Committee that would watch over this field and work in collaboration with the FILACP Security Committee and with its Chapters and Committees.

Related to the use of antibiotic prophylaxis, which as we indicate in the survey is the one that follows the recommendations of the Sanford Guide to Antimicrobial Therapy and of the World Health Organization (WHO), and which is carried out with 2 gr. of intravenous cefazolin administered between 30 to 60 minutes before the surgical incision with a new dose at 6 hours, or in case of allergy to beta-lactams with vancomycin as recommended dose, in slow infusion 1 or 2 hours before surgery, 86% of FILACP surgeons respond to use it, although the most common answer is that they start it already in the operating room in the first moments of surgery. In this sense, Avellaneda-Oviedo et al, who published in this journal in 2016 and article analyzing the protocols for the use of antibiotic prophylaxis in breast surgery, alerts us to, despite knowing these theoretical protocols designed to optimize, unify, facilitate and standardize processes, when they are brought to the practice, it’s common to make execution errors that diminish their effectiveness. In this interesting article, simple but reflecting a reality present in our usual practice, the author comments on the 5 points analyzed in his hospital experience regarding the use of prophylactic antibiotics in breast surgery of any type: 1.- indication of the prophylaxis, 2.- adequate choice of antibiotic, 3.- dose and administration via, 4.- time of administration of the first dose, and 5.- duration of prophylaxis. A percentage of correct application exceeding 90% is reflected in all the quality indicators, except in point 4, time of administration of the first antibiotic dose, since in many cases it is done without the elapse of at least 15 minutes until surgery or after having started it; the reasons are usually due to the lack of coordination between the hospital plant teams and the operating room stuff: during the transfer from the floor to the operating room, patient is generally
led on a stretcher by a caretaker, with perfusions closed, sometimes patient reaches an ante-surgery room, where if the state of the line is not monitored, the medication can continue without passing, and so it is usual for administration to be reassumed with the patient on the operating table, reason why time does not elapse enough between the start of prophylaxis administration and the skin incision. It is interesting to reflect on these points to, in the author’s words, how improvements in the organizational circuit that guarantee the best time and place for the administration of antibiotic prophylaxis, are necessary.

Another issue to study is the marked medical protectionism that leads 93% of the surgeons surveyed to maintain the use of antibiotics in the postoperative period, and mostly for an average of 1 week, without taking into account the recommendations of international guides. Its prolonged use would be different when implants are used in breast reconstruction surgery, in which some authors justify their use due to their possible influence on the reduction of local infections.(15)

At this point of the discussion, it’s interesting to talk about the use of drains in the postoperative period: 66% of the respondents say not to use them although the remaining 44% who use aspiration drains maintain them even at an average of 1 to 3 days.(16)

With regard to the reasons for breast implants surgery, they are mostly aesthetic, with an average of 70% throughout all the surveys; we notice a slight increase in its use in reconstructive surgery, from 12 to 13.6%, possibly related to the greater access of women to this surgery, and also an increase in secondary surgery, from 11 to 17%. It is interesting that in other published surveys on the use of breast implants, as well as in the statistics published by ISAPS, reference is only made to the use of implants in augmentation surgery, without considering their use in reconstructive surgery.(6,9, 11,12,17)

About preoperative imaging studies as an evidence of the situation of the breast before implant placement, 40% of our respondents use ultrasound, a test that according to international standards would be sufficient in relation to age and history of patients undergoing primary augmentation surgery. Those using mammography as the first test decreased over our survey period from 40 to 15.7% and those using preoperative magnetic resonance increased from 5 to 19.44%; this last point could be related to the increase in secondary surgery, from 11 to 17%. It is interesting that in other published surveys on the use of breast implants, as well as in the statistics published by ISAPS, reference is only made to the use of implants in augmentation surgery, without considering their use in reconstructive surgery.(6,9, 11,12,17)

Regarding the most used incision in breast implants surgery by FILACP plastic surgeons, we found a slight variation over time of preference for areolar incision, which in 2012 was the most used with 56% compared to 36% of submammary incision, suffered a slight decrease to 47% in 2016 compared to 48.9 of submammary and rebounded to 51.5% in 2018 compared to 42.7% of submammary. Other incisions, such as axillary, are in a clear decline, from 6 to 3.1%.

Breast implants placement plane was of special interest in our surveys: starting from similar values between subglandular and submuscular planes in 2012, with 30% and 33% respectively, we see a progressive decrease in the use of subglandular plane that goes from 28.2% in 2016 to 22.1% in 2018, and an increase in submuscular plane that goes from 38% in 2016 to 39.6% in 2018. The so-called dual plane, which in 2012 occupied 17% of the responses, has increased to 28.2% in 2016 to be 23.3% in 2018, while sub-fascial plane, which was only 20% in 2012, it has been decreasing to 17.2% in 2016 and 15.1% in 2018.

These last two paragraphs, regarding the elected incision and plane, present the greatest difference in our Ibero-Latin American study compared to data collected by Hidalgo et al.(6) in their survey on use of breast implants in USA, where the most frequent incision, with 83.9%, was inframammary, and the most commonly used plane was partially submammary one, with 79.5%.

About implants size, the average preferred by approximately 48% of our respondents over time is 300-400 cc., followed by almost 38% between 200 to 300 cc, and with an increase from 7 to 11% of those who use implants larger than 400 cc. Regarding this point, there would be interesting questions to analyze in future studies. For example, how is this preference of volumes by country, since we are aware of the different tastes, anatomies and fashions among countries in Latin America, and the most marked difference between these and the two European FILACP countries, Spain and Portugal. On the other hand, it would be interesting to see whether or not the use of large volumes of implants is related to the high percentage of complications such as capsular contracture, rupture, displacement, etc., reflected in other studies.(19) We know that implants are not manufactured to be wrinkled or folded, and that sometimes an incorrect dissection of the pocket that must accommodate them can cause the large-volume implant not to be perfectly extended and so, since the early days of the postoperative period, suffer distortions that favor its subsequent
breakage, or produce folds and edges that weaken the implant and erode the tissues that cover it, favoring its extrusion. On the other hand, pressure on breast tissues caused by large-volume implants, favors ischemia and the consequent creation of an environment lacking in oxygenation which leads to the development of infection or biofilm that is so closely related to capsular contraction. Don’t forget in this point the recorded increase throughout our study period of secondary surgeries and the numerous publications that associate greater complications and patients long term dissatisfaction when large volume implants are used.

So we got the second part of our presentation of results. As we said before, from this point we introduced the variable BIA-ALCL and the influence of the new international regulations on the availability of breast implants. A point throughout our 10 years of data collection that, although it was not foreseen at the time we started, provided us with a novel field to evaluate the updating of knowledge by FILACP plastic surgeons, as well as its ability to adapt changes, with judgment, in its habitual uses in breast augmentation surgery with implants.

Throughout the surveys, from 2012 to 2018, we had seen the general preference of our respondents for silicone gel implants compared to saline, a preference that reached 99.1% in 2018, and within these, 96.9% for the cohesive type gel.

One of the factors mainly analyzed in BIA-ALCL is implants texturing, and several publications have pointed out the possible association between texturing type and degree and the higher incidence of the pathology. In December 2018, the European Health Authorities decided not to renew the CE marking, and therefore the withdrawal of its sale in the countries of its influence, for Microcell® and Biocell® implants of Allergan®. On the same date, in Latin America, Brazil and Argentina accepted the same regulation. A short time later, in April 2019, France, that have an active lymphoma registry in which detected an increase in BIA-ALCL cases, and whose health authorities were especially sensitive after the problem arisen years before with PIP® implants, decided to withdraw macrotextured and polyurethane implants from its national market publishing the list of brands and models involved in this suspension. This situation, although it raises some concern, is not followed by the rest of the countries in the European area, and only followed restrictions about Allergan Biocell® and Microcell®. In December 2019, Australia, with one of the most active national implant registries worldwide and with important researches on BIA-ALCL, decides to withdraw from its national market a list of grade 3 and 4 macro-texturing implants (including polyurethane) and some grade 3 implants. But the most important turning point emerged in July 2019 when Allergan® decides the voluntary withdrawal from the world market of its Biocell® implants and expanders. How did this withdrawal is influencing the uses of FILACP surgeons and how did the alert due to the withdrawal in some countries of other models considered as macro-textured and even some micro-textured implants? This was our question and our comparison with the trend that until this moment had been registered (Table II): comparing to the increase in the use of textured implants among Ibero-Latin American surgeons from 63% in 2012 to 85.1% in 2016, we observed a decrease thereafter the new regulations from 71.1% in 2018 to 53.80% in 2020, while the use of smooth implants went from 27% in 2012 to 12.7% in 2016, to rise to 24% in 2018 and to 42% in 2020.

In 2020, 74.6% of our respondents said not to be Biocell® users and 72.13% said that they had never used polyurethane-coated implants. This suggests that not Biocell® not polyurethane were the most widespread implants in our geographic area. We also note the influence among FILACP surgeons with the decision to withdraw certain textures and marks by the aforementioned countries: 37.85% answered that they had voluntarily stopped using these implants to the question asked in 2020 survey, as well as 17.51% of those who used polyurethane-coated implants had stopped using them.

A clear influence of the moratorium that the FDA countries have suffered regarding the use of implant models and textures, is the difference between our data and those that Hidalgo et al. and Tandon et al. presented in their respective studies in USA where the use of smooth implants was preferred, with 40% of surgeons claiming to use them preferentially and 44% claiming to use smooth implants and sometimes textured implants in the study by Hidalgo et al., and 92.2% of surgeons who use smooth implants in the study by Tandon et al. This last author also points out a slight increase in the use of textured implants from 2.3% to 13% in his study, mainly between 2012 and 2013 in relation to the FDA approval of the most important anatomical implant models, and before problems with BIA-ALCL changed these trends again.

Looking for more knowledge about how Ibero-Latin American plastic surgeons differentiate among micro-macro-nanotexture implants concept, or about how they are up to date with the changes in international classifications that claim to avoid confusing concepts such as nano-implant to incorporate this degree to that of smooth implants, we asked our respondents to opt for marking their preference between macro and micro-nanotexturing, also leaving the response option “I do not
use textured implants” in the sense that answers should be the same as those who answered in the previous question that they used smooth implants. Here is where we have detected that this confusion is real, when compared to 42% who had already told us to use smooth implants, only 25.47% appeared now saying not to use textured implants, and 56.75% who said they used micro-nano-textured implants, surely because of in the previous less detailed question, included their nano-textured implants among the smooth ones. This makes us believe that an international regulation is really necessary to equally mark the degree of texturing of the implants, universal for all brands and models, beyond manufacturers’ own specifications.

Regarding the use of polyurethane implants, we see that if the preference among our respondents is not very marked, 4.2% in 2020 which has not changed much from 4.9% in 2018, could be more ingrained in some countries than in others as there are 2 world manufacturers of this implants, one in Brazil and other in Germany, with a quite marked influence in their closest geographical areas. So we tried to see responses by country, although this was not the most specific design of our survey. Given the low number of responses from Brazil, we did not find this data valuable for this country, so we collected the other countries who said to use polyurethane-coated implants, counting responses from Chile (13.30%), Mexico (6.77%), Peru (5.88%), Spain (3.19%), Nicaragua (3.13%), Colombia (2.34%), Argentina (1.49%), Ecuador (1.45%), Dominican Republic (1%) and Venezuela (0.48%). We were surprised by the high percentage of users of polyurethane-coated implants in Chile, so we asked directly to the President of the Chilean Society of Plastic Surgery who confirmed the data extrapolated by the survey. And in order to assess the rest of the general percentage based on the number of participants per country, we made the general average for their responses, obtaining 3.9% which was really close to 4.2% of polyurethane users in 2020 survey.

We cannot make a data comparison on the use of polyurethane-coated implants with other similar surveys, since they generally refer only to FDA-approved implants, among which polyurethane implants have not been listed.

About the most used implants shape, we see in our surveys a constancy of the preference for round implants over anatomical ones, with an evolution to the increase from 77% in 2012 to 85.2% in 2020. It seems that, in front of what seemed the great commercial boom, and the lot of publications, presentations, and time dedicated in congresses to the advantages of anatomical implants, the Ibero-Latin American market has been constant in its preference for round implants. Here we have also thought about the influence from the different countries of Ibero Latinoamerica, since variations in round and anatomical implants both in availability and in economic level, taking into account the higher cost of anatomical implants in general, could also create a response bias. For example Benito (9) talks about 53.2% of Spanish plastic surgeons who used anatomical implants in 2016, and in our 2020 survey the countries that gave the greatest number of responses in favor of the use of anatomical implants were Spain and Mexico, with 37.46% and 26.37%, respectively. If we exclude these countries from the general responses to avoid their over-influence, in the other ones the increase in favor of round implants changes significantly, standing up to 80.7% in 2016, 81.5% in 2018 and 92.6% in 2020. We believe that this last increase may also have been influenced by the increasing number of surgeons in recent times in favor of the use of implants with micro or nano-textured surfaces.

Continuing with the influence of BIA-ALCL in the selection and use of breast implants in our area, and even more in relation to the way in which the knowledge of its diagnosis and treatment has influenced surgical practice in secondary surgeries in patients with breast implants, we analyzed the responses to questions about the management of the periprosthetic capsule and cases notification. Responses in favor of surgical capsulectomy were majority, with a progressive decrease in partial capsulectomy to 28.7% compared to 41.5% of complete capsulectomy in 2020. As our question was related to the usual attitude towards a periprosthetic capsule in secondary breast implant surgery, without specifying conditions of suspected BIA-ALCL, intraoperative findings of signs of this pathology, or special characteristics of the capsule (thickness, calcifications, etc.), we understand that, 70.2% of our respondents considerer necessary to remove the periprosthetic capsule, and that almost half of them perform complete capsulectomy, while the rest, 28.7% do partial capsulectomy. In our opinion, complete capsulectomy should always be recommended as a way to avoid any kind of residual biological imprint on the remaining tissue in contact with the new implant, compared to other authors who, taking advantage of possible iatrogenesis that could occur in the removal of the posterior capsule on the costal plane, they recommend doing only partial capsulectomy, usually anterior, and only complete in cases of recurrent contracture in cases with an accurate diagnosis of BIA-ALCL.

Any periprosthetic capsule removed, as a rule, should be sent to an anatomopathological study, and if there is clinical suspicion of BIA-ALCL or confirmed preoperative diagnosis of this pathology, we must also make the
corresponding indication in the study request for the pathologist to start the corresponding diagnostic protocol. Awareness of FILACP plastic surgeons in this topic is increasing, from 54% who responded always send the excised periprosthetic capsule for pathology study in 2012 to 62.9% who answered the same in 2020. However, we see with concern that 37.1% of colleagues don’t systematically sent the periprosthetic tissue to study, perhaps mediated by the increased cost that the test may entail, and relying on the simple macroscopic examination of the capsule.

Focused on the assessment of the knowledge that Ibero-Latin American plastic surgeons have about BIA-ALCL through the information provided to them by both FILACP and their respective National Societies, it is interesting to see that 77.2% of the respondents say to be satisfy with the information received from FILACP and 78.53% with that received from their National Society. It is evident, looking at the academic programs of both the regional and biennial congresses of FILACP, and the national congresses of the countries, that this topic has occupied many hours of presentations, round tables, master classes, and in recent years, also videoconferences within the Continuing Education Program that the Federation established since 2016. As far as we can see, it was at the VIII Central American and Caribbean Regional Congress of FILACP in Punta Cana (Dominican Republic) in September 2011, where the first presentation of updated knowledge on the subject took place, at that time of great novelty, as in March 2010 Brody

Table VII. Implants use preferences in the 2020 FILACP survey (expressed in %)

<table>
<thead>
<tr>
<th>Country</th>
<th>Smooth</th>
<th>Textured</th>
<th>Polyurethane</th>
<th>Anatomical</th>
<th>Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>65.02</td>
<td>33.49</td>
<td>1.49</td>
<td>9.32</td>
<td>90.68</td>
</tr>
<tr>
<td>Bolivia</td>
<td>22.55</td>
<td>77.45</td>
<td>0</td>
<td>2.36</td>
<td>97.64</td>
</tr>
<tr>
<td>Brasil</td>
<td>14.17</td>
<td>61.25</td>
<td>24.58</td>
<td>15.83</td>
<td>84.17</td>
</tr>
<tr>
<td>Chile</td>
<td>29.40</td>
<td>57.30</td>
<td>13.30</td>
<td>24.30</td>
<td>75.70</td>
</tr>
<tr>
<td>Colombia</td>
<td>52.51</td>
<td>45.15</td>
<td>2.34</td>
<td>7.61</td>
<td>92.39</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>68.75</td>
<td>31.25</td>
<td>0</td>
<td>9.25</td>
<td>90.75</td>
</tr>
<tr>
<td>Ecuador</td>
<td>33.68</td>
<td>64.86</td>
<td>1.45</td>
<td>8.09</td>
<td>91.91</td>
</tr>
<tr>
<td>El Salvador</td>
<td>97.50</td>
<td>2.50</td>
<td>0</td>
<td>5.0</td>
<td>95.0</td>
</tr>
<tr>
<td>España</td>
<td>23.14</td>
<td>73.67</td>
<td>3.19</td>
<td>37.46</td>
<td>62.54</td>
</tr>
<tr>
<td>Guatemala</td>
<td>29.0</td>
<td>71.0</td>
<td>0</td>
<td>1.50</td>
<td>98.5</td>
</tr>
<tr>
<td>Honduras</td>
<td>51.40</td>
<td>48.60</td>
<td>0</td>
<td>7.20</td>
<td>92.80</td>
</tr>
<tr>
<td>México</td>
<td>39.26</td>
<td>53.97</td>
<td>6.77</td>
<td>26.37</td>
<td>73.63</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>22.69</td>
<td>74.19</td>
<td>3.13</td>
<td>15.19</td>
<td>84.81</td>
</tr>
<tr>
<td>Paraguay</td>
<td>33.3</td>
<td>66.67</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Perú</td>
<td>55.65</td>
<td>38.46</td>
<td>5.88</td>
<td>5.58</td>
<td>94.42</td>
</tr>
<tr>
<td>Rep. Dominicana</td>
<td>47.60</td>
<td>51.40</td>
<td>1</td>
<td>5.15</td>
<td>94.85</td>
</tr>
<tr>
<td>Uruguay</td>
<td>37.50</td>
<td>62.5</td>
<td>0</td>
<td>8.79</td>
<td>91.25</td>
</tr>
<tr>
<td>Venezuela</td>
<td>81.92</td>
<td>17.60</td>
<td>0.48</td>
<td>4.52</td>
<td>95.48</td>
</tr>
</tbody>
</table>

Table VIII. Trend in implants use preference by FILACP surgeons: 2012-2020 (expressed in %)

<table>
<thead>
<tr>
<th>Country</th>
<th>Smooth</th>
<th>Textured</th>
<th>Anatomical</th>
<th>Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>23.64</td>
<td>65.00</td>
<td>61.16</td>
<td>88.88</td>
</tr>
<tr>
<td>Colombia</td>
<td>20.90</td>
<td>52.51</td>
<td>51.01</td>
<td>62.02</td>
</tr>
<tr>
<td>Chile</td>
<td>3.68</td>
<td>29.40</td>
<td>18.94</td>
<td>24.58</td>
</tr>
<tr>
<td>Ecuador</td>
<td>7.27</td>
<td>33.68</td>
<td>19.04</td>
<td>15.79</td>
</tr>
<tr>
<td>España</td>
<td>13.74</td>
<td>23.14</td>
<td>19.04</td>
<td>16.23</td>
</tr>
<tr>
<td>México</td>
<td>20.32</td>
<td>35.26</td>
<td>18.94</td>
<td>24.58</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>29.00</td>
<td>22.69</td>
<td>18.94</td>
<td>24.58</td>
</tr>
<tr>
<td>Perú</td>
<td>34.17</td>
<td>55.65</td>
<td>18.94</td>
<td>24.58</td>
</tr>
<tr>
<td>Rep. Dominicana</td>
<td>12.30</td>
<td>47.60</td>
<td>18.94</td>
<td>24.58</td>
</tr>
<tr>
<td>Venezuela</td>
<td>65.52</td>
<td>81.92</td>
<td>18.94</td>
<td>24.58</td>
</tr>
</tbody>
</table>

Note: countries with the highest number of responses are selected for this table.
et al. made their first presentation collecting 34 cases of what they called “Anaplastic non-Hodgkin lymphoma of T cells associated with one type of breast implants” at the AAPS (American Association of Plastic Surgeons) Congress in San Antonio (Texas, USA). Since that date, it is difficult to find an academic congress program in the geographical area of FILACP in which the theme has not been dealt with, both from a national and international perspective, with constant updating of clinical knowledge of the pathology, diagnostic methods, treatment protocols, case presentation, consensus meetings, etc.

The various educational levels of FILACP have participated in this work and mainly the Breast and Oncological Surgery Chapters and the Safety and Breast Implants Registry Committees, in addition, of course, of numerous members of the Federation who have personally shared their special knowledge and interest in the subject. To further facilitate international collaboration in this field, FILACP, through its Implant Registry Committee, joined ICOBRA (International Collaboration of Breast Registry Activities) in 2017 and as a result of all this activity, in September 2019 presented its actions for data collection and implementation of diagnosis and treatment protocols for BIA-ALCL at the First World Consensus Meeting on BIA-ALCL held in Rome (Italy), under the leadership of Dr. Clemens and Dr. Santanelli di Pompeo. But we must bear in mind that there is still work to be done in order to reach this 20% of colleagues who still demand more information on the subject, and of course keep constantly updating the new knowledge about this illness.

It was not an easy task to have an idea of the number of cases of BIA-ALCL diagnosed in our geographical area. The disparity of case collection systems, in some countries by the national health authorities, in others by the national societies of plastic surgeons, in others by the national societies of Mastology or Senology in multidisciplinary collaboration, etc., made difficult to have a general and reliable database. There are also scarce and disparate data in this regard in international scientific publications, generally in English, and which also mostly claim to collect only data provided in that language. The first case published from the Latin American area and for our specialty is that of Torres-Rivero et al. from Mexico, in 2016, in this journal, that being the only international scientific publication of the specialty in Spanish, gathers a total of 5 articles on the subject, with those by Fernández Sobrino et al., in 2017, Umaña Ordoñez et al., Vera García et al., and Casado Sánchez et al. in 2019, up to a total of 8 cases published in our geographical area.

Because of this difficult access to the case count, we included in the 2020 survey 4 questions in this regard to know if our respondents had diagnosed any case of BIA-ALCL, that was also in the 2016 survey, and whether they had communicated that diagnosis to the national health authorities, the national society of Plastic Surgery and the implant manufacturer. Compared to 7 cases that we quantified in the responses to our 2016 survey, at the same time when Hidalgo already reported 7% of its respondents with cases and announced a higher prevalence of the disease in the nearby future, we collected 71 affirmative responses in our 2020 survey (13.37% of the respondents), although only 40 confirmed that they had notified the case to the interested entities.

We decided to communicate directly with the National Societies and ask them for the number of cases diagnosed in their country. Even though we are aware that data obtained does not reflect all possible national cases, since other specialties may also collect cases, it was really interesting how Presidents of the FILACP National Societies immediately collaborated sending us the data that they were aware of or the contact with the person in charge. In some countries, cases are those directly provided by the national health agencies, as is the case of Spain, although it’s pending 2020 update scheduled for April-May, surely due to a delay related to the coincident situation with the COVID 19 pandemic; in others, mainly in the smaller countries of the Central American-Caribbean area, it is the National Society that collects data; and in others, it’s the result of a multidisciplinary collaboration.

Total number of cases contributed by FILACP countries in April 2020 is 106 with 2 deaths, one in Colombia and one in Brazil. It was not our initial interest to obtain particular data from these cases regarding the type of implant, the way in which the pathology was presented, etc., although, in general, we can say that they were all related to textured or polyurethane implants, with different brands involved. The only 2 cases of death suggest that the criterion of good prognosis of the disease in our geographical area is also fulfilled when the diagnosis and treatment are timely and appropriate. As evidenced by most of the international publications that try to establish the possible incidence of the disease in their respective environments, or even globally, we could not assess the collected number of cases in terms of what they represent as incidence of BIA-ALCA in the Ibero-Latin American environment, for the same reason, since we also do not know the value of the necessary denominator of the equation, that is the total number of breast implants in all these countries. But thinking about what we said at the beginning of this article about the high number of surgeons in FILACP, more than 5000, and that surgery with breast implants is one of the most per-
formed in Ibero-Latin America, these 106 cases must be evaluated in its fair proportion within the updated world casuistry figures. We agree with the needing to create national implants registries to get all the necessary data in this regard; these registries are only available in few countries, and in FILACP, only in Spain since December 2017, when it was created by the Spanish Agency for Medicines and Health Products, under the Ministry of Health, Social Services and Equality, in collaboration with the Spanish Society of Plastic, Reconstructive and Aesthetic Surgery, now beginning to give its first data.

We can affirm, as a result of the data collected in this 10 years follow-up, that besides the preferences on the use of breast implants presented in this article, trend among FILACP respondents, surely influenced by the knowledge of factors related to BIA-ALCA etiology, go towards the increasing use of smooth and round implants (Table VII and VIII). In the coming future it will be necessary to study how this trend may influence not only the incidence of BIA-ALCA, but also other possible reasons for secondary surgery in patients with breast implants.

Conclusions

This study on the trend of use of breast implants over 10 years presented by the FILACP Implant Registry Committee and the collected BIA-ALCL cases among plastic surgeons in the Ibero-Latin American area, are an important and updated data contribution in an international environment that usually only collects data obtained from Anglo-Saxon professionals and publications, in the hope that the contribution of a large, important and experienced geographical environment of professionals, will be taken into account, from their own information sources.

Acknowledgments

The authors thank the facilities provided by FILACP Presidents in charge during the 10 years of this trend study: Drs. José Tariki, Reinaldo Kube, Julio D. Kirschbaum, Guillermo Vázquez and Alejandro Duarte. Also specially thank to those colleagues who contributed data from FILACP National Societies: Drs. Martín Colombo (Argentina), Javier Ruiz (Bolivia), Alexander Piassi (Brazil), Rafael Rodriguez (Cuba), Ernesto Barbosa (Colombia), Mario A. Quesada (Costa Rica), Claudio Thomas and Cristian Erazo (Chile), Edison Ramos (Ecuador), Guillermo Peña (Honduras), Jesús Cuenca (Mexico), Mauricio Mendieta (Nicaragua), Luis Picard-Ami (Panama), Enrique Asta (Paraguay), Gustavo Núñez (Peru), Fabiana Cardoso (Portugal), Norma Cruz (Puerto Rico), Aniceto Rodriguez (Dominican Republic), Eduardo Revelo (El Salvador), Gonzalo Fossati (Uruguay) and Edgar Martínez (Venezuela). And finally, the authors thank to Pablo Orcajo and Víncio Rodríguez for their technical assistance in the elaboration and distribution of the questionnaires.

Author’s address

Dr. José Sainz Arregui
info@sainzarregui.com
Dra. María del Mar Vaqueromariadelmarvaqueroperez@gmail.com

References


